I U C L I D

D a t a s e t

Existing Chemical	Substance ID: 50-00-0
CAS No.	50-00-0
EINECS Name	formaldehyde
EINECS No.	200-001-8
Molecular Formula	CH2O

Dataset created by: EUROPEAN COMMISSION – European Chemicals Bureau

This dossier is a compilation based on data reported by the European Chemicals Industry following 'Council Regulation (EEC) No. 793/93 on the Evaluation and Control of the Risks of Existing Substances'. All (non-confidential) information from the single datasets, submitted in the IUCLID/HEDSET format by individual companies, was integrated to create this document.

The data have not undergone any evaluation by the European Commission.

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1.0.1 OECD and Company Information

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Telefax: 0331/523443
Telex: 314392

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Town: 20138 MILANO
Country: Italy
Phone: 02/580301

Name: ALDER S.p.A.
Street: RIVA CADAMOSTO 6
Town: 34147 TRIESTE
Country: Italy
Phone: 040822220
Telefax: 040815365

Name: Atochem
Town: 92080 Paris la Defense
Country: France

Source: ECB – Existing Chemicals Ispra (VA)
Hoechst AG Frankfurt/Main
Vianova Resins GmbH Mainz-Kastel

Name: Atochem
Street: 4, Cours Michelet
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Country: France

Name: Bakelite AG
Street: Gennaer Stra¿e 2-4
Town: D-58609 Iserlohn-Letmathe
Country: Germany

Source: ECB – Existing Chemicals Ispra (VA)
Hoechst AG Frankfurt/Main
Vianova Resins GmbH Mainz-Kastel

Name: Bakelite AG
Street: Gennaer Straße 2-4
Town: D-58609 Iserlohn-Letmathe
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Telex: 82 72 75

Name: Bakelite Italia S.p.A.
Street: Via Mazzini, 792–4
Town: I–21058 Solbiate Olona (VA)
Country: Italy

Source: ECB – Existing Chemicals Ispra (VA)
Hoechst AG Frankfurt/Main
Vianova Resins GmbH Mainz–Kastel

Name: Bakelite Italia S.p.A.
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Town: I–21058 Solbiate Olona (VA)
Country: Italy
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Name: BASF AG
Street: Karl–Bosch–Str
Town: 67056 Ludwigshafen
Country: Germany

Source: ECB – Existing Chemicals Ispra (VA)
Hoechst AG Frankfurt/Main
Vianova Resins GmbH Mainz–Kastel

Name: BASF AG
Street: Karl–Bosch–Str
Town: 67056 Ludwigshafen
Country: Germany

Name: Bayer AG
Town: 51368 Leverkusen
Country: Germany

Source: ECB – Existing Chemicals Ispra (VA)
Hoechst AG Frankfurt/Main
Vianova Resins GmbH Mainz–Kastel

Name: Bayer AG
Town: 51368 Leverkusen
Country: Germany

Name: BORDEN (UK) LTD.
Street: ROWNHAMS ROAD
Town: SO52 9ZB NORTH BADDESLEY ,SOUTHAMPTON
Country: United Kingdom

Source: ECB – Existing Chemicals Ispra (VA)
Hoechst AG Frankfurt/Main
Vianova Resins GmbH Mainz–Kastel

Name: BORDEN (UK) LTD.
Street: ROWNHAMS ROAD
Town: SO52 9ZB NORTH BADDESLEY ,SOUTHAMPTON
Country: United Kingdom
Phone: 0703 732131
Telefax: 0703 740116
Telex: 47212

Name: Caldic Chemie B.V.
Street: Blaak 22
Town: 3011 TA Rotterdam
Country: Netherlands
Phone: 010–4136420
Telefax: 010–4047458

Name: CALDIC CHEMIE PRODUKTIE B.V.
Street: SCHANSDIJK 12
Town: 4761 RH ZEVENBERGEN
Country: Netherlands
Phone: 0168–324550
Telefax: 0168–328275
Telex: 54599

Name: Casco Nobel AB
Street: Box 115 38
Town: 100 61 STOCKHOLM
Country: Sweden

Source: ECB – Existing Chemicals Ispra (VA)
Hoechst AG Frankfurt/Main
Vianova Resins GmbH Mainz–Kastel

Name: Casco Nobel AB
Street: Box 115 38
Town: 100 61 STOCKHOLM
Country: Sweden
Phone: +46 8 7343 44 96

Name: Cheminova Agro A/S
Street: P.O. Box 9
Town: 7620 Lemwig
Country: Denmark

Name: CIBA UK
Street: Ciba Composites Tolling Group
Town: CB24QD Duxford, Cambridge
Country: United Kingdom

Source: ECB – Existing Chemicals Ispra (VA)
Hoechst AG Frankfurt/Main
Vianova Resins GmbH Mainz–Kastel

Name: CIBA UK
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Telefax: +44 223 838 362

Name: CYTEC INDUSTRIES B.V.
Street: P.O.Box 5195 , Botlekweg 175
Town: 3197 ZH Rotterdam
Country: Netherlands

Name: Degussa AG
Street: Weissfrauenstrasse 9
Town: 60287 Frankfurt am Main
Country: Germany

Source: ECB – Existing Chemicals Ispra (VA)
Hoechst AG Frankfurt/Main
Vianova Resins GmbH Mainz–Kastel

Name: Degussa AG
Street: Weissfrauenstrasse 9
Town: 60287 Frankfurt am Main
Country: Germany

Name: DERIVADOS FORESTALES, S.A.
Street: Passeig de Sant Joan, 15
Town: 08010 Barcelona
Country: Spain

Source: ECB – Existing Chemicals Ispra (VA)
Hoechst AG Frankfurt/Main
Vianova Resins GmbH Mainz–Kastel

Name: DERIVADOS FORESTALES, S.A.
Street: Passeig de Sant Joan, 15
Town: 08010 Barcelona
Country: Spain
Phone: (34–3) 232 50 11
Telefax: (34–3) 232 14 60
Telex: 98789 DEFOR E

Name: DYNO INDUSTRIER A.S.
Town: 2000 LILLESTRÑM
Country: Norway

Source: ECB – Existing Chemicals Ispra (VA)
Hoechst AG Frankfurt/Main
Vianova Resins GmbH Mainz–Kastel

Name: DYNO INDUSTRIER A.S.
Town: 2000 LILLESTRØM
Country: Norway
Phone: 4763897100
Telefax: 4763897610

Name: Fantoni SPA
Street: Zona Industriale
Town: 33010 OSOPPO
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Phone: ++3904329761
Telefax: ++390432986246
Telex: 450053

Name: FORMOL Y DERIVADOS, S.A.
Street: Passeig de Sant Joan, 15
Town: 08010 Barcelona
Country: Spain

Source: ECB - Existing Chemicals Ispra (VA)
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Vianova Resins GmbH Mainz-Kastel

Name: FORMOL Y DERIVADOS, S.A.
Street: Passeig de Sant Joan, 15
Town: 08010 Barcelona
Country: Spain
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Telefax: (34-3) 232 14 60
Telex: 98789 DEFOR E

Name: GAF-Huels Chemie GmbH
Street: Postfach
Town: 45764 Marl
Country: Germany

Source: ECB - Existing Chemicals Ispra (VA)
Hoechst AG Frankfurt/Main
Vianova Resins GmbH Mainz-Kastel

Name: GAF-Huels Chemie GmbH
Street: Postfach
Town: 45764 Marl
Country: Germany
Phone: +49/2365/49-5758
Telefax: +49/2365/49-4101

Name: Harald Pihl AB
Street: Box 4134
Town: 181 04 LIDINGÍ
Country: Sweden

Source: ECB - Existing Chemicals Ispra (VA)

Hoechst AG Frankfurt/Main
Vianova Resins GmbH Mainz–Kastel

Name: Harald Pihl AB
Street: Box 4134
Town: 181 04 LIDINGÖ
Country: Sweden
Phone: 08–7315600
Telefax: 08–7310540
Telex: 19999

Name: Helm AG
Street: Nordkanalstrasse 28
Town: 20097 Hamburg
Country: Germany
Phone: +49402375–0
Telefax: +49402375–90
Telex: 2170150

Name: Helm Austria GesmbH
Street: Kärntner Ring 11 – 13
Town: 1010 Wien
Country: Austria
Phone: 513 38 10
Telefax: 513 38 04

Name: Hoechst AG
Town: 65903 Frankfurt/Main
Country: Germany

Source: ECB – Existing Chemicals Ispra (VA)
Hoechst AG Frankfurt/Main
Vianova Resins GmbH Mainz–Kastel

Name: Hoechst AG
Street: Postfach 80 03 20 Brüningstrasse 50
Town: 65903 Frankfurt/Main
Country: Germany

Name: Hoechst Marrion Roussel Deutschland GmbH
Town: 65926 Frankfurt am Main
Country: Germany

Name: ICI Chemicals & Polymers Limited
Street: PO Box 14, The Heath
Town: WA7 4QF Runcorn, Cheshire
Country: United Kingdom

Source: ECB – Existing Chemicals Ispra (VA)
Hoechst AG Frankfurt/Main
Vianova Resins GmbH Mainz–Kastel

Name: ICI Chemicals & Polymers Limited
Street: PO Box 14, The Heath
Town: WA7 4QF Runcorn, Cheshire
Country: United Kingdom

Name: Industrias Quimicas del Urumea, S.A.
Street: C/. Navarra Epele, 39
Town: E-20120 Hernani (Guip·zcoa)
Country: Spain

Source: ECB – Existing Chemicals Ispra (VA)
Hoechst AG Frankfurt/Main
Vianova Resins GmbH Mainz-Kastel

Name: Industrias Quimicas del Urumea, S.A.
Street: C/. Navarra Epele, 39
Town: E-20120 Hernani (Guipúzcoa)
Country: Spain
Phone: +34/43/557408
Telefax: +34/43/556769
Telex: 36396 iqu e

Name: Krems Chemie AG
Street: Hafenstra¿e 77
Town: 3500 Krems
Country: Austria

Source: ECB – Existing Chemicals Ispra (VA)
Hoechst AG Frankfurt/Main
Vianova Resins GmbH Mainz-Kastel

Name: Krems Chemie AG
Street: Hafenstrasse 77
Town: A-3500 Krems
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Name: LIRI INDUSTRIALE S.R.L.
Street: VIA VERNEA,2
Town: 10042 NICHELINO (TO)
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Vianova Resins GmbH Mainz-Kastel

Name: LIRI INDUSTRIALE S.R.L.
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Telex: 27052 nestox S

Name: Neste Resins B.V.
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Town: NL–9930 AC Delfzijl
Country: Netherlands

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Hoechst AG Frankfurt/Main
Vianova Resins GmbH Mainz–Kastel

Name: Neste Resins B.V.
Street: P.O.Box 109
Town: NL–9930 AC Delfzijl
Country: Netherlands
Phone: +31–5960–48125
Telefax: +31–5960–48169

Name: Neste Resins OY
Town: FIN–49401 Hamina
Country: Finland

Source: ECB – Existing Chemicals Ispra (VA)
Hoechst AG Frankfurt/Main
Vianova Resins GmbH Mainz–Kastel

Name: Neste Resins Oy
Street: P.O.Box 80 Öljysatamantie 16
Town: FIN–49401 Hamina
Country: Finland

Name: NEUBER GES.M.B.H.
Street: BRÜCKENGASSE 1
Town: 1060 WIEN
Country: Austria
Phone: 0222/599950
Telefax: 0222/5970200

Name: NORKEM LIMITED
Street: NORKEM HOUSE, BEXTON LANE
Town: WA16666 9FB KNUTSFORD
Country: United Kingdom
Phone: 01565 755550
Telefax: 01565 755496

Name: Perstorp AB
Town: S-28480 Perstorp
Country: Sweden

Source: ECB - Existing Chemicals Ispra (VA)
Hoechst AG Frankfurt/Main
Vianova Resins GmbH Mainz-Kastel

Name: Perstorp AB
Town: S-28480 Perstorp
Country: Sweden
Phone: 0435-38000
Telefax: 0435-38100
Telex: 72000 PERSTP S

Name: Perstorp SpA,Div. Polyols
Street: Via Sempione 13
Town: I-21053 Castellanza(VA)
Country: Italy

Source: ECB - Existing Chemicals Ispra (VA)
Hoechst AG Frankfurt/Main
Vianova Resins GmbH Mainz-Kastel

Name: Perstorp SpA,Div. Polyols
Street: Via Sempione 13
Town: I-21053 Castellanza(VA)
Country: Italy
Phone: 0331-523405
Telefax: 0331-670190
Telex: 323652

Name: PROTEX S.A
Street: 6 rue Barb¿s
Town: F-92305 LEVALLOIS PERRET
Country: France

Source: ECB - Existing Chemicals Ispra (VA)
Hoechst AG Frankfurt/Main
Vianova Resins GmbH Mainz-Kastel

Name: PROTEX S.A
Street: 6 rue Barbès
Town: F-92305 LEVALLOIS PERRET
Country: France
Phone: 33-(1)-47-57-74-00
Telefax: 33-(1)-47-57-69-28
Telex: 46499-0

Name: RWE-DEA Aktiengesellschaft f³r Mineraloel und Chemie
Street: Ueberseering 40
Town: 22297 Hamburg
Country: Germany

Source: ECB – Existing Chemicals Ispra (VA)
Hoechst AG Frankfurt/Main
Vianova Resins GmbH Mainz–Kastel

Name: RWE–DEA Aktiengesellschaft für Mineraloel und Chemie
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Town: 22297 Hamburg
Country: Germany
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Telefax: 040–6375–3496
Telex: 21151320

Name: S.A. POLIALCO
Street: Passeig Sant Joan 15
Town: 08010 Barcelona
Country: Spain

Source: ECB – Existing Chemicals Ispra (VA)
Hoechst AG Frankfurt/Main
Vianova Resins GmbH Mainz–Kastel

Name: S.A. POLIALCO
Street: Passeig Sant Joan 15
Town: 08010 Barcelona
Country: Spain
Phone: (34–3) 232 50 11
Telefax: (34–3) 232 14 60
Telex: 98789 DEFOR E

Name: SADEPAN CHIMICA SRL
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Town: 46019 VIADANA
Country: Italy
Phone: 0375–7871
Telefax: 0375–787200
Telex: 305201

Name: SKW Trostberg
Street: Postfach 1262
Town: 83303 Trostberg
Country: Germany

Source: ECB – Existing Chemicals Ispra (VA)
Hoechst AG Frankfurt/Main
Vianova Resins GmbH Mainz–Kastel

Name: SKW Trostberg
Street: Postfach 1262
Town: 83303 Trostberg
Country: Germany
Phone: 08621/86–0

Name: Société Francaise Hoechst
Street: 1, Terrasse Bellini
Town: 92080 Paris la Defense
Country: France

Name: SociÚtÚ Francaise Hoechst
Town: 92080 Paris la Defense
Country: France

Source: ECB – Existing Chemicals Ispra (VA)
Hoechst AG Frankfurt/Main
Vianova Resins GmbH Mainz–Kastel

Name: STRATHCLYDE CHEMICAL COMPANY LIMITED
Street: HIGH STREET
Town: PA5 8SP JOHNSTONE
Country: United Kingdom

Source: ECB – Existing Chemicals Ispra (VA)
Hoechst AG Frankfurt/Main
Vianova Resins GmbH Mainz–Kastel

Name: STRATHCLYDE CHEMICAL COMPANY LIMITED
Street: HIGH STREET
Town: PA5 8SP JOHNSTONE
Country: United Kingdom
Phone: 0505 331611
Telefax: 0505 323242

Name: SYNTHITE LIMITED
Street: DENBIGH ROAD
Town: CH7 1BT MOLD
Country: United Kingdom

Source: ECB – Existing Chemicals Ispra (VA)
Hoechst AG Frankfurt/Main
Vianova Resins GmbH Mainz–Kastel

Name: SYNTHITE LIMITED
Street: DENBIGH ROAD
Town: CH7 1BT MOLD
Country: United Kingdom
Phone: 0352 752521
Telefax: 0352 700182
Telex: 61303

Name: Ticona Polymerwerke GmbH
Street: An der B 43
Town: 65451 Kelsterbach
Country: Germany

Source: ECB – Existing Chemicals Ispra (VA)
Hoechst AG Frankfurt/Main
Vianova Resins GmbH Mainz–Kastel

Name: Ticona Polymerwerke GmbH
Street: An der B 43
Town: 65451 Kelsterbach
Country: Germany

Name: Vianova Resins GmbH
Street: Postfach 86
Town: 55247 Mainz–Kastel
Country: Germany

Name: Ísterreichische HIAG–Werke
Street: Seybelgasse 20
Town: 1235 Wien
Country: Austria

Source: ECB – Existing Chemicals Ispra (VA)
Hoechst AG Frankfurt/Main
Vianova Resins GmbH Mainz–Kastel

Name: Österreichische HIAG–Werke
Street: Seybelgasse 20
Town: 1235 Wien
Country: Austria

Name: Österreichische NOVOPAN Holzindustrie Ges.m.b.H Nachf.
Street: Turmgasse 43
Town: 8700 Leoben
Country: Austria
Phone: 03842 – 22631 0
Telefax: 03842 – 22631 12

1.0.2 Location of Production Site

–

1.0.3 Identity of Recipients

–

1.1 General Substance Information

Substance type: inorganic
Physical status: solid

Substance type: organic
Physical status: gaseous

Substance type: organic
Physical status: liquid

Substance type: organic
Physical status: solid

Substance type:
Physical status:
Source: ECB – Existing Chemicals Ispra (VA)
Hoechst AG Frankfurt/Main
Vianova Resins GmbH Mainz-Kastel

Substance type:
Physical status:

1.1.1 Spectra

–

1.2 Synonyms

Aldehido fórmico
Source: FORMOL Y DERIVADOS, S.A. Barcelona
DERIVADOS FORESTALES, S.A. Barcelona
S.A. POLIALCO Barcelona
S.A. POLIALCO Barcelona
ECB – Existing Chemicals Ispra (VA)
Hoechst AG Frankfurt/Main
Vianova Resins GmbH Mainz-Kastel

aldeide formica-formalina-metanale
Source: Fantoni SPA OSOPPO

Ameisensaeurealdehyd
Source: Bayer AG Leverkusen

Ameisensäurealdehyd
Source: Bayer AG Leverkusen
ECB – Existing Chemicals Ispra (VA)
Hoechst AG Frankfurt/Main
Vianova Resins GmbH Mainz-Kastel

BFV
Source: FORMOL Y DERIVADOS, S.A. Barcelona
DERIVADOS FORESTALES, S.A. Barcelona
S.A. POLIALCO Barcelona
S.A. POLIALCO Barcelona
ECB – Existing Chemicals Ispra (VA)
Hoechst AG Frankfurt/Main
Vianova Resins GmbH Mainz-Kastel

Fanoformo
Source: FORMOL Y DERIVADOS, S.A. Barcelona
DERIVADOS FORESTALES, S.A. Barcelona
S.A. POLIALCO Barcelona
S.A. POLIALCO Barcelona
ECB – Existing Chemicals Ispra (VA)
Hoechst AG Frankfurt/Main
Vianova Resins GmbH Mainz-Kastel

Formaldehyd
Source: BASF AG Ludwigshafen
Hoechst AG Frankfurt/Main
SKW Trostberg Trostberg
Hoechst AG Frankfurt/Main
Vianova Resins GmbH Mainz–Kastel

Formaldehyde
Source: ICI Chemicals & Polymers Limited Runcorn, Cheshire

FORMALDEHYDE
Source: DYNO INDUSTRIER A.S. LILLESTRØM

Formaldehyde (8CI, 9CI)
Source: BASF AG Ludwigshafen
BASF AG Ludwigshafen
ECB – Existing Chemicals Ispra (VA)
Hoechst AG Frankfurt/Main
Vianova Resins GmbH Mainz–Kastel

Formaldehyde 50 % in water
Source: Société Francaise Hoechst Paris la Defense

Formaldehyde gas
Source: Degussa AG Frankfurt am Main

Formaldehyde solution
Source: BASF AG Ludwigshafen

Formaldehyde solution
Source: Degussa AG Frankfurt am Main
(1)

Formaldehyde, gas
Source: BASF AG Ludwigshafen

Formaldehyde, solution
Source: SKW Trostberg Trostberg

Formaldehydloesung 37 Gew.–%
Source: Hoechst AG Frankfurt/Main
Hoechst AG Frankfurt/Main
Ticona Polymerwerke GmbH Kelsterbach

Formaldehydloesung 50 Gew.–%
Source: Société Francaise Hoechst Paris la Defense

Formalin
Source: Industrias Quimicas del Urumea, S.A. Hernani (Guipúzcoa)
Bakelite Italia S.p.A. Solbiate Olona (VA)
Österreichische NOVOPAN Holzindustrie Ges.m.b.H Nachf. Leoben
ICI Chemicals & Polymers Limited Runcorn, Cheshire
Cheminova Agro A/S Lemwig
Bayer AG Leverkusen
BASF AG Ludwigshafen
Hoechst AG Frankfurt/Main
Degussa AG Frankfurt am Main

SKW Trostberg Trostberg
RWE–DEA Aktiengesellschaft für Mineraloel und Chemie Hamburg
GAF–Huels Chemie GmbH Marl
Bakelite AG Iserlohn–Letmathe
Hoechst AG Frankfurt/Main
Vianova Resins GmbH Mainz–Kastel

FORMALIN
Source: CIBA UK Duxford, Cambridge
SYNTHITE LIMITED MOLD

formalin
Source: Neste Resins Oy Hamina

Formalin ; Formol ; Aldehylde Formique
Source: Atochem Paris la Defense

FORMALIN SOLUTION
Source: BORDEN (UK) LTD. NORTH BADDESLEY ,SOUTHAMPTON

FORMALIN, FORMOL
Source: STRATHCLYDE CHEMICAL COMPANY LIMITED JOHNSTONE

Formalin, Methanal, Ameisenaldehyd
Source: NEUBER GES.M.B.H. WIEN

Formalina
Source: FORMOL Y DERIVADOS, S.A. Barcelona
DERIVADOS FORESTALES, S.A. Barcelona
S.A. POLIALCO Barcelona
FORMOL Y DERIVADOS, S.A. Barcelona
ECB – Existing Chemicals Ispra (VA)
Hoechst AG Frankfurt/Main
Vianova Resins GmbH Mainz–Kastel

FORMALINA, OSSIDO DI METILENE, ALDEIDE FORMICA.
Source: LIRI INDUSTRIALE S.R.L. NICHELINO (TO)

FORMALINA, OSSIDO DI METILENE, METANALE
Source: ALDER S.p.A. TRIESTE

formaline
Source: Caldic Chemie B.V. Rotterdam
CALDIC CHEMIE PRODUKTIE B.V. ZEVENBERGEN

FORMALINE – FORMOL –ALDEHYDE FORMIQUE
Source: PROTEX S.A LEVALLOIS PERRET

formaline, formol, methanal, methyl aldehyde, paraform
Source: Neste Resins B.V. Delfzijl

Formalith
Source: BASF AG Ludwigshafen
Degussa AG Frankfurt am Main
BASF AG Ludwigshafen
ECB – Existing Chemicals Ispra (VA)
Hoechst AG Frankfurt/Main

Vianova Resins GmbH Mainz-Kastel

Formhydrat
Source: Bayer AG Leverkusen
Bayer AG Leverkusen
ECB – Existing Chemicals Ispra (VA)
Hoechst AG Frankfurt/Main
Vianova Resins GmbH Mainz-Kastel

Formic aldehyde
Source: BASF AG Ludwigshafen
Degussa AG Frankfurt am Main
SKW Trostberg Trostberg
BASF AG Ludwigshafen
ECB – Existing Chemicals Ispra (VA)
Hoechst AG Frankfurt/Main
Vianova Resins GmbH Mainz-Kastel

formic aldehyde
Source: Huels AG Marl
GAF-Huels Chemie GmbH Marl

Formol
Source: Industrias Quimicas del Urumea, S.A. Hernani (Guipúzcoa)
FORMOL Y DERIVADOS, S.A. Barcelona
DERIVADOS FORESTALES, S.A. Barcelona
S.A. POLIALCO Barcelona
ICI Chemicals & Polymers Limited Runcorn, Cheshire
Bayer AG Leverkusen
BASF AG Ludwigshafen
Degussa AG Frankfurt am Main
Industrias Quimicas del Urumea, S.A. Hernani (Guip·zcoa)
ECB – Existing Chemicals Ispra (VA)
Hoechst AG Frankfurt/Main
Vianova Resins GmbH Mainz-Kastel

Formol Formalina Aldehido Fórmico Metanal Metil-aldehido Fanoformo BFV Óxido de metileno Oximetileno Oxometano Metilenglicol IVALON KARSAN LYSOFORM MORBICID
Source: FORMOL Y DERIVADOS, S.A. Barcelona
DERIVADOS FORESTALES, S.A. Barcelona
S.A. POLIALCO Barcelona

IVALON
Source: FORMOL Y DERIVADOS, S.A. Barcelona
DERIVADOS FORESTALES, S.A. Barcelona
S.A. POLIALCO Barcelona
FORMOL Y DERIVADOS, S.A. Barcelona
ECB – Existing Chemicals Ispra (VA)
Hoechst AG Frankfurt/Main
Vianova Resins GmbH Mainz-Kastel

KARSAN
Source: FORMOL Y DERIVADOS, S.A. Barcelona
DERIVADOS FORESTALES, S.A. Barcelona
S.A. POLIALCO Barcelona
FORMOL Y DERIVADOS, S.A. Barcelona
ECB – Existing Chemicals Ispra (VA)

Hoechst AG Frankfurt/Main
Vianova Resins GmbH Mainz-Kastel

LYSOFORM
Source: FORMOL Y DERIVADOS, S.A. Barcelona
DERIVADOS FORESTALES, S.A. Barcelona
S.A. POLIALCO Barcelona
FORMOL Y DERIVADOS, S.A. Barcelona
ECB - Existing Chemicals Ispra (VA)
Hoechst AG Frankfurt/Main
Vianova Resins GmbH Mainz-Kastel

MEFORM
Source: FORMOL Y DERIVADOS, S.A. Barcelona
DERIVADOS FORESTALES, S.A. Barcelona
FORMOL Y DERIVADOS, S.A. Barcelona
ECB - Existing Chemicals Ispra (VA)
Hoechst AG Frankfurt/Main
Vianova Resins GmbH Mainz-Kastel

Metanal
Source: FORMOL Y DERIVADOS, S.A. Barcelona
DERIVADOS FORESTALES, S.A. Barcelona
S.A. POLIALCO Barcelona
FORMOL Y DERIVADOS, S.A. Barcelona
ECB - Existing Chemicals Ispra (VA)
Hoechst AG Frankfurt/Main
Vianova Resins GmbH Mainz-Kastel

METANALE
Source: SADEPAN CHIMICA SRL VIADANA

METANALE-FORMALINA-ALDEIDE METILICA-OSSIDO DI METILENE-FORMOLO
Source: AGROLINZ MELAMIN ITALIA CASTELLANZA (VA)

Methaldehyd
Source: GAF-Huels Chemie GmbH Marl
GAF-Huels Chemie GmbH Marl
ECB - Existing Chemicals Ispra (VA)
Hoechst AG Frankfurt/Main
Vianova Resins GmbH Mainz-Kastel

Methaldehyde
Source: BASF AG Ludwigshafen
SKW Trostberg Trostberg
BASF AG Ludwigshafen
ECB - Existing Chemicals Ispra (VA)
Hoechst AG Frankfurt/Main
Vianova Resins GmbH Mainz-Kastel

methanal
Source: Caldic Chemie B.V. Rotterdam
RWE-DEA Aktiengesellschaft für Mineraloel und Chemie Hamburg

Methanal
Source: Perstorp SpA,Div. Polyols Castellanza(VA)
Perstorp AB Perstorp
Casco Nobel AB STOCKHOLM
Bayer AG Leverkusen
BASF AG Ludwigshafen
Hoechst AG Frankfurt/Main
Degussa AG Frankfurt am Main
GAF-Huels Chemie GmbH Marl
Hoechst AG Frankfurt/Main
Vianova Resins GmbH Mainz-Kastel

Methyl aldehyde
Source: BASF AG Ludwigshafen
Degussa AG Frankfurt am Main
BASF AG Ludwigshafen
ECB - Existing Chemicals Ispra (VA)
Hoechst AG Frankfurt/Main
Vianova Resins GmbH Mainz-Kastel

Methylaldehyd
Source: Bayer AG Leverkusen
Bayer AG Leverkusen
ECB - Existing Chemicals Ispra (VA)
Hoechst AG Frankfurt/Main
Vianova Resins GmbH Mainz-Kastel

METHYLALDEHYDE
Source: DYNO INDUSTRIER A.S. LILLESTRØM

Methylaldehyde
Source: SKW Trostberg Trostberg
SKW Trostberg Trostberg
ECB - Existing Chemicals Ispra (VA)
Hoechst AG Frankfurt/Main
Vianova Resins GmbH Mainz-Kastel

Methylene oxide
Source: BASF AG Ludwigshafen
SKW Trostberg Trostberg
GAF-Huels Chemie GmbH Marl
BASF AG Ludwigshafen
ECB - Existing Chemicals Ispra (VA)
Hoechst AG Frankfurt/Main
Vianova Resins GmbH Mainz-Kastel

Methylenoxid
Source: Bayer AG Leverkusen
Bayer AG Leverkusen
ECB - Existing Chemicals Ispra (VA)
Hoechst AG Frankfurt/Main
Vianova Resins GmbH Mainz-Kastel

Metil–aldehido
Source: FORMOL Y DERIVADOS, S.A. Barcelona
DERIVADOS FORESTALES, S.A. Barcelona
S.A. POLIALCO Barcelona
FORMOL Y DERIVADOS, S.A. Barcelona
ECB – Existing Chemicals Ispra (VA)
Hoechst AG Frankfurt/Main
Vianova Resins GmbH Mainz–Kastel

Metilenglicol
Source: FORMOL Y DERIVADOS, S.A. Barcelona
DERIVADOS FORESTALES, S.A. Barcelona
S.A. POLIALCO Barcelona
FORMOL Y DERIVADOS, S.A. Barcelona
ECB – Existing Chemicals Ispra (VA)
Hoechst AG Frankfurt/Main
Vianova Resins GmbH Mainz–Kastel

MORBICID
Source: FORMOL Y DERIVADOS, S.A. Barcelona
DERIVADOS FORESTALES, S.A. Barcelona
S.A. POLIALCO Barcelona

Morbicid
Source: BASF AG Ludwigshafen
BASF AG Ludwigshafen
ECB – Existing Chemicals Ispra (VA)
Hoechst AG Frankfurt/Main
Vianova Resins GmbH Mainz–Kastel

Oxido de metileno
Source: FORMOL Y DERIVADOS, S.A. Barcelona
DERIVADOS FORESTALES, S.A. Barcelona
S.A. POLIALCO Barcelona
FORMOL Y DERIVADOS, S.A. Barcelona
ECB – Existing Chemicals Ispra (VA)
Hoechst AG Frankfurt/Main
Vianova Resins GmbH Mainz–Kastel

Oximetileno
Source: FORMOL Y DERIVADOS, S.A. Barcelona
DERIVADOS FORESTALES, S.A. Barcelona
S.A. POLIALCO Barcelona
FORMOL Y DERIVADOS, S.A. Barcelona
ECB – Existing Chemicals Ispra (VA)
Hoechst AG Frankfurt/Main
Vianova Resins GmbH Mainz–Kastel

Oxometano
Source: FORMOL Y DERIVADOS, S.A. Barcelona
DERIVADOS FORESTALES, S.A. Barcelona
S.A. POLIALCO Barcelona
FORMOL Y DERIVADOS, S.A. Barcelona
ECB – Existing Chemicals Ispra (VA)
Hoechst AG Frankfurt/Main
Vianova Resins GmbH Mainz–Kastel

Oxomethan
Source: Bayer AG Leverkusen
Bayer AG Leverkusen
ECB – Existing Chemicals Ispra (VA)
Hoechst AG Frankfurt/Main
Vianova Resins GmbH Mainz–Kastel

Oxomethane
Source: BASF AG Ludwigshafen
SKW Trostberg Trostberg
GAF–Huels Chemie GmbH Marl
BASF AG Ludwigshafen
ECB – Existing Chemicals Ispra (VA)
Hoechst AG Frankfurt/Main
Vianova Resins GmbH Mainz–Kastel

Oxymethylen
Source: Bayer AG Leverkusen
Bayer AG Leverkusen
ECB – Existing Chemicals Ispra (VA)
Hoechst AG Frankfurt/Main
Vianova Resins GmbH Mainz–Kastel

Oxymethylene
Source: BASF AG Ludwigshafen
SKW Trostberg Trostberg
GAF–Huels Chemie GmbH Marl
GAF–Huels Chemie GmbH Marl
ECB – Existing Chemicals Ispra (VA)
Hoechst AG Frankfurt/Main
Vianova Resins GmbH Mainz–Kastel

p–Formaldehyd
Source: HMR Deutschland GmbH Frankfurt/Main
Hoechst Marrion Roussel Deutschland GmbH Frankfurt am Main

Paraform
Source: BASF AG Ludwigshafen
HMR Deutschland GmbH Frankfurt/Main
Hoechst Marrion Roussel Deutschland GmbH Frankfurt am Main
BASF AG Ludwigshafen
ECB – Existing Chemicals Ispra (VA)
Hoechst AG Frankfurt/Main
Vianova Resins GmbH Mainz–Kastel

Paraformaldehyde
Source: NORKEM LIMITED KNUTSFORD

1.3 Impurities

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1.4 Additives

–

1.5 Quantity

Quantity more than 1 000 000 tonnes
Source: ECB – Existing Chemicals Ispra (VA)
Hoechst AG Frankfurt/Main
Vianova Resins GmbH Mainz–Kastel

Quantity more than 1 000 000 tonnes

1.6.1 Labelling

Labelling: as in Directive 67/548/EEC
Symbols: T
Nota: B
D
Specific limits: yes
R–Phrases: (23/24/25) Toxic by inhalation, in contact with skin and if swallowed
(34) Causes burns
(40) Possible risks of irreversible effects
(43) May cause sensitization by skin contact
S–Phrases: (1/2) Keep locked up and out of reach of children
(26) In case of contact with eyes, rinse immediately with plenty of water and seek medical advice
(36/37/39) Wear suitable protective clothing, gloves and eye/face protection
(45) In case of accident or if you feel unwell, seek medical advice immediately (show the label where possible)
(51) Use only in well–ventilated areas

1.6.2 Classification

Classification: as in Directive 67/548/EEC
Class of danger: carcinogenic, category 3
R–Phrases: (40) Possible risks of irreversible effects

Classification: as in Directive 67/548/EEC
Class of danger: corrosive
R–Phrases: (34) Causes burns

Classification: as in Directive 67/548/EEC
Class of danger: toxic
R–Phrases: (23/24/25) Toxic by inhalation, in contact with skin and if swallowed

Classification: as in Directive 67/548/EEC
Class of danger:
R–Phrases: (43) May cause sensitization by skin contact

1.7 Use Pattern

Type: type
Category: Non dispersive use

Type: type
Category: Use in closed system
Source: ECB – Existing Chemicals Ispra (VA)
Hoechst AG Frankfurt/Main
Vianova Resins GmbH Mainz–Kastel

Type: type
Category: Use in closed system

Type: type
Category: Use resulting in inclusion into or onto matrix
Source: ECB – Existing Chemicals Ispra (VA)
Hoechst AG Frankfurt/Main
Vianova Resins GmbH Mainz–Kastel

Type: type
Category: Use resulting in inclusion into or onto matrix

Type: type
Category: Wide dispersive use
Source: ECB – Existing Chemicals Ispra (VA)
Hoechst AG Frankfurt/Main
Vianova Resins GmbH Mainz–Kastel

Type: type
Category: Wide dispersive use

Type: industrial
Category: Non dispersive use

Type: industrial
Category: Agricultural industry
Source: ECB – Existing Chemicals Ispra (VA)
Hoechst AG Frankfurt/Main
Vianova Resins GmbH Mainz–Kastel

Type: industrial
Category: Agricultural industry

Type: industrial
Category: Basic industry: basic chemicals

Type: industrial
Category: Chemical industry: used in synthesis

Type: industrial
Category: Leather processing industry
Source: ECB – Existing Chemicals Ispra (VA)
Hoechst AG Frankfurt/Main
Vianova Resins GmbH Mainz–Kastel

Type: industrial
Category: Leather processing industry

Type: industrial
Category: Metal extraction, refining and processing of metals
Source: ECB – Existing Chemicals Ispra (VA)
Hoechst AG Frankfurt/Main
Vianova Resins GmbH Mainz–Kastel

Type: industrial
Category: Metal extraction, refining and processing of metals

Type: industrial
Category: Paints, lacquers and varnishes industry
Source: ECB – Existing Chemicals Ispra (VA)
Hoechst AG Frankfurt/Main
Vianova Resins GmbH Mainz–Kastel

Type: industrial
Category: Paints, lacquers and varnishes industry

Type: industrial
Category: Paper, pulp and board industry
Source: ECB – Existing Chemicals Ispra (VA)
Hoechst AG Frankfurt/Main
Vianova Resins GmbH Mainz–Kastel

Type: industrial
Category: Paper, pulp and board industry

Type: industrial
Category: Personal and domestic use
Source: ECB – Existing Chemicals Ispra (VA)
Hoechst AG Frankfurt/Main
Vianova Resins GmbH Mainz–Kastel

Type: industrial
Category: Personal and domestic use

Type: industrial
Category: Polymers industry
Source: ECB – Existing Chemicals Ispra (VA)
Hoechst AG Frankfurt/Main
Vianova Resins GmbH Mainz–Kastel

Type: industrial
Category: Polymers industry

Type: industrial
Category: Public domain
Source: ECB – Existing Chemicals Ispra (VA)
Hoechst AG Frankfurt/Main
Vianova Resins GmbH Mainz–Kastel

Type: industrial
Category: Public domain

Type: industrial
Category: Textile processing industry
Source: ECB – Existing Chemicals Ispra (VA)
Hoechst AG Frankfurt/Main
Vianova Resins GmbH Mainz-Kastel

Type: industrial
Category: Textile processing industry

Type: industrial
Category: other
Source: ECB – Existing Chemicals Ispra (VA)
Hoechst AG Frankfurt/Main
Vianova Resins GmbH Mainz-Kastel

Type: industrial
Category: other

Type: use
Category: Adhesive, binding agents
Source: ECB – Existing Chemicals Ispra (VA)
Hoechst AG Frankfurt/Main
Vianova Resins GmbH Mainz-Kastel

Type: use
Category: Adhesive, binding agents

Type: use
Category: Bleaching agents
Source: ECB – Existing Chemicals Ispra (VA)
Hoechst AG Frankfurt/Main
Vianova Resins GmbH Mainz-Kastel

Type: use
Category: Bleaching agents

Type: use
Category: Cleaning/washing agents and disinfectants
Source: ECB – Existing Chemicals Ispra (VA)
Hoechst AG Frankfurt/Main
Vianova Resins GmbH Mainz-Kastel

Type: use
Category: Cleaning/washing agents and disinfectants

Type: use
Category: Complexing agents
Source: ECB – Existing Chemicals Ispra (VA)
Hoechst AG Frankfurt/Main
Vianova Resins GmbH Mainz-Kastel

Type: use
Category: Complexing agents

Type: use
Category: Construction materials additives
Source: ECB – Existing Chemicals Ispra (VA)
Hoechst AG Frankfurt/Main
Vianova Resins GmbH Mainz–Kastel

Type: use
Category: Construction materials additives

Type: use
Category: Corrosive inhibitors
Source: ECB – Existing Chemicals Ispra (VA)
Hoechst AG Frankfurt/Main
Vianova Resins GmbH Mainz–Kastel

Type: use
Category: Corrosive inhibitors

Type: use
Category: Cosmetics
Source: ECB – Existing Chemicals Ispra (VA)
Hoechst AG Frankfurt/Main
Vianova Resins GmbH Mainz–Kastel

Type: use
Category: Cosmetics

Type: use
Category: Electroplating agents
Source: ECB – Existing Chemicals Ispra (VA)
Hoechst AG Frankfurt/Main
Vianova Resins GmbH Mainz–Kastel

Type: use
Category: Electroplating agents

Type: use
Category: Explosives
Source: ECB – Existing Chemicals Ispra (VA)
Hoechst AG Frankfurt/Main
Vianova Resins GmbH Mainz–Kastel

Type: use
Category: Explosives

Type: use
Category: Fertilizers
Source: ECB – Existing Chemicals Ispra (VA)
Hoechst AG Frankfurt/Main
Vianova Resins GmbH Mainz–Kastel

Type: use
Category: Fertilizers

Type: use
Category: Flame retardants and fire preventing agents
Source: ECB – Existing Chemicals Ispra (VA)
Hoechst AG Frankfurt/Main
Vianova Resins GmbH Mainz–Kastel

Type: use
Category: Flame retardants and fire preventing agents

Type: use
Category: Foaming agents

Type: use
Category: Food/foodstuff additives
Source: ECB – Existing Chemicals Ispra (VA)
Hoechst AG Frankfurt/Main
Vianova Resins GmbH Mainz–Kastel

Type: use
Category: Food/foodstuff additives

Type: use
Category: Hydraulic fluids and additives

Type: use
Category: Impregnation agents
Source: ECB – Existing Chemicals Ispra (VA)
Hoechst AG Frankfurt/Main
Vianova Resins GmbH Mainz–Kastel

Type: use
Category: Impregnation agents

Type: use
Category: Insulating materials
Source: ECB – Existing Chemicals Ispra (VA)
Hoechst AG Frankfurt/Main
Vianova Resins GmbH Mainz–Kastel

Type: use
Category: Insulating materials

Type: use
Category: Intermediates

Type: use
Category: Laboratory chemicals
Source: ECB – Existing Chemicals Ispra (VA)
Hoechst AG Frankfurt/Main
Vianova Resins GmbH Mainz–Kastel

Type: use
Category: Laboratory chemicals

Type: use
Category: Non agricultural pesticides
Source: ECB – Existing Chemicals Ispra (VA)
Hoechst AG Frankfurt/Main
Vianova Resins GmbH Mainz–Kastel

Type: use
Category: Non agricultural pesticides

Type: use
Category: Pesticides
Source: ECB – Existing Chemicals Ispra (VA)
Hoechst AG Frankfurt/Main
Vianova Resins GmbH Mainz–Kastel

Type: use
Category: Pesticides

Type: use
Category: Pharmaceuticals
Source: ECB – Existing Chemicals Ispra (VA)
Hoechst AG Frankfurt/Main
Vianova Resins GmbH Mainz–Kastel

Type: use
Category: Pharmaceuticals

Type: use
Category: Reducing agents
Source: ECB – Existing Chemicals Ispra (VA)
Hoechst AG Frankfurt/Main
Vianova Resins GmbH Mainz–Kastel

Type: use
Category: Reducing agents

Type: use
Category: Stabilizers
Source: ECB – Existing Chemicals Ispra (VA)
Hoechst AG Frankfurt/Main
Vianova Resins GmbH Mainz–Kastel

Type: use
Category: Stabilizers

Type: use
Category: Surface–active agents

Type: use
Category: Tanning agents
Source: ECB – Existing Chemicals Ispra (VA)
Hoechst AG Frankfurt/Main
Vianova Resins GmbH Mainz–Kastel

Type: use
Category: Tanning agents

Type: use
Category: Vulcanizing agents
Source: ECB – Existing Chemicals Ispra (VA)
Hoechst AG Frankfurt/Main
Vianova Resins GmbH Mainz-Kastel

Type: use
Category: Vulcanizing agents

Type: use
Category: other: waessrige Loesungen als Germizide, Bakterizide und Fungizide.
Source: ECB – Existing Chemicals Ispra (VA)
Hoechst AG Frankfurt/Main
Vianova Resins GmbH Mainz-Kastel

Type: use
Category: other: waessrige Loesungen als Germizide, Bakterizide und Fungizide.

Type: use
Category: other
Source: ECB – Existing Chemicals Ispra (VA)
Hoechst AG Frankfurt/Main
Vianova Resins GmbH Mainz-Kastel

Type: use
Category: other

1.7.1 Technology Production/Use

-

1.8 Occupational Exposure Limit Values

Type of limit: MAC (NL)
Limit value: 1.5 mg/m3
Short term expos.
Limit value: 3 mg/m3
Schedule: 15 minute(s)
Source: Neste Resins B.V. Delfzijl
Caldic Chemie B.V. Rotterdam
Neste Resins B.V. Delfzijl
ECB – Existing Chemicals Ispra (VA)
Hoechst AG Frankfurt/Main
Vianova Resins GmbH Mainz-Kastel

Type of limit: MAC (NL)
Limit value: 1.5 mg/m3
Short term expos.
Limit value: 3 mg/m3
Schedule: 15 minute(s)
Frequency: 1 times
Source: CALDIC CHEMIE PRODUKTIE B.V. ZEVENBERGEN

Type of limit: MAK (DE)
Limit value: .6 mg/m3
Short term expos.
Limit value: 1.2 mg/m3
Schedule: 5 minute(s)
Frequency: 8 times
Source: Atochem Paris la Defense
Atochem Paris la Defense
ECB – Existing Chemicals Ispra (VA)
Hoechst AG Frankfurt/Main
Vianova Resins GmbH Mainz-Kastel

(2)

Type of limit: MAK (DE)
Limit value: .5 ml/m3
Short term expos.
Limit value: 1 ml/m3
Schedule: 5 minute(s)
Frequency: 8 times
Remark: Gefahr der Sensibilisierung; krebserzeugend: Gruppe IIIB; Schwangerschaft: Gruppe C
Source: Hoechst AG Frankfurt/Main
Société Francaise Hoechst Paris la Defense
Hoechst AG Frankfurt/Main
Ticona Polymerwerke GmbH Kelsterbach

(3) (4)

Type of limit: MAK (DE)
Limit value: .5 ml/m3
Short term expos.
Limit value: 1 ml/m3
Schedule: 5 minute(s)
Frequency: 8 times
Source: Industrias Quimicas del Urumea, S.A. Hernani (Guipúzcoa)

(5)

Type of limit: MAK (DE)
Limit value: .5 ml/m3
Short term expos.
Limit value: 1 ml/m3
Schedule: 5 minute(s)
Frequency: 8 times
Source: Bakelite Italia S.p.A. Solbiate Olona (VA)

(5)

Type of limit: MAK (DE)
Limit value: .5 ml/m3
Source: Krems Chemie AG Krems
Österreichische HIAG-Werke Wien

Type of limit: MAK (DE)
Limit value: .6 mg/m3
Short term expos.
Limit value: 1.2 mg/m3
Remark: Exposure under regular conditions is normally < 0.6 mg/m3
Source: DYNO INDUSTRIER A.S. LILLESTRØM

(6)

Type of limit: MAK (DE)
Limit value: .6 mg/m3
Short term expos.
Limit value: 1.2 mg/m3
Schedule: 5 minute(s)
Frequency: 8 times
Country: Germany
Remark: Section III B
Source: Bayer AG Leverkusen

Type of limit: MAK (DE)
Limit value: .5 ml/m3
Short term expos.
Limit value: 1 ml/m3
Schedule: 5 minute(s)
Frequency: 8 times
Source: BASF AG Ludwigshafen

(7) (8)

Type of limit: MAK (DE)
Limit value: .6 mg/m3
Remark: sensibilisierend
Source: BASF AG Ludwigshafen

(7) (8)

Type of limit: MAK (DE)
Limit value:
Remark: Krebserzeugend EG-Kategorie C3
Fortpflanzungsgefaehrdend Gruppe C
Source: BASF AG Ludwigshafen

(9)

Type of limit: MAK (DE)
Limit value: .5 ml/m3
Source: BASF AG Ludwigshafen

(7) (10)

Type of limit: MAK (DE)
Limit value: .6 mg/m3
Remark: sensibilisierend
Source: BASF AG Ludwigshafen

(7) (10)

Type of limit: MAK (DE)
Limit value:
Remark: Krebserzeugend EG-Kategorie C3
Fortpflanzungsgefaehrdend Gruppe C
Source: BASF AG Ludwigshafen

(7) (11) (10)

Type of limit: MAK (DE)
Limit value: .6 mg/m3
Country: Germany
Remark: Gefahr der Sensibilisierung
Krebserzeugend: Gruppe III B (Stoffe mit begruendetem Verdacht auf krebserzeugendes Potential)

Schwangerschaft: Gruppe C (Ein Risiko der Fruchtschaedigung braucht bei Einhaltung des MAK-Wertes und des BAT-Wertes nicht befuerchtet zu werden).
Source: Degussa AG Frankfurt am Main

(12)

Type of limit: MAK (DE)
Limit value: .5 ml/m3
Remark: Einstufung in EG-Krebskategorie 3
Source: SKW Trostberg Trostberg

Type of limit: MAK (DE)
Limit value: .5 ml/m3
Short term expos.
Limit value: .5 ml/m3
Country: Germany
Source: GAF-Huels Chemie GmbH Marl

Type of limit: MAK (DE)
Limit value: .6 mg/m3
Short term expos.
Limit value: .6 mg/m3
Country: Germany
Source: GAF-Huels Chemie GmbH Marl

Type of limit: MAK (DE)
Limit value: .5 ml/m3
Short term expos.
Limit value: 1 ml/m3
Schedule: 5 minute(s)
Frequency: 8 times
Source: Bakelite AG Iserlohn-Letmathe

Type of limit: MAK (DE)
Limit value: .5 ml/m3
Short term expos.
Limit value: 1 ml/m3
Schedule: 5 minute(s)
Frequency: 8 times
Remark: Gefahr der Sensibilisierung; krebserzeugend: Gruppe IIIB;
Schwangerschaft: Gruppe C; Spitzenbegrenzung: Kategorie I
Source: Hoechst AG Frankfurt/Main
Vianova Resins GmbH Mainz-Kastel

(13) (4)

Type of limit: MEL (UK)
Limit value: 2.5 mg/m3
Short term expos.
Limit value: 2.5 mg/m3
Remark: LTEL 2 ppm or 2.5 mg/m3 (8 hour TWA)
STEL 2 ppm or 2.5 mg/m3 (15 min TWA)
Source: ICI Chemicals & Polymers Limited Runcorn, Cheshire

Type of limit: MEL (UK)
Limit value: 2.5 mg/m3
Source: CIBA UK Duxford, Cambridge

Type of limit: MEL (UK)
Limit value: 2.5 mg/m3
Short term expos.
Limit value: 2.5 mg/m3
Schedule: 10 minute(s)
Frequency: 1 times
Source: STRATHCLYDE CHEMICAL COMPANY LIMITED JOHNSTONE
STRATHCLYDE CHEMICAL COMPANY LIMITED JOHNSTONE
ECB – Existing Chemicals Ispra (VA)
Hoechst AG Frankfurt/Main
Vianova Resins GmbH Mainz-Kastel

Type of limit: MEL (UK)
Limit value: 2.5 mg/m3
Short term expos.
Limit value: 2.5 mg/m3
Schedule: 10 minute(s)
Source: BORDEN (UK) LTD. NORTH BADDESLEY ,SOUTHAMPTON

Type of limit: TLV (US)
Limit value: 1.2 mg/m3
Short term expos.
Limit value: 2.5 mg/m3
Schedule: 15 minute(s)
Frequency: 4 times
Source: Atochem Paris la Defense
Atochem Paris la Defense
ECB – Existing Chemicals Ispra (VA)
Hoechst AG Frankfurt/Main
Vianova Resins GmbH Mainz-Kastel

(2)

Type of limit: TLV (US)
Limit value: .3 mg/m3
Source: LIRI INDUSTRIALE S.R.L. NICHELINO (TO)
LIRI INDUSTRIALE S.R.L. NICHELINO (TO)
ECB – Existing Chemicals Ispra (VA)
Hoechst AG Frankfurt/Main
Vianova Resins GmbH Mainz-Kastel

Type of limit: TLV (US)
Limit value: .37 mg/m3
Short term expos.
Limit value: .37 mg/m3
Source: AGROLINZ MELAMIN ITALIA CASTELLANZA (VA)

Type of limit: TLV (US)
Limit value: .37 mg/m3
Short term expos.
Limit value: .37 mg/m3
Schedule: 15 minute(s)
Frequency: 0 times
Source: SADEPAN CHIMICA SRL VIADANA

Type of limit: TLV (US)
Limit value: .3 ml/m3
Source: Fantoni SPA OSOPPO
Test substance: Il TLV della formaldeide è un TLV-C.

Type of limit: TLV (US)
Limit value: 2.45 mg/m3
Short term expos.
Limit value: 1.22 mg/m3
Schedule: 8 hour(s)
Source: ALDER S.p.A. TRIESTE

Type of limit: TLV (US)
Limit value: .9 mg/m3
Short term expos.
Limit value: 3 mg/m3
Schedule: 15 minute(s)
Source: Perstorp AB Perstorp
Perstorp AB Perstorp
ECB – Existing Chemicals Ispra (VA)
Hoechst AG Frankfurt/Main
Vianova Resins GmbH Mainz-Kastel

Type of limit: TLV (US)
Limit value:
Remark: Limit value: 1 ppm
Suspected human carinogen.
Source: BASF AG Ludwigshafen
BASF AG Ludwigshafen
ECB – Existing Chemicals Ispra (VA)
Hoechst AG Frankfurt/Main
Vianova Resins GmbH Mainz-Kastel

(14)

Type of limit: TLV (US)
Limit value: 1.2 mg/m3
Remark: Suspected human carcinogen.
Source: BASF AG Ludwigshafen
BASF AG Ludwigshafen
ECB – Existing Chemicals Ispra (VA)
Hoechst AG Frankfurt/Main
Vianova Resins GmbH Mainz–Kastel

(14)

Type of limit: TLV (US)
Limit value:
Remark: Limit value: 1 ppm
Suspected human carinogen.
Source: BASF AG Ludwigshafen

(15)

Type of limit: TLV (US)
Limit value: 1.2 mg/m3
Remark: Suspected human carcinogen.
Source: BASF AG Ludwigshafen

(15)

Type of limit: other
Limit value: .5 other
Short term expos.
Limit value: 1 other
Schedule: 15 minute(s)
Frequency: 1 times
Country: France : VLE : exposition de courte durée maximale tolérée¿
France : VME : exposition maximale tolérée
Remark: Unité de mesure : p.p.m. (partie par million)
Source: PROTEX S.A LEVALLOIS PERRET

(16)

Type of limit: other
Limit value: .6 mg/m3
Short term expos.
Limit value: 1.2 mg/m3
Source: Casco Nobel AB STOCKHOLM
Casco Nobel AB STOCKHOLM
ECB – Existing Chemicals Ispra (VA)
Hoechst AG Frankfurt/Main
Vianova Resins GmbH Mainz–Kastel

Type of limit: other
Limit value: .5 other
Short term expos.
Limit value: 1 other
Schedule: 15 minute(s)
Frequency: 1 times
Country: France : VLE : exposition de courte durÚe maximale tolÚrÚe_
France : VME : exposition maximale tolÚrÚe
Remark: UnitÚ de mesure : p.p.m. (partie par million)
Source: PROTEX S.A LEVALLOIS PERRET
ECB – Existing Chemicals Ispra (VA)
Hoechst AG Frankfurt/Main
Vianova Resins GmbH Mainz–Kastel

(17)

Type of limit: other
Limit value:
Short term expos.
Limit value: 1.3 mg/m3
Country: Finland_
Remark: skin notation
Source: Neste Resins OY Hamina
ECB – Existing Chemicals Ispra (VA)
Hoechst AG Frankfurt/Main
Vianova Resins GmbH Mainz–Kastel

(18)

Type of limit: other
Limit value:
Short term expos.
Limit value: 1.3 mg/m3
Country: Finland¿
Remark: skin notation
Source: Neste Resins Oy Hamina

(19)

Type of limit:
Limit value:
Country: France
Remark: VME 0.5 ppm
VLE 1 ppm (15 minutes frequency 4)
Source: Atochem Paris la Defense
Atochem Paris la Defense
ECB – Existing Chemicals Ispra (VA)
Hoechst AG Frankfurt/Main
Vianova Resins GmbH Mainz–Kastel

(20)

Type of limit:
Limit value:
Source: FORMOL Y DERIVADOS, S.A. Barcelona

(21)

Type of limit:
Limit value:
Source: FORMOL Y DERIVADOS, S.A. Barcelona

(22)

Type of limit:
Limit value:
Source: DERIVADOS FORESTALES, S.A. Barcelona

(21)

Type of limit:
Limit value:
Source: DERIVADOS FORESTALES, S.A. Barcelona

(22)

Type of limit:
Limit value:
Source: S.A. POLIALCO Barcelona

(21)

Type of limit:
Limit value:
Source: S.A. POLIALCO Barcelona

(22)

Type of limit:
Limit value: 2.5 mg/m3
Source: NORKEM LIMITED KNUTSFORD

1.9 Source of Exposure

Remark:
– Formaldehyd–Herstellung: 1 kg/t
– Ausgasung aus mit Harnstoff–Formaldehyd–Harz gebundenen Spanplatten u. Schaumstoffen
– Emmission aus Kfz mit Benzinmotoren: 26 u. 46 mg/km
– Emmission aus Kfz mit Benzinmotoren und Katalysator: 1,8 u. 2,4 mg/km
– Emmission aus Kfz mit Dieselmotorren ohne Katalysator: 21 u. 7,9 mg/km
– in Dieselabgasen 23 mg/m3
– Emmission Kachelofen: < 1–15 mg/m3

Großbritannien (1974/75):
Emmission aus Kfz–Abgasen (Ottomotor): 3 300 t/a
Emmission aus Diesel–Abgasen: 40 000 t/a

Emmission aus stationärer Verbrennung: 66 000 t/a

Niederlande (1980)
Emmission aus stationären Quellen: 200 t/a
Emmission aus Kfz–Abgasen: 1 800 t/a

Emmission USA (ca. 1980): aus Kfz–Abgasen 300 000 t/a
Emmission USA (1988): ca. 14 000 t/a
Entstehung durch photochemische Reaktionen in der Atmosphäre: Los–Angeles–Gebiet (1981): 8 400 – 59 000 t/a

Source: Hoechst AG Frankfurt/Main
Vianova Resins GmbH Mainz–Kastel

(23)

Remark: Insgesamt in die Umwelt eintretende Menge (Schätzung): weltweit 1 000 000 t/a (vorwiegend aus Verbrennungsprozessen)

Source: Hoechst AG Frankfurt/Main
Vianova Resins GmbH Mainz–Kastel

(23)

Remark: Nicht–anthropogene Quellen:
im interstelleren Raum ubiquitär vorhanden
Bestandteil des Stoffwechsels von Lebewesen

Source: Hoechst AG Frankfurt/Main
Vianova Resins GmbH Mainz–Kastel

(23)

Remark: Gases issued from the purge during the absorption sequence (4 t/h) go to boiler. Non condensable gases from the distillation are reprocessing as raw materials like methanol.
Methanol alcohol forms the raw material for conversion to formaldehyde by an oxidation process. Methanol vapour, mixed with filtered pre–heated air, is passed over an oxide catalyst maintained by exothermic reaction at a high temperature. The resultant gases are cooled and scrubbed to give a solution of formaldehyde in water, adjusted usually to 36.6 % w/w strength, or to other strengths as required.

Source: Atochem Paris la Defense
ECB – Existing Chemicals Ispra (VA)
Hoechst AG Frankfurt/Main
Vianova Resins GmbH Mainz–Kastel

Memo: Emissionserklaerung 1992
Remark: Release into the atmosphere on production site in 1992: 900 kg/a
Source: GAF–Huels Chemie GmbH Marl

(24)

Remark: Caldic produceert formaldehyde door gebruik te maken van twee verschillende productieprocessen namelijk:
a) oxidatie van methanol m.b.v. een Mo–katalysator
b) dehydrogenatie van methanol m.b.v. een Ag–katalysator

De geproduceerde formaldehyde–oplossingen worden opgeslagen in opslagtanks. Vanuit deze opslagtanks worden via diverse

beladingssystemen schepen, spoorwagons en tankauto’s beladen.

De afgassen afkomstig van de formaldehyde–fabrieken, de overdrukventielen van de opslagtanks en de afzuiging van de beladingssystemen, worden afgezogen naar een thermische naverbrander, alwaar deze worden verbrand.

De plaatsen waar formaldehyde–oplossingen vrij kunnen komen door bijvoorbeeld een lekkage of morsing, zijn voorzien van een vloeistof–dichte vloer. Van hieruit worden de opgevangenformaldehyde–oplossingen geloosd naar een biologische afvalwaterzuiveringsinstallatie.

Source: Caldic Chemie B.V. Rotterdam

Remark: PRODUKTIE–PROCES FORMALDEHYDE
Formaldehyde wordt geproduceerd in een geheel gesloten installatie en aansluitend continu naar een opslagtank gepompt.

Vanuit de opslagtank wordt de formaldehyde in tankauto’s geladen en naar klanten afgevoerd.

Het geheel van produktieproces, tankopslag en laadinstallatie voor tankauto’s is aangesloten op een katalytische naverbrandingsinstallatie.

De totale emissie welke via de schoorsteen van de naverbrandingsinstallatie wordt uitgestoten, bedraagt ongeveer 280 kg per jaar.

Source: CALDIC CHEMIE PRODUKTIE B.V. ZEVENBERGEN

Remark: Gases issued from the purge during the absorption sequence (4 t/h) go to boiler. Non condensable gases from the distillation are reprocessing as raw materials like methanol.
Methanol alcohol forms the raw material for conversion to formaldehyde by an oxidation process. Methanol vapour, mixed with filtered pre–heated air, is passed over an oxide catalyst maintained by exothermic reaction at a high temperature. The resultant gases are cooled and scrubbed to give a solution of formaldehyde in water, adjusted usually to 36.6 % w/w strength, or to other strengths as required.

Source: Atochem Paris la Defense

Remark: Catalyse
Procédé de fabrication : $CH_3OH + O_2 \longrightarrow CH_2O$

CH_2O ainsi formé est absorbé sur colonne par de l’eau.
Fabrication en système clos, d’où source de pollution pour l’environnement très ponctuelle
exemple : volume d’eau sur colonne d’absorption insuffisant.
Dans ce cas, la concentration autour de la colonne à l’air libre, reste inférieur à 1 ppm au delà de 10 m.
La conduite de l’appareillage de production étant

automatique, le personnel n'est pas exposé.
Source: PROTEX S.A LEVALLOIS PERRET

Remark: Formaldehyde is produced by dehydrogenation of methanol at 600 °C in the presence of Ag catalysts.
Source: Industrias Quimicas del Urumea, S.A. Hernani (Guipúzcoa)

Remark: Formaldeide è usata per la condensazione di resine fenolo/formaldeide, melamina/formaldeide, ed urea/formaldeide. La reazione avviene in autoclave a temperature comprese tra i 90°C ed i 100°C e a pressione atmosferica. Nelle resine permane una quantità di formaldeide non reagita variabile tra lo 0,1% ed il 3%. Le resine vengono poi usate nell'impregnazione di carta per l'industria dei laminati e nobilitati.
Source: LIRI INDUSTRIALE S.R.L. NICHELINO (TO)

Remark: Formaldehyde is produced by dehydrogenation of methanol in the presence of Mo catalysts.
Source: Bakelite Italia S.p.A. Solbiate Olona (VA)

Source: Inalazione dei vapori durante la manipolazione.
SADEPAN CHIMICA SRL VIADANA

Source: impianti di produzione, carico autotreni, laboratorio chimico
ALDER S.p.A. TRIESTE

Remark: Wide ranging trace level exposure from formaldehyde products in building materials and natural sources.
Source: ICI Chemicals & Polymers Limited Runcorn, Cheshire

Remark: During manufacture of formaldehyde, releases to the environment are minimal and subject to strict controls underthe UK Control of Pollution legislation.
Use of the product is primarily in wide dispersive applications eg. in the manufacture of chipboard, blockboardand plywood, under strict factory conditions used by experienced practitioners.
Source: CIBA UK Duxford, Cambridge

Remark: WE CAN ONLY COMMENT ON PRODUCTION AND HANDLING WITHIN OUR PREMISES. WE CANNOT COMMENT ON EXPOSURE GENERATED BY PEOPLE WHO PURCHASE THE PRODUCT.
OUR PLANT PRODUCES FORMALDEHYDE BY THE DIHYDROGENATION OF METHANOL USING A SILVER CRYSTAL CATALYST. THE ONLY ESCAPE OF FORMALDEHYDE IS WITH THE SCRUBBED VENT GAS TO ATMOSPHERE. THE FORMALDEHYDE CONTENT OF THIS GAS IS ABOUT 10ppm AND EQUALS TO ABOUT 1KG OF FORMALDEHYDE PER DAY.
SINCE METHANOL IS INTRODUCED AT ONE END OF THE PROCESS AND FORMALDEHYDE IS DELIVERED TO A STORAGE TANK AT THE OTHER END, WITHOUT CONTACT WITH THE ATMOSPHERE AND NEVER BEING SEEN, WE ASSUME THAT THIS IS A CLOSED PROCESS. WE ONLY HAVE ONE MANUFACTURING SITE AT THE ADDRESS SHOWN.
Source: STRATHCLYDE CHEMICAL COMPANY LIMITED JOHNSTONE

Remark: Two production sites. Closed process, off–gases from the process are burned. About 95% of the production of formaldehyde is used on–site.
Source: DYNO INDUSTRIER A.S. LILLESTRØM

Remark: In einer Fallstudie an Bewohnern von mit Harnstoffformaldehyd–Schaum isolierten Haeusern konnte kein Zusammenhang der verschiedensten subjektiven Beschwerden mit den gemessenen Formaldehyd–Konzentrationen nachgewiesen werden.
Source: BASF AG Ludwigshafen
(25)

Remark: In einer Fallstudie an Bewohnern von mit Harnstoffformaldehyd–Schaum isolierten Haeusern konnte kein Zusammenhang der verschiedensten subjektiven Beschwerden mit den gemessenen Formaldehyd–Konzentrationen nachgewiesen werden.
Source: BASF AG Ludwigshafen
(26)

Remark: Formaldehyde is produced by oxidation of methanol at 250 – 350 °C in the presence of Fe/Mo oxide catalysts.
Source: Bakelite AG Iserlohn–Letmathe

Remark: Relevante Emissionen in das betriebliche Abwasser sind nichtzu erwarten. Die gesetzlichen Bestimmungen werden eingehalten.
Source: HMR Deutschland GmbH Frankfurt/Main
Hoechst Marrion Roussel Deutschland GmbH Frankfurt am Main

Remark: Formaldehyde is produced by dehydrogenation of methanol at 600 ¿C in the presence of Ag catalysts.
Source: Industrias Quimicas del Urumea, S.A. Hernani (Guip·zcoa)
ECB – Existing Chemicals Ispra (VA)
Hoechst AG Frankfurt/Main
Vianova Resins GmbH Mainz–Kastel

Remark: Formaldeide ¿ usata per la condensazione di resine fenolo/formaldeide, melamina/formaldeide, ed urea/formaldeide. La reazione avviene in autoclave a temperature comprese tra i 90¿C ed i 100¿C e a pressione atmosferica. Nelle resine permane una quantitÓ di formaldeide non reagita variabile tra lo 0,1% ed il 3%. Le resine vengono poi usate nell’impregnazione di carta per l’industria dei laminati e nobilitati.
Source: LIRI INDUSTRIALE S.R.L. NICHELINO (TO)
ECB – Existing Chemicals Ispra (VA)
Hoechst AG Frankfurt/Main
Vianova Resins GmbH Mainz–Kastel

Remark: Formaldehyde is produced by dehydrogenation of methanol in the presence of Mo catalysts.
Source: Bakelite Italia S.p.A. Solbiate Olona (VA)
ECB – Existing Chemicals Ispra (VA)
Hoechst AG Frankfurt/Main
Vianova Resins GmbH Mainz–Kastel

Remark: Wide ranging trace level exposure from formaldehyde products in building materials and natural sources.
Source: ICI Chemicals & Polymers Limited Runcorn, Cheshire
ECB – Existing Chemicals Ispra (VA)
Hoechst AG Frankfurt/Main
Vianova Resins GmbH Mainz–Kastel

Remark: During manufacture of formaldehyde, releases to the environment are minimal and subject to strict controls underthe UK Control of Pollution legislation.
Use of the product is primarily in wide dispersive applications eg. in the manufacture of chipboard, blockboardand plywood, under strict factory conditions used by experienced practitioners.
Source: CIBA UK Duxford, Cambridge
ECB – Existing Chemicals Ispra (VA)
Hoechst AG Frankfurt/Main
Vianova Resins GmbH Mainz–Kastel

Remark: WE CAN ONLY COMMENT ON PRODUCTION AND HANDLING WITHIN OUR PREMISES. WE CANNOT COMMENT ON EXPOSURE GENERATED BY PEOPLE WHO PURCHASE THE PRODUCT.
OUR PLANT PRODUCES FORMALDEHYDE BY THE DIHYDROGENATION OF METHANOL USING A SILVER CRYSTAL CATALYST. THE ONLY ESCAPE OF FORMALDEHYDE IS WITH THE SCRUBBED VENT GAS TO ATMOSPHERE. THE FORMALDEHYDE CONTENT OF THIS GAS IS ABOUT 10ppm AND EQUALS TO ABOUT 1KG OF FORMALDEHYDE PER DAY.
SINCE METHANOL IS INTRODUCED AT ONE END OF THE PROCESS AND FORMALDEHYDE IS DELIVERED TO A STORAGE TANK AT THE OTHER END, WITHOUT CONTACT WITH THE ATMOSPHERE AND NEVER BEING SEEN, WE ASSUME THAT THIS IS A CLOSED PROCESS. WE ONLY HAVE ONE MANUFACTURING SITE AT THE ADDRESS SHOWN.
Source: STRATHCLYDE CHEMICAL COMPANY LIMITED JOHNSTONE
ECB – Existing Chemicals Ispra (VA)
Hoechst AG Frankfurt/Main
Vianova Resins GmbH Mainz–Kastel

Remark: Two production sites. Closed process, off–gases from the process are burned. About 95% of the production of formaldehyde is used on–site.
Source: DYNO INDUSTRIER A.S. LILLESTRÑM
ECB – Existing Chemicals Ispra (VA)
Hoechst AG Frankfurt/Main
Vianova Resins GmbH Mainz–Kastel

Remark: Formaldehyde is produced by oxidation of methanol at 250 – 350 ¿C in the presence of Fe/Mo oxide catalysts.
Source: Bakelite AG Iserlohn–Letmathe
ECB – Existing Chemicals Ispra (VA)
Hoechst AG Frankfurt/Main
Vianova Resins GmbH Mainz–Kastel

1.10.1 Recommendations/Precautionary Measures

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1.10.2 Emergency Measures

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1.11 Packaging

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1.12 Possib. of Rendering Subst. Harmless

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1.13 Statements Concerning Waste

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1.14.1 Water Pollution

Classified by: KBwS (DE)
Labelled by: KBwS (DE)
Class of danger: 2 (water polluting)
Source: Hoechst AG Frankfurt/Main
Société Francaise Hoechst Paris la Defense
Hoechst AG Frankfurt/Main
Ticona Polymerwerke GmbH Kelsterbach
(27) (4)

Classified by: KBwS (DE)
Labelled by:
Class of danger: 2 (water polluting)
Source: Bayer AG Leverkusen
BASF AG Ludwigshafen

Classified by: KBwS (DE)
Labelled by: KBwS (DE)
Class of danger: 2 (water polluting)
Source: Degussa AG Frankfurt am Main
(28)

Classified by: KBwS (DE)
Labelled by: KBwS (DE)
Class of danger: 2 (water polluting)
Source: SKW Trostberg Trostberg

Classified by: KBwS (DE)
Labelled by: KBwS (DE)
Class of danger: 2 (water polluting)
Country: Germany
Remark: Katalog-Nr.: 112
Source: GAF-Huels Chemie GmbH Marl

Classified by: KBwS (DE)
Labelled by:
Class of danger: 2 (water polluting)
Remark: Kenn-Nr. 112 (Wassergefährdungsklasse - WGK)
Source: Hoechst AG Frankfurt/Main
Vianova Resins GmbH Mainz-Kastel

(29) (4)

1.14.2 Major Accident Hazards

Legislation: Stoerfallverordnung (DE)
Substance listed: yes
Source: Hoechst AG Frankfurt/Main
Société Francaise Hoechst Paris la Defense
Hoechst AG Frankfurt/Main
Ticona Polymerwerke GmbH Kelsterbach
Test substance: Formaldehyd >= 50 Gew.-%

(30)

Legislation: Stoerfallverordnung (DE)
Substance listed:
Remark: App. II, No. 169 (in concentrations >= 50 % by vol.)
Source: Bayer AG Leverkusen

Legislation: Stoerfallverordnung (DE)
Substance listed: yes
Remark: Stoerfall-Stoff-No. 169
according formaldehyde >= 50 %
Source: BASF AG Ludwigshafen

(31)

Legislation: Stoerfallverordnung (DE)
Substance listed: yes
Remark: Stoerfallstoff-Nr: 169
Source: BASF AG Ludwigshafen

Legislation: Stoerfallverordnung (DE)
Substance listed: yes
Remark: Störfall-Stoff-No. 169
according formaldehyde >= 50%
Source: BASF AG Ludwigshafen

(32)

Legislation: Stoerfallverordnung (DE)
Substance listed: yes
Remark: Störfall-Stoff-No. 4c
according formaldehyde < 50%.
Source: BASF AG Ludwigshafen

(32)

Legislation: Stoerfallverordnung (DE)
Substance listed: yes
Remark: Appendix II, Nr.: 169
Source: Degussa AG Frankfurt am Main

(33)

Legislation: Stoerfallverordnung (DE)
Substance listed:
No. in Directive: 4
Remark: betrifft Stoffgruppe 4c (giftige Stoffe)
Source: SKW Trostberg Trostberg

Legislation: Stoerfallverordnung (DE)
Substance listed: yes
Country: Germany
Remark: im Anhang IV genannt (Kat.2; giftig)
Source: GAF-Huels Chemie GmbH Marl

(34)

Legislation: Stoerfallverordnung (DE)
Substance listed: yes
Remark: Kenn-Nr. 169
Source: Hoechst AG Frankfurt/Main
Vianova Resins GmbH Mainz-Kastel
Test substance: Formaldehyd >= 50 Gew.-%

(35)

1.14.3 Air Pollution

Classified by: TA-Luft (DE)
Labelled by: TA-Luft (DE)
Number:
Class of danger: I
Source: Hoechst AG Frankfurt/Main
Société Francaise Hoechst Paris la Defense
Hoechst AG Frankfurt/Main
Ticona Polymerwerke GmbH Kelsterbach

(36)

Classified by: TA-Luft (DE)
Labelled by:
Number: 3.1.7 (organic substances)
Class of danger: I
Source: Bayer AG Leverkusen

Classified by: TA-Luft (DE)
Labelled by: TA-Luft (DE)
Number: 3.1.7 (organic substances)
Class of danger: I
Source: BASF AG Ludwigshafen
SKW Trostberg Trostberg

Classified by: TA-Luft (DE)
Labelled by: TA-Luft (DE)
Number: 3.1.7 (organic substances)
Class of danger: I
Source: Degussa AG Frankfurt am Main
(37)

Classified by: TA-Luft (DE)
Labelled by: TA-Luft (DE)
Number: 3.1.7 (organic substances)
Class of danger: I
Country: Germany
Remark: Anhang E
Source: GAF-Huels Chemie GmbH Marl
(34)

Classified by: TA-Luft (DE)
Labelled by:
Number: 3.1.7 (organic substances)
Class of danger: I
Source: Hoechst AG Frankfurt/Main
Vianova Resins GmbH Mainz-Kastel
(38)

1.15 Additional Remarks

Remark: Afvalverwerking
Tijdens het produktieproces ontstaat, behoudens calamiteiten, geen afval.
Wel is het mogelijk eventuele ontstane residuen of restantenter vernietiging af te voeren naar de verbrandingsinstallatie van A.V.R. te Rotterdam.

Transportinformatie
Alle geproduceerde formaldehyde wordt door middel van tankauto's afgevoerd naar afnemers.
De tankauto's dienen te voldoen aan de regels van het regelement VLG/ADR.
Source: CALDIC CHEMIE PRODUKTIE B.V. ZEVENBERGEN

Remark: WE DO NOT DISPOSE OF FORMALDEHYDE AND HAVE LITTLE DATA ON THIS.
TRANSPORT IS IN BULK ROAD TANKS OR ON FLAT LORRIES IN 1000 LITRE, 205 LITRE OR 25 LITRE CONTAINERS AND IS TRANSPORTED UNDER C.H.I.P.S REGULATIONS AND OTHER PERTINANT U.K. REGULATIONS.
WE TRANSPORT ABOUT 200 TONNES PER WEEK AND 50% IS IN BULK AND 50% IN CONTAINERS
Source: STRATHCLYDE CHEMICAL COMPANY LIMITED JOHNSTONE

Remark: Emmissions to water are removed in a biological water treatment plant
Source: DYNO INDUSTRIER A.S. LILLESTRØM

Remark: Produkt enthaelt max. 0.015 % Ameisensaeure
Source: SKW Trostberg Trostberg

Remark: Die Testsubstanz ist unter Beachtung der Sonderabfallvorschriften einer hierfür zugelassenen Sonderabfallverbrennungsanlage zuzuführen.
Source: HMR Deutschland GmbH Frankfurt/Main
Hoechst Marrion Roussel Deutschland GmbH Frankfurt am Main

Remark: WE DO NOT DISPOSE OF FORMALDEHYDE AND HAVE LITTLE DATA ON THIS.
TRANSPORT IS IN BULK ROAD TANKS OR ON FLAT LORRIES IN 1000 LITRE, 205 LITRE OR 25 LITRE CONTAINERS AND IS TRANSPORTED UNDER C.H.I.P.S REGULATIONS AND OTHER PERTINANT U.K. REGULATIONS.
WE TRANSPORT ABOUT 200 TONNES PER WEEK AND 50% IS IN BULK AND 50% IN CONTAINERS
Source: STRATHCLYDE CHEMICAL COMPANY LIMITED JOHNSTONE
ECB – Existing Chemicals Ispra (VA)
Hoechst AG Frankfurt/Main
Vianova Resins GmbH Mainz–Kastel

Remark: Emmissions to water are removed in a biological water treatment plant
Source: DYNO INDUSTRIER A.S. LILLESTRÑM
ECB – Existing Chemicals Ispra (VA)
Hoechst AG Frankfurt/Main
Vianova Resins GmbH Mainz–Kastel

Remark: Produkt enthaelt max. 0.015 % Ameisensaeure
Source: SKW Trostberg Trostberg
ECB – Existing Chemicals Ispra (VA)
Hoechst AG Frankfurt/Main
Vianova Resins GmbH Mainz–Kastel

1.16 Last Literature Search

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1.17 Reviews

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1.18 Listings e.g. Chemical Inventories

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2.1 Melting Point

Value: = -118 degree C
Source: BASF AG Ludwigshafen
Reliability: (2) valid with restrictions
Declaration of national institution
(7)

Value: = -117 degree C
Source: BASF AG Ludwigshafen
Reliability: (2) valid with restrictions
Manufacturer data
(39)

Value: = -92 degree C
Source: BASF AG Ludwigshafen
Reliability: (2) valid with restrictions
verified data
(40)

Value: < 15 - 15 degree C
Decomposition: no
Sublimation: no
Source: LIRI INDUSTRIALE S.R.L. NICHELINO (TO)

Value:
Decomposition: ambiguous
Sublimation: no
Method: OECD Guide-line 102 "Melting Point/Melting Range"
Year: 1981
GLP: no data
Remark: Solution instable au refroidissement avec précipitation du polymère (CH2O)n au dessous de 40°C.
Source: PROTEX S.A LEVALLOIS PERRET

Value: <
Source: Fantoni SPA OSOPPO

Value:
Decomposition: no
Sublimation: no
GLP: no data
Source: ALDER S.p.A. TRIESTE
Test substance: non applicabile perchè sostanza gassosa a temp. ambiente

Value:
Decomposition: ambiguous
Sublimation: no
GLP: no data
Source: STRATHCLYDE CHEMICAL COMPANY LIMITED JOHNSTONE

2.2 Boiling Point

Value: = –21 degree C
Source: BASF AG Ludwigshafen
Reliability: (2) valid with restrictions
Competent author
(41)

Value: = –20 degree C
Source: BASF AG Ludwigshafen
Reliability: (2) valid with restrictions
Handbook, (secondary quotation)
(42)

Value: = –19.2 degree C
Source: BASF AG Ludwigshafen
Reliability: (2) valid with restrictions
Declaration of national institution
(7)

Value: = –19 degree C
Source: BASF AG Ludwigshafen
Reliability: (2) valid with restrictions
Handbook
(43)

Value: = 19.1 degree C at 1013 hPa
Source: BASF AG Ludwigshafen
Reliability: (2) valid with restrictions
Handbook
(44)

Value: = 97 – 97 degree C
Decomposition: no
Source: LIRI INDUSTRIALE S.R.L. NICHELINO (TO)

Value: ca. 99 – 100 degree C at 1013 hPa
Decomposition: no
Source: Fantoni SPA OSOPPO

Value: ca. 99 degree C at 1013 hPa
Decomposition: no
Method: OECD Guide–line 103 "Boiling Point/boiling Range"
Year: 1981
GLP: no data
Source: PROTEX S.A LEVALLOIS PERRET

Value: ca. 99 degree C at 1013 hPa
Decomposition: no
Method: other
GLP: yes
Source: ALDER S.p.A. TRIESTE

Value: ca. 100 degree C at 1.013 hPa
Decomposition: no
GLP: no data
Source: STRATHCLYDE CHEMICAL COMPANY LIMITED JOHNSTONE

Value: = 160 - 180 degree C
Source: NORKEM LIMITED KNUTSFORD

2.3 Density

Type: density
Value: = .8153 g/cm3 at -20 degree C
Source: BASF AG Ludwigshafen
Reliability: (2) valid with restrictions
Declaration of national institution
(7)

Type: density
Value: = .816 g/cm3 at -19 degree C
Source: BASF AG Ludwigshafen
Reliability: (2) valid with restrictions
Competent author
(41)

Type: relative density
Value: ca. 1.07 g/cm3 at 18 degree C
Method: other
GLP: yes
Source: ALDER S.p.A. TRIESTE

Type: relative density
Value: ca. 1.1 - 1.15 g/cm3 at 18 degree C
Method: other
Source: Fantoni SPA OSOPPO

Type: density
Value: = 1.11 - 1.14 g/cm3 at 20 degree C
Source: LIRI INDUSTRIALE S.R.L. NICHELINO (TO)

Type: relative density
Value: 1.129 - 1.137 g/cm3 at 20 degree C
Method: OECD Guide-line 109 "Density of Liquids and Solids"
Year: 1981
GLP: no data
Source: PROTEX S.A LEVALLOIS PERRET
(45)

Type: relative density
Value: ca. 1.075 - 1.098 g/cm3 at 25 degree C
Method: Directive 84/449/EEC, A.3 "Relative Density"
GLP: no data
Source: STRATHCLYDE CHEMICAL COMPANY LIMITED JOHNSTONE

Type: relative density
Value: = .7 - .8 kg/m3
Source: NORKEM LIMITED KNUTSFORD

Type: relative density
Value: = 1.03
Remark: relative density of vapour (air = 1.00)
Source: BASF AG Ludwigshafen
Reliability: (2) valid with restrictions
Handbook
(46)

Type: relative density
Value: = 1.04
Remark: relative density of vapour (air = 1.00)
Source: BASF AG Ludwigshafen
Reliability: (2) valid with restrictions
Declaration of national institution
(7)

Type: relative density
Value: = 1.067
Remark: relative density of vapour (air = 1.00)
Source: BASF AG Ludwigshafen
Reliability: (2) valid with restrictions
Competent author
(47)

2.3.1 Granulometry

-

2.4 Vapour Pressure

Value: = 1.33 hPa at 20 degree C
Method: other (calculated)
Source: Fantoni SPA OSOPPO

Value: ca. 1.33 hPa at 20 degree C
Method: other (measured)
GLP: yes
Source: ALDER S.p.A. TRIESTE
(48)

Value: = 4378 hPa at 20 degree C
Source: BASF AG Ludwigshafen
Reliability: (2) valid with restrictions
Manufacturer data
(39)

Value: = 4420 hPa at 20 degree C
Source: BASF AG Ludwigshafen
Reliability: (2) valid with restrictions
Handbook, (secondary quotation)
(42)

Value: ca. .002 hPa at 25 degree C
GLP: no data
Source: STRATHCLYDE CHEMICAL COMPANY LIMITED JOHNSTONE

Value: = 1.45 hPa at 25 degree C
Source: NORKEM LIMITED KNUTSFORD

Value: = 1.7 - 1.7 hPa at 25 degree C
Source: LIRI INDUSTRIALE S.R.L. NICHELINO (TO)

Value: = 5176 hPa at 25 degree C
Method: other (calculated)
Year: 1998
Source: BASF AG Ludwigshafen
Reliability: (2) valid with restrictions
Calculated value, accepted method
(49)

Value: 6 - 9 hPa at 50 degree C
Method: OECD Guide-line 104 "Vapour Pressure Curve"
Year: 1981
GLP: no data
Source: PROTEX S.A LEVALLOIS PERRET

2.5 Partition Coefficient

log Pow: = 0
Method: other (calculated)
Year:
Source: BASF AG Ludwigshafen
Reliability: (2) valid with restrictions
Competent author
(50)

log Pow: ca. .35
Method: other (measured)
Year: 1995
GLP: no data
Source: ALDER S.p.A. TRIESTE
(51)

log Pow: = .35 at 25 degree C
Method: other (measured)
Year: 1948
Source: BASF AG Ludwigshafen
Reliability: (2) valid with restrictions
Documented test parameters in accordance with the relating standard methods; secondary quotation
(52)

log Pow: = .35
Method: other (calculated)
Year: 1998
Source: BASF AG Ludwigshafen
Reliability: (2) valid with restrictions
Calculated value, accepted method
(53)

log Pow:
Method:
Year:
Remark: pas de données disponibles
Source: PROTEX S.A LEVALLOIS PERRET

2.6.1 Water Solubility

Value: ca. 400 g/l at 18 degree C
Qualitative: miscible
pH: ca. 2.5 – 4 at 400 g/l and 18 degree C
GLP: no data
Source: STRATHCLYDE CHEMICAL COMPANY LIMITED JOHNSTONE

Value: = 95 other: wt% at 20 degree C
Source: BASF AG Ludwigshafen
Reliability: (2) valid with restrictions
Competent author
(41)

Value: > 100 vol% at 20 degree C
Qualitative: miscible
pH: 2.5 – 4.5 at 44 vol% and 20 degree C
Method: OECD Guide-line 105 "Water Solubility"
Year: 1981
GLP: no data
Source: PROTEX S.A LEVALLOIS PERRET

Value: > 100 g/l at 20 degree C
Qualitative: soluble
pH: ca. 2.5 – 4 at 37 vol% and 20 degree C
Method: other
GLP: yes
Source: ALDER S.p.A. TRIESTE

Qualitative: of very high solubility
Source: LIRI INDUSTRIALE S.R.L. NICHELINO (TO)

Remark: completely soluble
Source: BASF AG Ludwigshafen
Reliability: (2) valid with restrictions
Declaration of national institution
(7)

2.6.2 Surface Tension

-

2.7 Flash Point

Value: = –53.2 degree C
Type:
Method: other: estimated by method described by Shebeko
Year:
Source: BASF AG Ludwigshafen
Reliability: (2) valid with restrictions
verified data
(40)

Value: > 55 degree C
Type: closed cup
Method: other
Year:
GLP: yes
Source: ALDER S.p.A. TRIESTE
Test condition: il punto di infiammabilità dipende dal contenuto di metanolo

Value: > 60 degree C
Type: closed cup
Method:
Year:
GLP: no data
Source: STRATHCLYDE CHEMICAL COMPANY LIMITED JOHNSTONE

Value: = 70 degree C
Type:
Method:
Year:
Source: NORKEM LIMITED KNUTSFORD

Value: ca. 80 degree C
Type: closed cup
Method: other
Year: 1960
GLP: no data
Remark: Méthode AFNOR NFT 60/03
Source: PROTEX S.A LEVALLOIS PERRET

Value: = 85 degree C
Type: closed cup
Method:
Year:
Source: LIRI INDUSTRIALE S.R.L. NICHELINO (TO)

Value: ca. 85 degree C
Type: closed cup
Method:
Year:
Source: Fantoni SPA OSOPPO

2.8 Auto Flammability

Value: ca. 300 degree C
Source: BASF AG Ludwigshafen
Reliability: (2) valid with restrictions
Competent author
(47)

Value: ca. 430 degree C at 1013 hPa
Method: other: aucune donnée
GLP: no data
Source: PROTEX S.A LEVALLOIS PERRET

Value: = 430 degree C
Source: Fantoni SPA OSOPPO

Value: ca. 430 degree C
Source: ALDER S.p.A. TRIESTE
Test condition: valore relativo a sostanza gassosa
(54)

Value:
Remark: Non ci sono dati
Source: LIRI INDUSTRIALE S.R.L. NICHELINO (TO)

Value:
Remark: NO DATA AVAILABLE
Source: STRATHCLYDE CHEMICAL COMPANY LIMITED JOHNSTONE

Value:
Remark: ignition temperature: 430 degree C
Source: BASF AG Ludwigshafen
Reliability: (2) valid with restrictions
Declaration of national institution
(7)

Value:
Remark: autoignition temperature: 424 degree C
Source: BASF AG Ludwigshafen
Reliability: (2) valid with restrictions
verified data
(49)

2.9 Flammability

Result: flammable
Method: Directive 84/449/EEC, A.10 "Flammability (solids)"
Year: 1984
GLP: no data
Source: PROTEX S.A LEVALLOIS PERRET

Result: non flammable
GLP: no data
Source: STRATHCLYDE CHEMICAL COMPANY LIMITED JOHNSTONE

Result: other
Source: Fantoni SPA OSOPPO

Result: other
Result: dipende dal contenuto di metanolo, considerato un liquido combustibile
Source: ALDER S.p.A. TRIESTE

2.10 Explosive Properties

Result: not explosive
Source: Fantoni SPA OSOPPO

Result: not explosive
GLP: no data
Source: STRATHCLYDE CHEMICAL COMPANY LIMITED JOHNSTONE

Result: other
Method: other: aucune donnée
GLP: no data
Remark: les vapeurs peuvent former des mélanges explosifs avec l'air
Source: PROTEX S.A LEVALLOIS PERRET

Result:
Remark: Not explosive because of the chemical structure
Source: BASF AG Ludwigshafen
Reliability: (2) valid with restrictions
expert judgement

(55)

2.11 Oxidizing Properties

Result: no oxidizing properties
Source: Fantoni SPA OSOPPO

Result: no oxidizing properties
GLP: no data
Source: STRATHCLYDE CHEMICAL COMPANY LIMITED JOHNSTONE

Result: other: pas de données disponibles
Source: PROTEX S.A LEVALLOIS PERRET

Result:
Source: ALDER S.p.A. TRIESTE
Test substance: è un forte riducente!

Result:
Remark: No oxidizing properties because of the chemical structure
Source: BASF AG Ludwigshafen
Reliability: (2) valid with restrictions
expert judgement

(55)

2.12 Additional Remarks

Remark: Explosive limits in air: 7 – 72 vol.%
Source: BASF AG Ludwigshafen
Reliability: (2) valid with restrictions
Declaration of national institution
(7)

Remark: Explosive limits in air: 7 – 73 vol.%
Source: BASF AG Ludwigshafen
Reliability: (2) valid with restrictions
Handbook
(56)

Remark: Critical properties:
critical temperature: 402.7 K
critical pressure: 65.9 bar
critical volume: 99.5 cm3/mol (estimated)
critical compressibility factor: 0.197 (estimated)
acentric factor: 0.253
Source: BASF AG Ludwigshafen
Reliability: (2) valid with restrictions
verified data
(57)

3.1.1 Photodegradation

Type: air
INDIRECT PHOTOLYSIS
Sensitizer: OH
Rate constant: = .0000000000084 cm3/(molecule * sec)
Method: other (measured)
Year: **GLP:**
Test substance: other TS: Formaldehyde C–13
Remark: (Secondary quotation)
Source: BASF AG Ludwigshafen
Test condition: 299 +–2 K
Reliability: (1) valid without restriction
Competent author
(58)

Type: air
INDIRECT PHOTOLYSIS
Sensitizer: OH
Rate constant: ca. .000000000014 cm3/(molecule * sec)
Method: other (measured)
Year: **GLP:**
Test substance: other TS: Formaldehyde d1
Remark: (Secondary quotation)
Source: BASF AG Ludwigshafen
Test condition: 298 K
Reliability: (1) valid without restriction
Competent author
(58)

Type: air
INDIRECT PHOTOLYSIS
Sensitizer: OH
Rate constant: = .00000000001 cm3/(molecule * sec)
Method: other (measured)
Year: **GLP:**
Test substance:
Source: BASF AG Ludwigshafen
Test condition: 298 K
Reliability: (1) valid without restriction
Competent author
(59)

Type: air
Light source: Sun light
DIRECT PHOTOLYSIS
Halflife t1/2: = 1 – 2 hour(s)
Method: other (measured)
Year: **GLP:**
Test substance:
Remark: Urban air with the effect of sunlight
Source: BASF AG Ludwigshafen
Reliability: (1) valid without restriction
Official assessment
(60)

Type: air
Light source: Sun light
DIRECT PHOTOLYSIS
Halflife t1/2: = 4.1 hour(s)
Method: other (measured)
Year: **GLP:**
Test substance:
Remark: Direct photolysis with sunlight at sea-level and 40 degrees latitude; speed of reaction amounts 4.7*10e-5/sec.
Source: BASF AG Ludwigshafen
Reliability: (1) valid without restriction
Original Literature without fault

(61)

Type: air
Method: other (measured)
Year: **GLP:**
Test substance:
Remark: Direct photolysis in the air; primary process: CH2O + hv --> H + HCO; quantum yield at 25 deg C
lambda 2890-3392 Angstroem: 0.701 - 0.00 quantum yield
Source: BASF AG Ludwigshafen
Reliability: (1) valid without restriction
Competent authors, no faults identified

(62)

Type: air
INDIRECT PHOTOLYSIS
Sensitizer: NO3
Rate constant: = .000000000000000323 cm3/(molecule * sec)
Method: other (calculated)
Year: **GLP:**
Test substance:
Remark: Secondary quotation
Source: BASF AG Ludwigshafen
Test condition: 298 K
Reliability: (2) valid with restrictions
Competent author

(63)

Type: air
INDIRECT PHOTOLYSIS
Sensitizer: O3
Rate constant: <= 0 cm3/(molecule * sec)
Method: other (calculated)
Year: **GLP:**
Test substance:
Source: BASF AG Ludwigshafen
Test condition: 298 K
Reliability: (2) valid with restrictions
Calculated value, accepted method

(64)

Type: air
INDIRECT PHOTOLYSIS
Sensitizer: NO3
Rate constant: = .00000000000000058 cm3/(molecule * sec)
Method: other (calculated)
Year: **GLP:**
Test substance:
Source: BASF AG Ludwigshafen
Test condition: 298 K
Reliability: (2) valid with restrictions
Competent author, (secondary literature)
(65)

Type: air
INDIRECT PHOTOLYSIS
Sensitizer: OH
Rate constant: = .0000000000096 cm3/(molecule * sec)
Method: other (calculated)
Year: **GLP:**
Test substance:
Source: BASF AG Ludwigshafen
Test condition: 298 K
Reliability: (2) valid with restrictions
Competent author, (secondary literature)
(65)

Type: air
INDIRECT PHOTOLYSIS
Sensitizer: OH
Method:
Year: **GLP:**
Test substance:
Remark: Formaldehyd is listed as hazardous air pollutant under Title III of CAAA (Clean Air Act Amendments) with an atmospheric lifetime of 30–36 hours.
Source: BASF AG Ludwigshafen
(66)

Type: air
INDIRECT PHOTOLYSIS
Sensitizer: other: Br
Rate constant: = .000000000001 cm3/(molecule * sec)
Method:
Year: **GLP:**
Test substance:
Source: BASF AG Ludwigshafen
Test condition: 298 K
(65)

Type: air
INDIRECT PHOTOLYSIS
Sensitizer: other: Cl
Rate constant: = .000000000073 cm3/(molecule * sec)
Method:
Year: **GLP:**
Test substance:
Source: BASF AG Ludwigshafen
Test condition: 298 K

(65)

Type: air
Light source: Sun light
Conc. of subst.: at 150 degree C
DIRECT PHOTOLYSIS
Halflife t1/2: 1 - 3 hour(s)
INDIRECT PHOTOLYSIS
Degradation: ca. 100 % after 30 hour(s)
Method:
Year: **GLP:**
Test substance:
Source: STRATHCLYDE CHEMICAL COMPANY LIMITED JOHNSTONE

Type:
Method:
Year: **GLP:**
Test substance:
Remark: Pas de données disponibles
Source: PROTEX S.A LEVALLOIS PERRET

3.1.2 Stability in Water

Type: biotic
Degradation: = 87 - 96 % after 14 day
and 25 degree C
Method: other
Year: **GLP:** no data
Test substance:
Source: ALDER S.p.A. TRIESTE

(67)

Type:
Method:
Year: **GLP:**
Test substance:
Remark: Pas de données disponibles
Source: PROTEX S.A LEVALLOIS PERRET

Type:
Method:
Year: **GLP:**
Test substance:
Source: STRATHCLYDE CHEMICAL COMPANY LIMITED JOHNSTONE

3.1.3 Stability in Soil

Type: **Radiolabel:**
Concentration:
Cation exch. capac.
Microbial biomass:
Method:
Year: **GLP:**
Test substance:
Remark: Pas données disponibles
Source: PROTEX S.A LEVALLOIS PERRET

3.2 Monitoring Data (Environment)

Type of measurement: background concentration
Medium: air
Remark: WE HAVE LITTLE INFORMATION IN THIS AREA. WE HAVE OVER THE YEARS MEASURED FORMALDEHYDE USING DRAAGER TUBES WITHIN OUR FORMALDEHYDE MANUFACTURING UNIT AND THROUGHOUT OUR SITE. WITHIN THE MANUFACTURING UNIT THESE HAVE BEEN LESS THAN 2ppm, AND WITHIN OUR SITE IT IS NOT DETECTED. THE DATA IS INSUFFICIENT AND HAS NEVER BEEN GATHERED IN SUCH A MANNER AS TO PERMIT STATISTICAL ANALYSIS
Source: STRATHCLYDE CHEMICAL COMPANY LIMITED JOHNSTONE

Type of measurement:
Medium:
Remark: Pas de données disponibles
Source: PROTEX S.A LEVALLOIS PERRET

3.3.1 Transport between Environmental Compartments

Type: volatility
Media: water – air
Method: other: calculation
Year: 1995
Result: Henry Law Constant: 0.03 Pa*m3/mol
Source: BASF AG Ludwigshafen
Reliability: (1) valid without restriction
Calculation accepted (standard method)

(68) (69)

Type: volatility
Media: water – air
Method: other: calculation
Year:
Result: Henry Law Constant: 1.6*10e–4 atm*l/mol
Source: BASF AG Ludwigshafen
Reliability: (1) valid without restriction
Calculation accepted (standard method)
(70)

Type:
Media:
Method:
Year:
Remark: Pas de données disponibles
Source: PROTEX S.A LEVALLOIS PERRET

Type:
Media:
Method:
Year:
Source: STRATHCLYDE CHEMICAL COMPANY LIMITED JOHNSTONE

3.3.2 Distribution

Media: air – biota – sediment(s) – soil – water
Method: Calculation according Mackay, Level I
Year: 1995
Result: Preferred aiming compartment: water (99%)
Source: BASF AG Ludwigshafen
Reliability: (1) valid without restriction
Calculation accepted (standard method)
(68) (69)

Media:
Method:
Year:
Remark: Pas de données disponibles
Source: PROTEX S.A LEVALLOIS PERRET

3.4 Mode of Degradation in Actual Use

Remark: Pas de données disponibles
Source: PROTEX S.A LEVALLOIS PERRET

3.5 Biodegradation

Type: aerobic
Inoculum: activated sludge, industrial
Concentration: 284 mg/l related to Test substance
Degradation: = 63 - 77 % after 7 day
Result: other: biodegradable
Method: other: Respirometric Test
Year: 1979 **GLP:** no
Test substance: other TS: formaldehyde 35%
Result: TOC-elimination: 63/77%; O2/C-ratio: 2.1/2.4; Concentration of test substance: 284/320 mg/l
Source: BASF AG Ludwigshafen
Reliability: (1) valid without restriction
Documented test parameters in accordance with the relating standard methods

(71)

Type: aerobic
Inoculum: other: formaldehyde containing effluents of hospitals
Method: other: ArtEV-Procedure
Year: 1996 **GLP:** no
Test substance:
Result: 18.2-20.8 g/l formaldehyde were eliminated 99.99% (degradation rate: 728 mg/l*d).
Source: BASF AG Ludwigshafen
Reliability: (2) valid with restrictions
Study not in accordance with a defined standard method, but meets generally accepted scientific principles

(72)

Type: aerobic
Inoculum: activated sludge, industrial
Degradation: = 63 - 81 % after 7 day
Method: other: Respirometric Test
Year: 1979 **GLP:** no
Test substance: other TS: formaldehyde 35%
Remark: Formaldehyde is biologically degradable after adaptation:
O2/C relation: less 1
Respiration inhibition after 24 hours incubation:
EC20 = 60 mg/l; EC50 = 500 mg/l
Source: BASF AG Ludwigshafen
Test condition: TOC-concentration: 60 and 120 mg/l
Reliability: (2) valid with restrictions
Study not in accordance with a defined standard method, but meets generally accepted scientific principles

(73)

Type: aerobic
Inoculum: other: not pre–acclimated inoculum
Degradation: = 90 % after 28 day
Result: readily biodegradable
Method: OECD Guide–line 301 D "Ready Biodegradability: Closed Bottle Test"
Year: 1990 **GLP:** no
Test substance:
Result: %THOD
Source: BASF AG Ludwigshafen
Test condition: Concentration of test substance: 2–5 mg/l
Reliability: (2) valid with restrictions
Documented test parameters in accordance with the relating standard methods

(74)

Type: aerobic
Inoculum:
Degradation: = 97.4 % after 5 day
Method: other: BOD5 Dilution Method
Year: 1976 **GLP:** no
Test substance:
Source: BASF AG Ludwigshafen

(75)

Type: aerobic
Inoculum: other: activated sludge, municipal treatment plant
Degradation: = 98 – 99 %
Method: other: Adaptation in a model treatment plant
Year: 1983 **GLP:** no
Test substance:
Remark: During adaptation period 2–8 days at each concentration in the influent degradation was followed 33 days at maximum concentration (2000 mg/l influent).
Source: BASF AG Ludwigshafen
Test condition: Step by step adaptation of 600 mg/l to 2000 mg/l formaldehyde

(76)

Type: aerobic
Inoculum: activated sludge, domestic
Method: other: Adaptation Test
Year: 1984 **GLP:** no
Test substance:
Remark: With adaptation and addition of glucose as cosubstrate formaldehyde (1000 mg/l) is biodegradable.
Source: BASF AG Ludwigshafen
Test condition: Concentration of test substance: step by step from 100 mg/l to 1000 mg/l

(77)

Type: aerobic
Inoculum: other: activated sludge, adapted (photo–effluent)
Degradation: = 18 %
Method: other: 14–C Degradation with synthetic photolaboratory effluent
Year: 1976 **GLP:** no
Test substance:
Result: %THCO2
Source: BASF AG Ludwigshafen
Test condition: Activated sludge from industrial treatment plant, incubation period: 5 days
Test substance: mixture of formaline, sulfite, thiosulfite

(78)

Type: aerobic
Inoculum: other: sludge, municipal
Concentration: 500 mg/l related to Test substance
Degradation: = 0 % after 1 day
Method: other: Respirometric Test (Warburg)
Year: 1966 **GLP:** no
Test substance:
Result: No degradation, toxic effects.
Source: BASF AG Ludwigshafen

(79)

Type: anaerobic
Inoculum: other: acetate/propionate enriched culture, adapted
Concentration: 400 mg/l related to Test substance
Degradation: = 55 – 60 % after 40 day
Method: other: Anaerobic Degradation Test
Year: 1988 **GLP:** no
Test substance:
Remark: SRT = Solid Retention Times
Result: 25% volatilization, biosorption and other physico–chemical processes (total 80% elimination)
Source: BASF AG Ludwigshafen
Test condition: Continuous addition of 400 mg/l

(80)

Type: aerobic
Inoculum: other fungi
Concentration: 1000 related to Test substance
Degradation: ca. 99.9 – 99.95 % after 24 hour(s)
Result: readily biodegradable
Method:
Year: **GLP:**
Test substance:
Source: Fantoni SPA OSOPPO

Type:
Inoculum:
Method:
Year: **GLP:**
Test substance:
Remark: Pas de données disponibles
Source: PROTEX S.A LEVALLOIS PERRET

Type:
Inoculum:
Method:
Year: **GLP:**
Test substance:
Source: LIRI INDUSTRIALE S.R.L. NICHELINO (TO)

Type:
Inoculum:
Method:
Year: **GLP:**
Test substance:
Source: GAF-Huels Chemie GmbH Marl

3.6 BOD5, COD or BOD5/COD Ratio

Method: other: BOD5 Test (DIN 38409/51)

Remark: BOD5 = 929.7 mg/g related to 100% active agent;
THOD = 1070 mg/g;
BOD5/THOD = 0.87
Source: BASF AG Ludwigshafen
Reliability: (1) valid without restriction
Documented test parameters in accordance with the relating standard methods

(81)

B O D 5

Method: ISO 5815 "Water quality - Determination of biochemical oxygen demand after 5 days (BOD5) - Dilution and seeding method"
Year: 1983 **GLP:** no data
Concentration: 16 mg/l related to Test substance
BOD5: ca. 350 mgO2/l

C O D

Method: ISO DP 6060 "Water quality - Determination of the chemical oxygen demand"
Year: 1983 **GLP:** no data
COD: ca. 470 mg/g substance

R A T I O B O D 5 / C O D

BOD5/COD: = .74

Remark: Précision très moyenne due à l'obligation d'opérer la mesure de la DBO sur des solutions très diluées en raison de l'effet biocide du formaldéhyde.
Source: PROTEX S.A LEVALLOIS PERRET

Method: other: Standard Dilution Method
Year: 1955 **GLP:** no

Result: BOD5 = 0.57 g/g (average value); THOD = 1.065 g/g
Source: BASF AG Ludwigshafen
(82)

3.7 Bioaccumulation

Species:
Exposure period:
Concentration:
BCF:
Elimination:
Method:
Year: **GLP:**
Test substance:
Remark: Pas de données disponibles
Source: PROTEX S.A LEVALLOIS PERRET

3.8 Additional Remarks

Result: Water pollution factors /BOD5 (different references):
60% of THOD
0.6–1.07 std. dil. at <260 mg/l
0.728
0.33–1.06 std. dil. sewage
1.06 std. dil. sew. (99.3%)
0.64 std. dil. sew. (60%)
0.33 std. dil. sew. at 2.5–10 ppm (31%)
0.45 std. dil. sew. at 1.7–20 ppm (42%)
1.10 manom 50% sew; at 260 ppm (103%)
0.57 manom 5% sew; at 260 ppm
0 Sierp, 10% sew; at 440 ppm
1.00 Warburg, 50% sew; at 130 ppm (94%)
1.10 Warburg, 25–50% sew; 250 ppm (103%)
Source: BASF AG Ludwigshafen
(83)

Result: BOD20: 1.228 (115%)
Source: BASF AG Ludwigshafen
(83)

Remark: Impact on biodegradation processes:
inhibition of anaerobic sludge digestion at 100 mg/l
aerobic degradation at 135–175 mg/l
methane fermentation can be acclimated up to 15%
formaldehyde (150 g/l)
Source: BASF AG Ludwigshafen
(83)

Remark: Different strains of bacteria decomposing formaldehyde have been isolated from activated sludge, mainly belonging to Pseudomonas. Less numerous were Achromobacter, Flavobacterium, Mycobacterium and Xanthomonas.
Source: BASF AG Ludwigshafen

(84)

Remark: Pseudomonas induces at growth on C1 (not glucose or peptone) 2 soluble enzyme systems, which oxidize formaldehyde. Formaldehyde itself is no substrate.
Source: BASF AG Ludwigshafen

(85)

Remark: Formaldehyde degradation was tested in a Warburg respirometer with a pure culture of alcaligenes faecalis. Oxygen uptake stopped after brief period, the authors concluded inhibition.
Source: BASF AG Ludwigshafen

(86)

Remark: Formaldehyde–casein–oil–complex was metabolized by ruminants (sheep). 14–CO2 and 14–CH4 was released, no formaldehyde accumulation in tissues.
Source: BASF AG Ludwigshafen

(87)

Remark: Respirometric test on degradation inhibition with 10–500 mg/l formaldehyde in municipal sewage showed 55% inhibition at 500 mg/l. Primary degradation after 2.5 days totally (240 mg/l).
Source: BASF AG Ludwigshafen

(88)

Remark: Formaldehyde inhibits anaerobic degradation of contents of chemical toilets at shock–loading: 200 mg/l (200 ppm).
Source: BASF AG Ludwigshafen

(89)

AQUATIC ORGANISMS

4.1 Acute/Prolonged Toxicity to Fish

Type: flow through
Species: Cyprinus carpio (Fish, fresh water)
Exposure period: 2 hour(s)
Unit: mg/l **Analytical monitoring:** no data
LC50: = 74
Method: other: acute toxicity test; "flow through bioassay"
Year: **GLP:** no data
Test substance: other TS
Remark: Reliability: 2 (reliable with restrictions)
Source: BASF AG Ludwigshafen
Test substance: formaldehyde; no data on purity of the compound

(90)

Type: flow through
Species: Ictalurus melas (Fish, fresh water)
Exposure period: 24 hour(s)
Unit: mg/l **Analytical monitoring:** no data
LC50: = 69.2
Method: other: acute toxicity test; "flow through bioassay"
Year: **GLP:** no
Test substance: other TS
Remark: fingerling; pH 6.5, water hardness 8, water temperature 12 degrees Centigrade
Reliability: 2 (reliable with restrictions)
Source: BASF AG Ludwigshafen
Test substance: formaldehyde; no data on purity of the compound

(91)

Type: flow through
Species: Ictalurus melas (Fish, fresh water)
Exposure period: 96 hour(s)
Unit: mg/l **Analytical monitoring:** no data
LC50: = 24.8
Method: other: acute toxicity test; "flow through bioassay"
Year: **GLP:** no
Test substance: other TS
Remark: fingerling; pH 6.5, water hardness 8, water temperature 12 degrees Centigrade
Reliability: 2 (reliable with restrictions)
Source: BASF AG Ludwigshafen
Test substance: formaldehyde; no data on purity of the compound

(91)

Type: flow through
Species: Ictalurus melas (Fish, fresh water)
Exposure period: 96 hour(s)
Unit: mg/l **Analytical monitoring:** no data
LC50: = 62.1
Method: other: acute toxicity test; "flow through bioassay"
Year: **GLP:** no
Test substance: other TS
Remark: fingerling; pH 6.5–9.5, water hardness 8, water temperature 12 degrees Centigrade
Reliability: 2 (reliable with restrictions)
Source: BASF AG Ludwigshafen
Test substance: formaldehyde; no data on purity of the compound

(91)

Type: flow through
Species: Ictalurus punctatus (Fish, fresh water)
Exposure period: 3 hour(s)
Unit: mg/l **Analytical monitoring:** no data
LC50: = 198
Method: other: acute toxicity test; "flow through bioassay"
Year: **GLP:** no
Test substance: other TS
Remark: fingerling; pH 6.5, water hardness 8, water temperature 12 degrees Centigrade
Reliability: 2 (reliable with restrictions)
Source: BASF AG Ludwigshafen
Test substance: formaldehyde; no data on purity of the compound

(91)

Type: flow through
Species: Ictalurus punctatus (Fish, fresh water)
Exposure period: 6 hour(s)
Unit: mg/l **Analytical monitoring:** no data
LC50: = 92.8
Method: other: acute toxicity test; "flow through bioassay"
Year: **GLP:** no
Test substance: other TS
Remark: fingerling; pH 6.5, water hardness 8, water temperature 12 degrees Centigrade
Reliability: 2 (reliable with restrictions)
Source: BASF AG Ludwigshafen
Test substance: formaldehyde; no data on purity of the compound

(91)

Type: flow through
Species: Ictalurus punctatus (Fish, fresh water)
Exposure period: 24 hour(s)
Unit: mg/l **Analytical monitoring:** no data
LC50: = 48.8
Method: other: acute toxicity test; "flow through bioassay"
Year: **GLP:** no
Test substance: other TS
Remark: fingerling; pH 6.5, water hardness 8, water temperature 12 degrees Centigrade
Reliability: 2 (reliable with restrictions)
Source: BASF AG Ludwigshafen
Test substance: formaldehyde; no data on purity of the compound

(91)

Type: flow through
Species: Ictalurus punctatus (Fish, fresh water)
Exposure period: 96 hour(s)
Unit: mg/l **Analytical monitoring:** no data
LC50: = 26.3
Method: other: acute toxicity test; "flow through bioassay"
Year: **GLP:** no
Test substance: other TS
Remark: fingerling; pH 6.5, water hardness 8, water temperature 12 degrees Centigrade
Reliability: 2 (reliable with restrictions)
Source: BASF AG Ludwigshafen
Test substance: formaldehyde; no data on purity of the compound

(91)

Type: flow through
Species: Ictalurus punctatus (Fish, fresh water)
Exposure period: 96 hour(s)
Unit: mg/l **Analytical monitoring:** no data
LC50: = 65.8
Method: other: acute toxicity test; "flow through bioassay"
Year: **GLP:** no
Test substance: other TS
Remark: fingerling; pH 6.5, water hardness 8, water temperature 12 degrees Centigrade
Reliability: 2 (reliable with restrictions)
Source: BASF AG Ludwigshafen
Test substance: formaldehyde; no data on purity of the compound

(91)

Type: flow through
Species: Lepomis cyanellus (Fish, fresh water)
Exposure period: 24 hour(s)
Unit: mg/l **Analytical monitoring:** no data
LC50: = 129
Method: other: acute toxicity test; "flow through bioassay"
Year: **GLP:** no
Test substance: other TS
Remark: fingerling; pH 6.5, water hardness 8, water temperature 12 degrees Centigrade
Reliability: 2 (reliable with restrictions)
Source: BASF AG Ludwigshafen
Test substance: formaldehyde; no data on purity of the compound

(91)

Type: flow through
Species: Lepomis cyanellus (Fish, fresh water)
Exposure period: 96 hour(s)
Unit: mg/l **Analytical monitoring:** no data
LC50: = 69.2
Method: other: acute toxicity test; "flow through bioassay"
Year: **GLP:** no
Test substance: other TS
Remark: fingerling; pH 6.5, water hardness 8, water temperature 12 degrees Centigrade
Reliability: 2 (reliable with restrictions)
Source: BASF AG Ludwigshafen
Test substance: formaldehyde; no data on purity of the compound

(91)

Type: flow through
Species: Lepomis gibbosus (Fish, fresh water)
Exposure period: 3 hour(s)
Unit: mg/l **Analytical monitoring:** no data
LC50: = 916
Method: other: acute toxicity test; "flow through bioassay"
Year: **GLP:** no
Test substance: other TS
Remark: fingerling; pH 6.5, water hardness 8, water temperature 12 degrees Centigrade
Reliability: 2 (reliable with restrictions)
Source: BASF AG Ludwigshafen
Test substance: formaldehyde; no data on purity of the compound

(91)

Type: flow through
Species: Lepomis gibbosus (Fish, fresh water)
Exposure period: 6 hour(s)
Unit: mg/l **Analytical monitoring:** no data
LC50: = 640
Method: other: acute toxicity test; "flow through bioassay"
Year: **GLP:** no
Test substance: other TS
Remark: fingerling; pH 6.5, water hardness 8, water temperature 12 degrees Centigrade
Reliability: 2 (reliable with restrictions)
Source: BASF AG Ludwigshafen
Test substance: formaldehyde; no data on purity of the compound

(91)

Type: flow through
Species: Lepomis gibbosus (Fish, fresh water)
Exposure period: 24 hour(s)
Unit: mg/l **Analytical monitoring:** no data
LC50: = 84.4
Method: other: acute toxicity test; "flow through bioassay"
Year: **GLP:** no
Test substance: other TS
Remark: fingerling; pH 6.5, water hardness 8, water temperature 12 degrees Centigrade
Reliability: 2 (reliable with restrictions)
Source: BASF AG Ludwigshafen
Test substance: formaldehyde; no data on purity of the compound

(91)

Type: flow through
Species: Lepomis gibbosus (Fish, fresh water)
Exposure period: 96 hour(s)
Unit: mg/l **Analytical monitoring:** no data
LC50: = 40
Method: other: acute toxicity test; "flow through bioassay"
Year: **GLP:** no
Test substance: other TS
Remark: fingerling; pH 6.5, water hardness 8, water temperature 12 degrees Centigrade
Reliability: 2 (reliable with restrictions)
Source: BASF AG Ludwigshafen
Test substance: formaldehyde; no data on purity of the compound

(91)

Type: flow through
Species: Lepomis macrochirus (Fish, fresh water)
Exposure period: 96 hour(s)
Unit: mg/l **Analytical monitoring:** no data
LC50: = 100
Method: other: acute toxicity test; "flow through bioassay"
Year: **GLP:** no
Test substance: other TS
Remark: fingerling; pH 6.5, water hardness 8, water temperature 12 degrees Centigrade
Reliability: 2 (reliable with restrictions)
Source: BASF AG Ludwigshafen
Test substance: formaldehyde; no data on purity of the compound

(91)

Type: flow through
Species: Micropterus dolomieui (Fish, fresh water, marine)
Exposure period: 24 hour(s)
Unit: mg/l **Analytical monitoring:** no data
LC50: = 88.8
Method: other: acute toxicity test; "flow through bioassay"
Year: **GLP:** no
Test substance: other TS
Remark: pH 6.5, water hardness 8, water temperature 12 degrees Centigrade
Reliability: 2 (reliable with restrictions)
Source: BASF AG Ludwigshafen
Test substance: formaldehyde; no data on purity of the compound

(91)

Type: flow through
Species: Micropterus dolomieui (Fish, fresh water, marine)
Exposure period: 96 hour(s)
Unit: mg/l **Analytical monitoring:** no data
LC50: = 54.4
Method: other: acute toxicity test; "flow through bioassay"
Year: **GLP:** no
Test substance: other TS
Remark: fingerling; pH 6.5, water hardness 8, water temperature 12 degrees Centigrade
Reliability: 2 (reliable with restrictions)
Source: BASF AG Ludwigshafen
Test substance: formaldehyde; no data on purity of the compound

(91)

Type: flow through
Species: Micropterus dolomieui (Fish, fresh water, marine)
Exposure period: 96 hour(s)
Unit: mg/l **Analytical monitoring:** no data
LC50: = 136
Method: other: acute toxicity test; "flow through bioassay"
Year: **GLP:** no
Test substance: other TS
Remark: fingerling; pH 6.5, water hardness 8, water temperature 12 degrees Centigrade
Reliability: 2 (reliable with restrictions)
Source: BASF AG Ludwigshafen
Test substance: formaldehyde; no data on purity of the compound

(91)

Type: flow through
Species: Micropterus salmoides (Fish, fresh water)
Exposure period: 6 hour(s)
Unit: mg/l **Analytical monitoring:** no data
LC50: = 412
Method: other: acute toxicity test; "flow through bioassay"
Year: **GLP:** no
Test substance: other TS
Remark: pH 6.5, water hardness 8, water temperature 12 degrees Centigrade
Reliability: 2 (reliable with restrictions)
Source: BASF AG Ludwigshafen
Test substance: formaldehyde; no data on purity of the compound

(91)

Type: flow through
Species: Micropterus salmoides (Fish, fresh water)
Exposure period: 24 hour(s)
Unit: mg/l **Analytical monitoring:** no data
LC50: = 113
Method: other: acute toxicity test; "flow through bioassay"
Year: **GLP:** no
Test substance: other TS
Remark: fingerling; pH 6.5, water hardness 8, water temperature 12 degrees Centigrade
Reliability: 2 (reliable with restrictions)
Source: BASF AG Ludwigshafen
Test substance: formaldehyde; no data on purity of the compound

(91)

Type: flow through
Species: Micropterus salmoides (Fish, fresh water)
Exposure period: 96 hour(s)
Unit: mg/l **Analytical monitoring:** no data
LC50: = 57.2
Method: other: acute toxicity test; "flow through bioassay"
Year: **GLP:** no
Test substance: other TS
Remark: fingerling; pH 6.5, water hardness 8, water temperature 12 degrees Centigrade
Reliability: 2 (reliable with restrictions)
Source: BASF AG Ludwigshafen
Test substance: formaldehyde; no data on purity of the compound

(91)

Type: flow through
Species: Micropterus salmoides (Fish, fresh water)
Exposure period: 96 hour(s)
Unit: mg/l **Analytical monitoring:** no data
LC50: = 143
Method: other: acute toxicity test; "flow through bioassay"
Year: **GLP:** no
Test substance: other TS
Remark: fingerling; pH 6.5, water hardness 8, water temperature 12 degrees Centigrade
Reliability: 2 (reliable with restrictions)
Source: BASF AG Ludwigshafen
Test substance: formaldehyde; no data on purity of the compound

(91)

Type: flow through
Species: Micropterus salmoides (Fish, fresh water)
Exposure period: 96 hour(s)
Unit: mg/l **Analytical monitoring:** no data
LC50: ca. 143
Method:
Year: 1977 **GLP:**
Test substance: no data
Source: STRATHCLYDE CHEMICAL COMPANY LIMITED JOHNSTONE

Type: flow through
Species: Salmo gairdneri (Fish, estuary, fresh water)
Exposure period: 3 hour(s)
Unit: mg/l **Analytical monitoring:** no data
LC50: = 492
Method: other: acute toxicity test; "flow through bioassay"
Year: **GLP:** no
Test substance: other TS
Remark: fingerling; pH 6.5, water hardness 8, water temperature 12 degrees Centigrade
Reliability: 2 (reliable with restrictions)
Source: BASF AG Ludwigshafen
Test substance: formaldehyde; no data on purity of the compound

(91)

Type: flow through
Species: Salmo gairdneri (Fish, estuary, fresh water)
Exposure period: 6 hour(s)
Unit: mg/l **Analytical monitoring:** no data
LC50: = 262
Method: other: acute toxicity test; "flow through bioassay"
Year: **GLP:** no
Test substance: other TS
Remark: fingerling; pH 6.5, water hardness 8, water temperature 12 degrees Centigrade
Reliability: 2 (reliable with restrictions)
Source: BASF AG Ludwigshafen
Test substance: formaldehyde; no data on purity of the compound

(91)

Type: flow through
Species: Salmo gairdneri (Fish, estuary, fresh water)
Exposure period: 24 hour(s)
Unit: mg/l **Analytical monitoring:** no data
LC50: = 120
Method: other: acute toxicity test; "flow through bioassay"
Year: **GLP:** no
Test substance: other TS
Remark: fingerling; pH 6.5, water hardness 8, water temperature 12 degrees Centigrade
Reliability: 2 (reliable with restrictions)
Source: BASF AG Ludwigshafen
Test substance: formaldehyde; no data on purity of the compound

(91)

Type: flow through
Species: Salmo salar (Fish, fresh water, marine)
Exposure period: 3 hour(s)
Unit: mg/l **Analytical monitoring:** no data
LC50: = 564
Method: other: acute toxicity test; "flow through bioassay"
Year: **GLP:** no
Test substance: other TS
Remark: fingerling; pH 6.5, water hardness 8, water temperature 12 degrees Centigrade
Reliability: 2 (reliable with restrictions)
Source: BASF AG Ludwigshafen
Test substance: formaldehyde; no data on purity of the compound

(91)

Type: flow through
Species: Salmo salar (Fish, fresh water, marine)
Exposure period: 6 hour(s)
Unit: mg/l **Analytical monitoring:** no data
LC50: = 336
Method: other: acute toxicity test; "flow through bioassay"
Year: **GLP:** no
Test substance: other TS
Remark: fingerling; pH 6.5, water hardness 8, water temperature 12 degrees Centigrade
Reliability: 2 (reliable with restrictions)
Source: BASF AG Ludwigshafen
Test substance: formaldehyde; no data on purity of the compound

(91)

Type: flow through
Species: Salmo salar (Fish, fresh water, marine)
Exposure period: 24 hour(s)
Unit: mg/l **Analytical monitoring:** no data
LC50: = 156
Method: other: acute toxicity test; "flow through bioassay"
Year: **GLP:** no
Test substance: other TS
Remark: fingerling; pH 6.5, water hardness 8, water temperature 12 degrees Centigrade
Reliability: 2 (reliable with restrictions)
Source: BASF AG Ludwigshafen
Test substance: formaldehyde; no data on purity of the compound

(91)

Type: flow through
Species: Salvelinus namaycush (Fish, fresh water)
Exposure period: 6 hour(s)
Unit: mg/l **Analytical monitoring:** no data
LC50: = 241
Method: other: acute toxicity test; "flow through bioassay"
Year: **GLP:** no
Test substance: other TS
Remark: fingerling; pH 6.5, water hardness 8, water temperature 12 degrees Centigrade
Reliability: 2 (reliable with restrictions)
Source: BASF AG Ludwigshafen
Test substance: formaldehyde; no data on purity of the compound

(91)

Type: flow through
Species: Salvelinus namaycush (Fish, fresh water)
Exposure period: 24 hour(s)
Unit: mg/l **Analytical monitoring:** no data
LC50: = 56.4
Method: other: acute toxicity test; "flow through bioassay"
Year: **GLP:** no
Test substance: other TS
Remark: fingerling; pH 6.5, water hardness 8, water temperature 12 degrees Centigrade
Reliability: 2 (reliable with restrictions)
Source: BASF AG Ludwigshafen
Test substance: formaldehyde; no data on purity of the compound

(91)

Type: flow through
Species: Salvelinus namaycush (Fish, fresh water)
Exposure period: 96 hour(s)
Unit: mg/l **Analytical monitoring:** no data
LC50: = 40
Method: other: acute toxicity test; "flow through bioassay"
Year: **GLP:** no
Test substance: other TS
Remark: fingerling; pH 6.5, water hardness 8, water temperature 12 degrees Centigrade
Reliability: 2 (reliable with restrictions)
Source: BASF AG Ludwigshafen
Test substance: formaldehyde; no data on purity of the compound

(91)

Type: flow through
Species: Salvelinus namaycush (Fish, fresh water)
Exposure period: 96 hour(s)
Unit: mg/l **Analytical monitoring:** no data
LC50: = 100
Method: other: acute toxicity test; "flow through bioassay"
Year: **GLP:** no
Test substance: other TS
Remark: fingerling; pH 6.5, water hardness 8, water temperature 12 degrees Centigrade
Reliability: 2 (reliable with restrictions)
Source: BASF AG Ludwigshafen
Test substance: formaldehyde; no data on purity of the compound

(91)

Type: static
Species: Anguilla rostrata (Fish, estuary)
Exposure period: 96 hour(s)
Unit: mg/l **Analytical monitoring:** no data
LC50: = 31.1
Method: other: acute toxicity test; "static bioassay"
Year: **GLP:** no data
Test substance: other TS
Remark: American eel, glass stage
Reliability: 2 (reliable with restrictions)
Source: BASF AG Ludwigshafen
Test substance: formaldehyde; no data on purity of the compound
(92) (93) (94)

Type: static
Species: Anguilla rostrata (Fish, estuary)
Exposure period: 96 hour(s)
Unit: mg/l **Analytical monitoring:** no data
LC50: = 83.1
Method: other: acute toxicity test; "static bioassay"
Year: **GLP:** no data
Test substance: other TS
Remark: American eel, black stage
Reliability: 2 (reliable with restrictions)
Source: BASF AG Ludwigshafen
Test substance: formaldehyde; no data on purity of the compound
(92) (93) (94)

Type: static
Species: Anguilla rostrata (Fish, estuary)
Exposure period: 96 hour(s)
Unit: mg/l **Analytical monitoring:** no data
LC50: = 122.1
Method: other: acute toxicity test; "static bioassay"
Year: **GLP:** no data
Test substance: other TS
Remark: American eel, yellow stage
Reliability: 2 (reliable with restrictions)
Source: BASF AG Ludwigshafen
Test substance: formaldehyde; no data on purity of the compound
(92) (93) (94)

Type: static
Species: Brachydanio rerio (Fish, fresh water)
Exposure period: 96 hour(s)
Unit: mg/l **Analytical monitoring:** no data
LC50: = 41
Method: other: acute toxicity test; "static bioassay"
Year: **GLP:** no data
Test substance: other TS
Remark: Reliability: 2 (reliable with restrictions)
Source: BASF AG Ludwigshafen
Test substance: formaldehyde; no data on purity of the compound
(95)

Type: static
Species: Ictalurus punctatus (Fish, fresh water)
Exposure period: 24 hour(s)
Unit: mg/l **Analytical monitoring:** no data
LC50: = 50.7
Method: other: acute toxicity test; "static bioassay"
Year: **GLP:** no
Test substance: other TS
Remark: Reliability: 2 (reliable with restrictions)
Source: BASF AG Ludwigshafen
Test substance: formaldehyde; no data on purity of the compound

(96)

Type: static
Species: Ictalurus punctatus (Fish, fresh water)
Exposure period: 48 hour(s)
Unit: mg/l **Analytical monitoring:** no data
LC50: = 35.5
Method: other: acute toxicity test; "static bioassay"
Year: **GLP:** no
Test substance: other TS
Remark: Reliability: 2 (reliable with restrictions)
Source: BASF AG Ludwigshafen
Test substance: formaldehyde; no data on purity of the compound

(96)

Type: static
Species: Lepomis gibbosus (Fish, fresh water)
Exposure period: 24 hour(s)
Unit: mg/l **Analytical monitoring:** no data
LC50: = 53.7
Method: other: acute toxicity test; "static bioassay"
Year: **GLP:** no data
Test substance: other TS
Remark: fingerling
Reliability: 2 (reliable with restrictions)
Source: BASF AG Ludwigshafen
Test substance: formaldehyde; no data on purity of the compound

(97)

Type: static
Species: Lepomis gibbosus (Fish, fresh water)
Exposure period: 24 hour(s)
Unit: mg/l **Analytical monitoring:** no data
LC50: = 68.5
Method: other: acute toxicity test; "static bioassay"
Year: **GLP:** no
Test substance: other TS
Remark: fingerling
Reliability: 2 (reliable with restrictions)
Source: BASF AG Ludwigshafen
Test substance: formaldehyde; no data on purity of the compound

(96)

Type: static
Species: Lepomis gibbosus (Fish, fresh water)
Exposure period: 48 hour(s)
Unit: mg/l **Analytical monitoring:** no data
LC50: = 34
Method: other: acute toxicity test; "static bioassay"
Year: **GLP:** no
Test substance: other TS
Remark: fingerling
Reliability: 2 (reliable with restrictions)
Source: BASF AG Ludwigshafen
Test substance: formaldehyde; no data on purity of the compound

(97)

Type: static
Species: Lepomis gibbosus (Fish, fresh water)
Exposure period: 48 hour(s)
Unit: mg/l **Analytical monitoring:** no data
LC50: = 51.8
Method: other: acute toxicity test; "static bioassay"
Year: **GLP:** no
Test substance: other TS
Remark: fingerling
Reliability: 2 (reliable with restrictions)
Source: BASF AG Ludwigshafen
Test substance: formaldehyde; no data on purity of the compound

(96)

Type: static
Species: Lepomis gibbosus (Fish, fresh water)
Exposure period: 96 hour(s)
Unit: mg/l **Analytical monitoring:** no data
LC50: = 25.2
Method: other: acute toxicity test; "static bioassay"
Year: **GLP:** no
Test substance: other TS
Remark: fingerling
Reliability: 2 (reliable with restrictions)
Source: BASF AG Ludwigshafen
Test substance: formaldehyde; no data on purity of the compound

(97)

Type: static
Species: Leuciscus idus (Fish, fresh water)
Exposure period: 48 hour(s)
Unit: mg/l **Analytical monitoring:** no data
LC50: = 22
Method: other: acute toxicity test; "static bioassay"
Year: **GLP:** no data
Test substance: other TS
Remark: Reliability: 2 (reliable with restrictions)
Source: BASF AG Ludwigshafen
Test substance: formaldehyde; no data on purity of the compound

(95)

Type: static
Species: Morone saxatilis (Fish, estuary, marine)
Exposure period: 24 hour(s)
Unit: mg/l **Analytical monitoring:** no data
LC50: = 31.8
Method: other: acute toxicity test; "static bioassay"
Year: **GLP:** no data
Test substance: other TS
Remark: Reliability: 2 (reliable with restrictions)
Source: BASF AG Ludwigshafen
Test substance: formaldehyde; no data on purity of the compound
(98)

Type: static
Species: Morone saxatilis (Fish, estuary, marine)
Exposure period: 48 hour(s)
Unit: mg/l **Analytical monitoring:** no data
LC50: = 11.8
Method: other: acute toxicity test; "static bioassay"
Year: **GLP:** no data
Test substance: other TS
Remark: Reliability: 2 (reliable with restrictions)
Source: BASF AG Ludwigshafen
Test substance: formaldehyde; no data on purity of the compound
(98)

Type: static
Species: Morone saxatilis (Fish, estuary, marine)
Exposure period: 96 hour(s)
Unit: mg/l **Analytical monitoring:** no data
LC50: = 6.7
Method: other: acute toxicity test; "static bioassay"
Year: **GLP:** no data
Test substance: other TS
Remark: Reliability: 2 (reliable with restrictions)
Source: BASF AG Ludwigshafen
Test substance: formaldehyde; no data on purity of the compound
(98)

Type: static
Species: Rasbora heteromorpha (Fish, marine)
Exposure period: 24 hour(s)
Unit: mg/l **Analytical monitoring:** no data
LC50: = 76
Method: other: acute toxicity test; "static bioassay"
Year: **GLP:** no data
Test substance: other TS
Remark: Reliability: 2 (reliable with restrictions)
Source: BASF AG Ludwigshafen
Test substance: formaldehyde; no data on purity of the compound
(99)

Type: static
Species: Rasbora heteromorpha (Fish, marine)
Exposure period: 48 hour(s)
Unit: mg/l **Analytical monitoring:** no data
LC50: = 50
Method: other: acute toxicity test; "static bioassay"
Year: **GLP:** no data
Test substance: other TS
Remark: Reliability: 2 (reliable with restrictions)
Source: BASF AG Ludwigshafen
Test substance: formaldehyde; no data on purity of the compound

(99)

Type: static
Species: Salmo gairdneri (Fish, estuary, fresh water)
Exposure period: 24 hour(s)
Unit: mg/l **Analytical monitoring:** no data
LC50: = 76.6
Method: other: acute toxicity test; "static bioassay"
Year: **GLP:** no data
Test substance: other TS
Remark: Reliability: 2 (reliable with restrictions)
Source: BASF AG Ludwigshafen
Test substance: formaldehyde; no data on purity of the compound

(96)

Type: static
Species: Salmo gairdneri (Fish, estuary, fresh water)
Exposure period: 48 hour(s)
Unit: mg/l **Analytical monitoring:** no data
LC50: = 59.2
Method: other: acute toxicity test; "static bioassay"
Year: **GLP:** no data
Test substance: other TS
Remark: Reliability: 2 (reliable with restrictions)
Source: BASF AG Ludwigshafen
Test substance: formaldehyde; no data on purity of the compound

(97)

Type: static
Species: Salmo gairdneri (Fish, estuary, fresh water)
Exposure period: 48 hour(s)
Unit: mg/l **Analytical monitoring:** no data
LC50: = 62.2
Method: other: acute toxicity test; "static bioassay"
Year: **GLP:** no data
Test substance: other TS
Remark: Reliability: 2 (reliable with restrictions)
Source: BASF AG Ludwigshafen
Test substance: formaldehyde; no data on purity of the compound

(96)

Type: static
Species: Salmo gairdneri (Fish, estuary, fresh water)
Exposure period: 96 hour(s)
Unit: mg/l **Analytical monitoring:** no data
LC50: 61.9 – 106
Method: other: acute toxicity test; "static bioassay"
Year: **GLP:** no
Test substance: other TS
Remark: fingerling; pH 6.5–9.5, water temperature 12 degrees Centigrade
Reliability: 2 (reliable with restrictions)
Source: BASF AG Ludwigshafen
Test substance: formaldehyde; no data on purity of the compound
(100)

Type: static
Species: Salmo gairdneri (Fish, estuary, fresh water)
Exposure period: 96 hour(s)
Unit: mg/l **Analytical monitoring:** no data
LC50: 89.5 – 112
Method: other: acute toxicity test; "static bioassay"
Year: **GLP:** no
Test substance: other TS
Remark: larvae; pH 6.5–9.5, water temperature 12 degrees Centigrade
Reliability: 2 (reliable with restrictions)
Source: BASF AG Ludwigshafen
Test substance: formaldehyde; no data on purity of the compound
(100)

Type: static
Species: Salmo gairdneri (Fish, estuary, fresh water)
Exposure period: 96 hour(s)
Unit: mg/l **Analytical monitoring:** no data
LC50: = 118
Method: other: acute toxicity test; "static bioassay"
Year: **GLP:** no data
Test substance: other TS
Remark: Reliability: 2 (reliable with restrictions)
water hardness 20, water
temperature 12 degrees Centigrade
Source: BASF AG Ludwigshafen
Test substance: formaldehyde; no data on purity of the compound
(100)

Type: static
Species: Salmo gairdneri (Fish, estuary, fresh water)
Exposure period: 96 hour(s)
Unit: mg/l **Analytical monitoring:** no data
LC50: 565 – 1020
Method: other: acute toxicity test; "static bioassay"
Year: **GLP:** no
Test substance: other TS
Remark: green eegs; pH 6.5–9.5, water temperature 12 degrees Centigrade
Reliability: 2 (reliable with restrictions)
Source: BASF AG Ludwigshafen
Test substance: formaldehyde; no data on purity of the compound

(101)

Type: static
Species: Salmo salar (Fish, fresh water, marine)
Exposure period: 96 hour(s)
Unit: mg/l **Analytical monitoring:** no data
LC50: = 173
Method: other: acute toxicity test; "static bioassay"
Year: **GLP:** no
Test substance: other TS
Remark: pH 6.5, water temperature 12 degrees Centigrade
Reliability: 2 (reliable with restrictions)
Source: BASF AG Ludwigshafen
Test substance: formaldehyde; no data on purity of the compound

(101)

Type: static
Species: Salmo trutta (Fish, fresh water, marine)
Exposure period: 24 hour(s)
Unit: mg/l **Analytical monitoring:** no data
LC50: = 120.3
Method: other: acute toxicity test; "static bioassay"
Year: **GLP:** no
Test substance: other TS
Remark: Reliability: 2 (reliable with restrictions)
Source: BASF AG Ludwigshafen
Test substance: formaldehyde; no data on purity of the compound

(96)

Type: static
Species: Salmo trutta (Fish, fresh water, marine)
Exposure period: 48 hour(s)
Unit: mg/l **Analytical monitoring:** no data
LC50: = 68.5
Method: other: acute toxicity test; "static bioassay"
Year: **GLP:** no
Test substance: other TS
Remark: Reliability: 2 (reliable with restrictions)
Source: BASF AG Ludwigshafen
Test substance: formaldehyde; no data on purity of the compound

(96)

Type: static
Species: Salvelinus fontinalis (Fish, estuary, fresh water)
Exposure period: 24 hour(s)
Unit: mg/l **Analytical monitoring:** no data
LC50: = 72.5
Method: other: acute toxicity test; "static bioassay"
Year: **GLP:** no
Test substance: other TS
Remark: Reliability: 2 (reliable with restrictions)
Source: BASF AG Ludwigshafen
Test substance: formaldehyde; no data on purity of the compound
(96)

Type: static
Species: Salvelinus fontinalis (Fish, estuary, fresh water)
Exposure period: 48 hour(s)
Unit: mg/l **Analytical monitoring:** no data
LC50: = 58.1
Method: other: acute toxicity test; "static bioassay"
Year: **GLP:** no
Test substance: other TS
Remark: Reliability: 2 (reliable with restrictions)
Source: BASF AG Ludwigshafen
Test substance: formaldehyde; no data on purity of the compound
(96)

Type: static
Species: Salvelinus namaycush (Fish, fresh water)
Exposure period: 24 hour(s)
Unit: mg/l **Analytical monitoring:** no data
LC50: = 81.4
Method: other: acute toxicity test; "static bioassay"
Year: **GLP:** no
Test substance: other TS
Remark: fingerling
Reliability: 2 (reliable with restrictions)
Source: BASF AG Ludwigshafen
Test substance: formaldehyde; no data on purity of the compound
(96)

Type: static
Species: Salvelinus namaycush (Fish, fresh water)
Exposure period: 48 hour(s)
Unit: mg/l **Analytical monitoring:** no data
LC50: = 61.8
Method: other: acute toxicity test; "static bioassay"
Year: **GLP:** no
Test substance: other TS
Remark: fingerling
Reliability: 2 (reliable with restrictions)
Source: BASF AG Ludwigshafen
Test substance: formaldehyde; no data on purity of the compound
(96)

Type:
Species: other
Exposure period: 25 hour(s)
Unit: mg/l **Analytical monitoring:**
LC50: = 83
Method:
Year: **GLP:**
Test substance:
Source: ALDER S.p.A. TRIESTE
Test condition: su pesce gatto

(102)

Type:
Species: other
Exposure period:
Unit: mg/l **Analytical monitoring:**
LC100: 25
Method:
Year: **GLP:**
Test substance:
Source: ALDER S.p.A. TRIESTE
Test condition: su goldfish

(102)

Type:
Species:
Exposure period:
Unit: **Analytical monitoring:**
Method:
Year: **GLP:**
Test substance:
Remark: Pas de données disponibles
Source: PROTEX S.A LEVALLOIS PERRET

Type: other
Species: Cyprinus carpio (Fish, fresh water)
Exposure period: 72 hour(s)
Unit: mg/l **Analytical monitoring:** no data
LC50: > 26.6
Method: other: acute toxicity test
Year: **GLP:** no
Test substance: other TS
Remark: Reliability: 2 (reliable with restrictions)
Source: BASF AG Ludwigshafen
Test substance: formaldehyde; no data on purity of the compound

(103)

Type: other
Species: Ictalurus melas (Fish, fresh water)
Exposure period: 72 hour(s)
Unit: mg/l **Analytical monitoring:** no data
LC50: = 17.1
Method: other: acute toxicity test
Year: **GLP:** no
Test substance: other TS
Remark: fingerling
Source: BASF AG Ludwigshafen
Test substance: formaldehyde; no data on purity of the compound
Reliability: (2) valid with restrictions

(103)

Type: other
Species: Ictalurus punctatus (Fish, fresh water)
Exposure period: 96 hour(s)
Unit: mg/l **Analytical monitoring:** no data
LC50: = 25.5
Method: other: no data
Year: **GLP:** no
Test substance: other TS
Remark: Reliability: 2 (reliable with restrictions)
Source: BASF AG Ludwigshafen
Test substance: formaldehyde; no data on purity of the compound

(104) (105)

Type: other
Species: Lepomis cyanellus (Fish, fresh water)
Exposure period: 72 hour(s)
Unit: mg/l **Analytical monitoring:** no data
LC50: > 34.2
Method: other: acute toxicity test
Year: **GLP:** no
Test substance: other TS
Remark: fingerling
Source: BASF AG Ludwigshafen
Test substance: formaldehyde; no data on purity of the compound
Reliability: (2) valid with restrictions

(103)

Type: other
Species: Lepomis cyanellus (Fish, fresh water)
Exposure period: 96 hour(s)
Unit: mg/l **Analytical monitoring:** no data
LC50: = 173
Method: other: acute toxicity test
Year: **GLP:** no
Test substance: other TS
Remark: water temperature 12 degrees Centigrade
Source: BASF AG Ludwigshafen
Test substance: formaldehyde; no data on purity of the compound
Reliability: (2) valid with restrictions

(101)

Type: other
Species: Lepomis cyanellus (Fish, fresh water)
Exposure period: 48 hour(s)
Unit: mg/l **Analytical monitoring:** no data
LC50: = 32.4
Method: other: no data
Year: **GLP:** no
Test substance: other TS
Source: BASF AG Ludwigshafen
Test substance: formaldehyde; no data on purity of the compound
Reliability: (2) valid with restrictions

(106)

Type: other
Species: Lepomis gibbosus (Fish, fresh water)
Exposure period: 72 hour(s)
Unit: mg/l **Analytical monitoring:** no data
LC50: > 30.4
Method: other: acute toxicity test
Year: **GLP:** no
Test substance: other TS
Remark: fingerling
Source: BASF AG Ludwigshafen
Test substance: formaldehyde; no data on purity of the compound
Reliability: (2) valid with restrictions

(103)

Type: other
Species: Leuciscus idus (Fish, fresh water)
Exposure period: 48 hour(s)
Unit: mg/l **Analytical monitoring:** no data
LC50: = 15
Method: other: no data
Year: **GLP:** no data
Test substance: other TS
Source: BASF AG Ludwigshafen
Test substance: formaldehyde; no data on purity of the compound
Reliability: (2) valid with restrictions

(106)

Type: other
Species: Micropterus salmoides (Fish, fresh water)
Exposure period: 72 hour(s)
Unit: mg/l **Analytical monitoring:** no data
LC50: > 38
Method: other: acute toxicity test
Year: **GLP:** no
Test substance: other TS
Remark: fingerling
Source: BASF AG Ludwigshafen
Test substance: formaldehyde; no data on purity of the compound
Reliability: (2) valid with restrictions

(103)

Type: other
Species: Salmo gairdneri (Fish, estuary, fresh water)
Exposure period: 24 hour(s)
Unit: mg/l **Analytical monitoring:** no data
LC50: 214 – 7200
Method: other: acute toxicity test
Year: **GLP:** no
Test substance: other TS
Remark: pH 7.5, water hardness 40–48,
water temperature 12 degrees Centigrade
Source: BASF AG Ludwigshafen
Test substance: formaldehyde; no data on purity of the compound
Reliability: (2) valid with restrictions
(101) (107)

Type: other
Species: Salmo gairdneri (Fish, estuary, fresh water)
Exposure period: 96 hour(s)
Unit: mg/l **Analytical monitoring:** no data
LC50: > 47.2
Method: other: acute toxicity test
Year: **GLP:** no
Test substance: other TS
Remark: fingerling
Source: BASF AG Ludwigshafen
Test substance: formaldehyde; no data on purity of the compound
Reliability: (2) valid with restrictions
(103)

Type: other
Species: Salmo gairdneri (Fish, estuary, fresh water)
Exposure period: 96 hour(s)
Unit: mg/l **Analytical monitoring:** no data
LC50: 440 – 618
Method: other: acute toxicity test
Year: **GLP:** no
Test substance: other TS
Remark: pH 7.5–8.2, water hardness
30–245, water temperature 12 degrees Centigrade
Source: BASF AG Ludwigshafen
Test substance: formaldehyde; no data on purity of the compound
Reliability: (2) valid with restrictions
(101)

Type: other
Species: Salmo gairdneri (Fish, estuary, fresh water)
Exposure period:
Unit: **Analytical monitoring:** no data
Method: other: no data
Year: **GLP:** no
Test substance: other TS
Remark: In rainbow trouts, toxicity of formaldehyde was increased with raising water temperature, decreasing water hardness, and increasing pH values changes of gill function, hypochloremia, decreased contents of both calcium and carbon dioxide in plasma, lowered pH of blood and reduced consumption of oxygen were observed.)
Source: BASF AG Ludwigshafen
Test substance: formaldehyde; no data on purity of the compound
Reliability: (2) valid with restrictions

(91)

Type: other
Species: Salmo salar (Fish, fresh water, marine)
Exposure period: 96 hour(s)
Unit: mg/l **Analytical monitoring:** no data
LC50: 198 – 435
Method: other: acute toxicity test
Year: **GLP:** no
Test substance: other TS
Remark: "eyed eggs"; pH 6.5–9.5, water temperature 12 degrees Centigrade
Source: BASF AG Ludwigshafen
Test substance: formaldehyde; no data on purity of the compound
Reliability: (2) valid with restrictions

(101)

Type: other
Species: Salmo salar (Fish, fresh water, marine)
Exposure period:
Unit: **Analytical monitoring:** no data
Method: other: no data
Year: **GLP:** no
Test substance: other TS
Remark: Changes of gill function, hypochloremia, decreased contents of both calcium and carbon dioxide in plasma, lowered pH of blood and reduced consumption of oxygen, increased levels of both hemoglobin and glucose in blood, increased protein concentration in plasma, and increased "packed" cell volumina were observed.
Source: BASF AG Ludwigshafen
Test substance: formaldehyde; no data on purity of the compound
Reliability: (2) valid with restrictions

(107) (108)

Type: other
Species: other: Golden Shiner
Exposure period: 72 hour(s)
Unit: mg/l **Analytical monitoring:** no data
LC50: = 23.6
Method: other: acute toxicity test
Year: **GLP:** no
Test substance: other TS
Source: BASF AG Ludwigshafen
Test substance: formaldehyde; no data on purity of the compound
Reliability: (2) valid with restrictions

(103)

Type: other
Species: other: Tilapia
Exposure period: 72 hour(s)
Unit: mg/l **Analytical monitoring:** no data
LC50: > 38
Method: other: acute toxicity test
Year: **GLP:** no
Test substance: other TS
Source: BASF AG Ludwigshafen
Test substance: formaldehyde; no data on purity of the compound
Reliability: (2) valid with restrictions

(103)

4.2 Acute Toxicity to Aquatic Invertebrates

Species: Daphnia magna (Crustacea)
Exposure period: 24 hour(s)
Unit: mg/l **Analytical monitoring:**
EC0: = 33
EC50: = 42
EC100: = 53
Method: other: Mobilization Inhibition Test
Year: **GLP:** no
Test substance: other TS: formaline 35%
Source: BASF AG Ludwigshafen
Test condition: 20 deg C; pH ca. 8.0
Reliability: (1) valid without restriction
Test procedure in accordance with generally accepted scientific standards and described in sufficient detail

(109)

Species: Daphnia magna (Crustacea)
Exposure period: 24 hour(s)
Unit: mg/l **Analytical monitoring:**
EC0: = 27
EC50: = 52
EC100: = 77
Method: other: Mobilization Inhibition Test
Year: **GLP:** no
Test substance: other TS: formaline 35%
Source: BASF AG Ludwigshafen
Test condition: tap water as test medium, free from chlorine; pH 7.6–7.7; 20–22 deg C
Reliability: (1) valid without restriction
Test procedure in accordance with generally accepted scientific standards and described in sufficient detail
(110)

Species: Daphnia magna (Crustacea)
Exposure period: 24 hour(s)
Unit: mg/l **Analytical monitoring:**
TLm : > 100 – 1000
Method: other: Acute Toxicity Test
Year: **GLP:** no
Test substance:
Remark: TLm = Median Tolerance Limit
Source: BASF AG Ludwigshafen
Test condition: Reference Dilution Water
(111)

Species: Daphnia magna (Crustacea)
Exposure period: 1 hour(s)
Unit: mg/l **Analytical monitoring:**
EC50: = 39
Method:
Year: **GLP:** no
Test substance:
Method: Juvenile Daphnia magna was exposed to a toxicant dilution series for 1 h, after which the substrate was added and the enzymatic inhibition (absence of fluorescence) was observed visually, using a long wave UV light (385 mm).
Remark: Conventional test (immobilzation; mean concentrations): EC50 (24 h) = 57 mg/l; EC50 (48 h) = 29 mg/l
Source: BASF AG Ludwigshafen
(112)

Species: other: Anodonta cygnea and Daphnia magna
Exposure period:
Unit: **Analytical monitoring:**
Method:
Year: **GLP:**
Test substance:
Remark: The effects of some ecotoxical model substances on the activity of frontal gill cilia of freshwater mussel Anodonta cygnea were studied in 1 and 24 h experiments with the results of standard Daphnia magna EC50 tests with the same substances.
Result: Toxicity of formaldehyde on the ciliary activity in Anodonta gills and on Daphnia magna:
EC (minimum, 2h) = 2 mg/l (Anodonta gills)
EC50 (24,48h) = 5,14 mg/l (Daphnia magna)
Source: BASF AG Ludwigshafen
Test substance: Concentrations calculated as formaldehyde

(113)

Species: other aquatic mollusc: Mytilus edulis
Exposure period:
Unit: **Analytical monitoring:**
Method:
Year: **GLP:**
Test substance:
Remark: The effects of sublethal concentrations of organic pollutants on intracellular energy–rich phosphates in blue mussels, Mytilus edulis, were investigated by in vivo P–NMR.
Result: 30 and 10 mg/l formaldehyde (96h exposition) caused reduction of byssal thread formation and reduction of ATP. No effect with 1 mg/l.
Source: BASF AG Ludwigshafen

(114)

Species: other aquatic crustacea: Palaemonetes kadiakensis
Exposure period: 24 hour(s)
Unit: **Analytical monitoring:**
Method: other: Acute Toxicity Test
Year: **GLP:** no
Test substance: other TS: formaline 37%
Result: LC50 (24h) = 1105 ul/l
Toxicity based on immobility
Source: BASF AG Ludwigshafen
Test condition: soft water at 16 deg C

(115)

Species: other aquatic crustacea: Penaeus sp.
Exposure period:
Unit: **Analytical monitoring:**
Method:
Year: **GLP:**
Test substance:
Remark: The 96 h LD50s for formaline under the conditions of these tests were 235 ppm at 28 deg C and 270 ppm at 22 deg C for the 60-70 mm and postlarval pink shrimp, respectively. Application levels of 25 ppm would be save for treatments of indefinite duration. Based on a 96 h observation period following dipping, 30 min dip treatments indicated treatment in the range of 150-250 ppm would be usable at temperatures of 22 deg C and below. Tests that utilized post-larval shrimp of poor condition and at 21 deg C showed no loss in excess of controls when given the same testing routine.
Source: BASF AG Ludwigshafen
Test condition: 4 sizes of shrimps; artificial sea salt (Instant ocean)

(116)

Species: other: Corbicula sp.
Exposure period: 24 hour(s)
Unit: **Analytical monitoring:**
Method: other: Acute Toxicity Test
Year: **GLP:** no
Test substance: other TS: formaline 37%
Result: LC50 (24h) = 800 ul/l
Toxicity based on ability to resist attempts to open valves and respond to tactile stimulus
Source: BASF AG Ludwigshafen
Test condition: soft water at 16 deg C

(115)

Species: other: Cypridopsis sp.
Exposure period: 24 hour(s)
Unit: **Analytical monitoring:**
Method: other: Acute Toxicity Test
Year: **GLP:** no
Test substance: other TS: formaline 37%
Result: LC50 (24h) = 1.15 ul/l
Toxicity based on immobility
Source: BASF AG Ludwigshafen
Test condition: soft water at 16 deg C

(115)

Species: other: Helisoma sp.
Exposure period: 24 hour(s)
Unit: **Analytical monitoring:**
Method: other: Acute Toxicity Test
Year: **GLP:** no
Test substance: other TS: formaline 37%
Result: LC50 (24h) = 710 ul/l
Toxicity based on ability to respond to tactile stimulus
Source: BASF AG Ludwigshafen
Test condition: soft water at 16 deg C

(115)

Species: other: Notonecta sp.
Exposure period: 24 hour(s)
Unit: **Analytical monitoring:**
Method: other: Acute Toxicity Test
Year: **GLP:** no
Test substance: other TS: formaline 37%
Result: LC50 (24h) = 4500 ul/l
Toxicity based on ability to respond to tactile stimulus
Source: BASF AG Ludwigshafen
Test condition: soft water at 16 deg C

(115)

Species: other: Streptocephalus seali
Exposure period: 24 hour(s)
Unit: mg/l **Analytical monitoring:**
EC0: > 25
Method: other: Acute Toxicity Test
Year: **GLP:** no
Test substance: other TS: formaline 37%
Result: EC10 (48h) = 25 mg/l
Source: BASF AG Ludwigshafen
Test condition: Static test in well water at 24 deg C

(117)

Species: Daphnia magna (Crustacea)
Exposure period: 48 hour(s)
Unit: mg/l **Analytical monitoring:** no data
LC50 : ca. 2
Method:
Year: 1973 **GLP:**
Test substance: no data
Source: STRATHCLYDE CHEMICAL COMPANY LIMITED JOHNSTONE

Species:
Exposure period:
Unit: **Analytical monitoring:**
Method:
Year: **GLP:**
Test substance:
Remark: Pas de données disponibles
Source: PROTEX S.A LEVALLOIS PERRET

4.3 Toxicity to Aquatic Plants e.g. Algae

Species: Scenedesmus quadricauda (Algae)
Endpoint:
Exposure period: 8 day
Unit: mg/l **Analytical monitoring:**
TGK : = 2.5
Method: other: Cell Multiplication Inhibition Test
Year: **GLP:** no
Test substance: other TS: formaline 35%
Source: BASF AG Ludwigshafen
Test condition: pH 7.0; bidest. water; 27 deg C
Reliability: (1) valid without restriction
Test procedure in accordance with generally accepted scientific standards and described in sufficient detail
(118)

Species: Scenedesmus sp. (Algae)
Endpoint:
Exposure period: 24 hour(s)
Unit: mg/l **Analytical monitoring:**
TGK : = .3
Method:
Year: **GLP:** no
Test substance:
Result: Starting inhibition of cell multiplication
Source: BASF AG Ludwigshafen
Test condition: 25 deg C; pH 7.5–7.8
(119)

Species: Scenedesmus quadricauda (Algae)
Endpoint:
Exposure period:
Unit: mg/l **Analytical monitoring:** no data
LC50 : ca. .3
Method:
Year: 1960 **GLP:**
Test substance: no data
Source: STRATHCLYDE CHEMICAL COMPANY LIMITED JOHNSTONE

Species:
Endpoint:
Exposure period:
Unit: **Analytical monitoring:**
Method:
Year: **GLP:**
Test substance:
Remark: Pas de données disponibles
Source: PROTEX S.A LEVALLOIS PERRET

4.4 Toxicity to Microorganisms e.g. Bacteria

Type: aquatic
Species: Chilomonas paramaecium (Protozoa)
Exposure period: 48 hour(s)
Unit: mg/l **Analytical monitoring:**
TGK : = 4.5
Method: other: Cell Multiplication Inhibition Test
Year: **GLP:** no
Test substance: other TS: formaline 35%
Source: BASF AG Ludwigshafen
Test condition: pH 6.9; bidest. water; 20 deg C
Reliability: (1) valid without restriction
Test procedure in accordance with generally accepted scientific standards and described in sufficient detail
(120)

Type: aquatic
Species: activated sludge, industrial
Exposure period: 7 day
Unit: mg/l **Analytical monitoring:**
EC10: > 1995
Method: other: Activated Sludge Respiration Inhibition Test
Year: 1979 **GLP:** no
Test substance: other TS: formaldehyde 35%
Remark: Support of respiration
Source: BASF AG Ludwigshafen
Reliability: (1) valid without restriction
Documented test parameters in accordance with the relating standard methods
(121)

Type: aquatic
Species: activated sludge
Exposure period: 30 minute(s)
Unit: mg/l **Analytical monitoring:**
EC20 : > 700
Method: other: Activated Sludge Respiration Inhibition Test
Year: 1979 **GLP:** no
Test substance: other TS: formaldehyde 35%
Remark: related to 100% active agent; 700 mg/l highest concentration tested
Source: BASF AG Ludwigshafen
Reliability: (1) valid without restriction
Documented test parameters in accordance with the relating standard methods
(121)

Type: aquatic
Species: Entosiphon sulcatum (Protozoa)
Exposure period: 72 hour(s)
Unit: mg/l **Analytical monitoring:**
TGK : = 22
Method: other: Cell Multiplication Inhibition Test
Year: **GLP:** no
Test substance: other TS: formaline 35%
Source: BASF AG Ludwigshafen
Test condition: pH 6.9; bidest. water; 25 deg C
Reliability: (1) valid without restriction
Test procedure in accordance with generally accepted scientific standards and described in sufficient detail
(122)

Type: aquatic
Species: Uronema parduzci (Protozoa)
Exposure period: 20 hour(s)
Unit: mg/l **Analytical monitoring:**
TGK : = 6.5
Method: other: Cell Multiplication Inhibition Test
Year: **GLP:** no
Test substance: other TS: formaline 35%
Source: BASF AG Ludwigshafen
Test condition: pH 6.9; bidest. water; 25 deg C
Reliability: (1) valid without restriction
Test procedure in accordance with generally accepted scientific standards and described in sufficient detail
(123)

Type: aquatic
Species: Pseudomonas putida (Bacteria)
Exposure period: 16 hour(s)
Unit: mg/l **Analytical monitoring:**
TGK : = 14
Method: other: Cell Multiplication Inhibition Test
Year: **GLP:** no
Test substance: other TS: formaline 35%
Source: BASF AG Ludwigshafen
Test condition: pH 7.0; bidest. water; 27 deg C
Reliability: (1) valid without restriction
Test procedure in accordance with generally accepted scientific standards and described in sufficient detail
(124)

Type: aquatic
Species: Microcystis aeruginosa (Bacteria)
Exposure period: 8 day
Unit: mg/l **Analytical monitoring:**
TGK : = .39
Method: other: Cell Multiplication Inhibition Test
Year: **GLP:** no
Test substance: other TS: formaline 35%
Source: BASF AG Ludwigshafen
Test condition: pH 7.0; bidest. water; 27 deg C
Reliability: (1) valid without restriction
Test procedure in accordance with generally accepted scientific standards and described in sufficient detail
(118)

Type: aquatic
Species: activated sludge, industrial
Exposure period:
Unit: mg/l **Analytical monitoring:**
EC50: = 1.714
EC20 : = 1.429
EC80 : = 4.286
Method: other: Toximeter experiments (model WWTP)
Year: 1979 **GLP:** no
Test substance: other TS: formaldehyde 100% (calculation)
Remark: influent: industrial sewage (BASF)
activated sludge: industrial (BASF) 2 g/l dry weight
outcome: stimulation with less than 1.429 mg/l TOC
Source: BASF AG Ludwigshafen
Reliability: (2) valid with restrictions
Study not in accordance with a defined standard method, but meets generally accepted scientific principles
(125)

Type: aquatic
Species: other protozoa: Colpoda aspera
Exposure period: 72 hour(s)
Unit: mg/l **Analytical monitoring:**
EC10: = 2.1
EC50: = 5.39
Method: other: Acute Toxicity Test
Year: 1995 **GLP:**
Test substance: other TS: Formaldehyde 37%
Source: BASF AG Ludwigshafen
Test condition: 25 deg C
Reliability: (2) valid with restrictions
Study not in accordance with a defined standard method, but meets generally accepted scientific principles
(126)

Type: aquatic
Species: Alcaligenes sp. (Bacteria)
Exposure period: 72 hour(s)
Unit: mg/l **Analytical monitoring:**
MIC : = 50
Method: other: Acute Toxicity Test
Year: 1995 **GLP:**
Test substance: other TS: Formaldehyde 37%
Remark: MIC = Minimum Inhibitory Concentration
Source: BASF AG Ludwigshafen
Test condition: 25 deg C
Reliability: (2) valid with restrictions
Study not in accordance with a defined standard method, but meets generally accepted scientific principles
(126)

Type: aquatic
Species: Pseudomonas fluorescens (Bacteria)
Exposure period: 16 hour(s)
Unit: mg/l **Analytical monitoring:**
TGK : = 14
Method: other: Modification of DEV L8 (1960)
Year: **GLP:** no
Test substance: other TS: formaline 35%
Remark: Glucose assimilation was measured
Source: BASF AG Ludwigshafen
Test condition: 25 deg C; bidest. water; pH 7.0
(127)

Type: aquatic
Species: Pseudomonas fluorescens (Bacteria)
Exposure period: 24 hour(s)
Unit: mg/l **Analytical monitoring:**
TGK : = 2
Method:
Year: **GLP:** no
Test substance:
Result: Starting inhibition of glucose inhibition
Source: BASF AG Ludwigshafen
Test condition: 25 deg C; pH 7.5-7.8
(119)

Type: aquatic
Species: Escherichia coli (Bacteria)
Exposure period: 24 hour(s)
Unit: mg/l **Analytical monitoring:**
TGK : = 1
Method:
Year: **GLP:** no
Test substance:
Result: Starting inhibition of glucose inhibition
Source: BASF AG Ludwigshafen
Test condition: 25 deg C; pH 7.5-7.8
(119)

Type: aquatic
Species: Photobacterium phosphoreum (Bacteria)
Exposure period: 30 minute(s)
Unit: mg/l **Analytical monitoring:**
EC50: ca. 16.5
Method: other: Microtox Toxicity Test
Year: **GLP:** no
Test substance:
Source: BASF AG Ludwigshafen

(128)

Type: aquatic
Species: activated sludge
Exposure period: 3 hour(s)
Unit: mg/l **Analytical monitoring:**
IC50 : = 20.4
Method: other: Respiration Inhibition Test (OECD)
Year: **GLP:** no
Test substance:
Remark: Probit-transformation analysis
Source: BASF AG Ludwigshafen

(129)

Type: aquatic
Species: other bacteria: Pseudomonas putida, not pre-acclimated
Exposure period:
Unit: mg/l **Analytical monitoring:**
NOEC : = 30
Method: other: Respiration Inhibition Test, modified
Year: 1990 **GLP:** no
Test substance:
Source: BASF AG Ludwigshafen

(74)

Type: aquatic
Species: other bacteria: Vibrio harveyi (marine organism)
Exposure period: 1 hour(s)
Unit: mg/l **Analytical monitoring:**
EC50: = 1.2
Method: other: Bioluminescent Direct Assay
Year: 1993 **GLP:** no
Test substance:
Result: unit: ppm
Source: BASF AG Ludwigshafen

(130)

Type: aquatic
Species: other bacteria: Vibrio harveyi (marine organism)
Exposure period: 5 hour(s)
Unit: mg/l **Analytical monitoring:**
EC50: = 3.7
Method: other: Bioluminescent Growth Assay
Year: 1993 **GLP:** no
Test substance:
Result: unit: ppm
Source: BASF AG Ludwigshafen

(130)

Type: aquatic
Species: Escherichia coli (Bacteria)
Exposure period:
Unit: mg/l **Analytical monitoring:** no data
LC50 : ca. 1
Method:
Year: 1960 **GLP:**
Test substance:
Source: STRATHCLYDE CHEMICAL COMPANY LIMITED JOHNSTONE

Type: aquatic
Species: Pseudomonas aeruginosa (Bacteria)
Exposure period: 1 minute(s)
Unit: g/l **Analytical monitoring:** no data
EC0: = 20
Method: other
Year: **GLP:** no data
Test substance: no data
Source: PROTEX S.A LEVALLOIS PERRET

(131)

4.5 Chronic Toxicity to Aquatic Organisms

4.5.1 Chronic Toxicity to Fish

Species:
Endpoint:
Exposure period:
Unit: **Analytical monitoring:**
Method:
Year: **GLP:**
Test substance:
Remark: Pas de données disponibles
Source: PROTEX S.A LEVALLOIS PERRET

4.5.2 Chronic Toxicity to Aquatic Invertebrates

Species:
Endpoint:
Exposure period:
Unit: **Analytical monitoring:**
Method:
Year: **GLP:**
Test substance:
Remark: Pas de données disponibles
Source: PROTEX S.A LEVALLOIS PERRET

Species:
Endpoint:
Exposure period:
Unit: **Analytical monitoring:**
Method:
Year: **GLP:**
Test substance:
Source: STRATHCLYDE CHEMICAL COMPANY LIMITED JOHNSTONE

TERRESTRIAL ORGANISMS

4.6.1 Toxicity to Soil Dwelling Organisms

Type:
Species:
Endpoint:
Exposure period:
Unit:
Method:
Year: **GLP:**
Test substance:
Remark: Pas de données disponibles
Source: PROTEX S.A LEVALLOIS PERRET

4.6.2 Toxicity to Terrestrial Plants

Species:
Endpoint:
Expos. period:
Unit:
Method:
Year: **GLP:**
Test substance:
Remark: Pas de données disponibles
Source: PROTEX S.A LEVALLOIS PERRET

4.6.3 Toxicity to other Non–Mamm. Terrestrial Species

Species:
Endpoint:
Expos. period:
Unit:
Method:
Year: **GLP:**
Test substance:
Remark: Pas de données disponibles
Source: PROTEX S.A LEVALLOIS PERRET

4.7 Biological Effects Monitoring

Remark: Pas de données disponibles
Source: PROTEX S.A LEVALLOIS PERRET

4.8 Biotransformation and Kinetics

Type:
Remark: Pas de données disponibles
Source: PROTEX S.A LEVALLOIS PERRET

Type:
Source: STRATHCLYDE CHEMICAL COMPANY LIMITED JOHNSTONE

4.9 Additional Remarks

Source: STRATHCLYDE CHEMICAL COMPANY LIMITED JOHNSTONE

(132)

5.1 Acute Toxicity

5.1.1 Acute Oral Toxicity

Type: LD50
Species: rat
Sex:
Number of Animals:
Vehicle:
Value: = 800 mg/kg bw
Method: other: pas d'indication
Year: **GLP:** no data
Test substance: no data
Source: PROTEX S.A LEVALLOIS PERRET
(133)

Type: LD50
Species: rat
Sex:
Number of Animals:
Vehicle:
Value: = 500 mg/kg bw
Method:
Year: **GLP:**
Test substance:
Source: ALDER S.p.A. TRIESTE
(134)

Type: LD50
Species: rat
Sex:
Number of Animals:
Vehicle:
Value: > 7000 mg/kg bw
Method:
Year: **GLP:**
Test substance:
Source: STRATHCLYDE CHEMICAL COMPANY LIMITED JOHNSTONE
(135)

Type: LD50
Species: rat
Sex:
Number of Animals:
Vehicle:
Value: = .68 mg/kg bw
Method:
Year: **GLP:**
Test substance:
Source: NORKEM LIMITED KNUTSFORD

Type: LD50
Species: rat
Sex:
Number of Animals:
Vehicle:
Value: = 800 mg/kg bw
Method: other: no data
Year: **GLP:** no
Test substance: no data
Remark: Reliability: 2 (reliable with restrictions)
Source: BASF AG Ludwigshafen
Test substance: formaldehyde; no data on purity of the compound
(136) (137)

Type: LD50
Species: rat
Sex:
Number of Animals:
Vehicle:
Value: 100 – 200 mg/kg bw
Method: other: no data
Year: **GLP:** no
Test substance: no data
Remark: Reliability: 2 (reliable with restrictions)
Source: BASF AG Ludwigshafen
Test substance: formaldehyde; no data on purity of the compound
(138)

Type: LD50
Species: mouse
Sex:
Number of Animals:
Vehicle:
Value: = 42 mg/kg bw
Method:
Year: **GLP:**
Test substance:
Source: ALDER S.p.A. TRIESTE
(134)

Type: LD50
Species: mouse
Sex:
Number of Animals:
Vehicle:
Value: = 42 mg/kg bw
Method: other: no data
Year: **GLP:** no
Test substance: no data
Remark: Reliability: 2 (reliable with restrictions)
Source: BASF AG Ludwigshafen
Test substance: formaldehyde; no data on purity of the compound
(139)

Type: LD50
Species: guinea pig
Sex:
Number of Animals:
Vehicle:
Value: = 260 mg/kg bw
Method:
Year: **GLP:**
Test substance:
Source: ALDER S.p.A. TRIESTE

(134)

Type: LD50
Species: guinea pig
Sex:
Number of Animals:
Vehicle:
Value: = 260 mg/kg bw
Method: other: no data
Year: **GLP:** no
Test substance: no data
Remark: Reliability: 2 (reliable with restrictions)
Source: BASF AG Ludwigshafen
Test substance: formaldehyde; no data on purity of the compound

(136)

Type: LDLo
Species: human
Sex:
Number of Animals:
Vehicle:
Value: = 108 mg/kg bw
Method:
Year: **GLP:**
Test substance:
Source: ALDER S.p.A. TRIESTE

(140)

5.1.2 Acute Inhalation Toxicity

Type: LC50
Species: rat
Sex:
Number of Animals:
Vehicle:
Exposure time: 4 hour(s)
Value: = 250 ppm
Method:
Year: **GLP:**
Test substance:
Source: ALDER S.p.A. TRIESTE

(141)

Type: LC50
Species: rat
Sex:
Number of Animals:
Vehicle:
Exposure time: 4 hour(s)
Value: = 1.1 mg/l
Method:
Year: **GLP:**
Test substance:
Source: NORKEM LIMITED KNUTSFORD

Type: LC50
Species: rat
Sex:
Number of Animals:
Vehicle:
Exposure time: 30 minute(s)
Value: = .984 mg/l
Method: other: no data
Year: **GLP:** no
Test substance: no data
Remark: LC50 = 816 ppm
Reliability: 2 (reliable with restrictions)
Source: BASF AG Ludwigshafen
Test substance: formaldehyde; no data on purity of the compound

(142)

Type: LC50
Species: rat
Sex:
Number of Animals:
Vehicle:
Exposure time: 4 hour(s)
Value: = .578 mg/l
Method: other: no data
Year: **GLP:** no
Test substance: no data
Remark: LC50 = 480 ppm
Reliability: 2 (reliable with restrictions)
Source: BASF AG Ludwigshafen
Test substance: formaldehyde; no data on purity of the compound

(143)

Type: LC50
Species: rat
Sex:
Number of Animals:
Vehicle:
Exposure time: unspecified
Value: = .203 mg/l
Method: other: no data
Year: **GLP:** no
Test substance: no data
Remark: LC50 = 168 ppm
Reliability: 2 (reliable with restrictions)
Source: BASF AG Ludwigshafen
Test substance: formaldehyde; no data on purity of the compound
(144)

Type: other
Species: rat
Sex:
Number of Animals:
Vehicle:
Exposure time: 4 hour(s)
Value: ca. 578 ppm
Method:
Year: 1979 **GLP:**
Test substance:
Source: STRATHCLYDE CHEMICAL COMPANY LIMITED JOHNSTONE
(145)

Type: other
Species: rat
Sex:
Number of Animals:
Vehicle:
Exposure time: 4 hour(s)
Value:
Method: other: no data
Year: **GLP:** no data
Test substance: no data
Result: The acute toxic effects of the test substance were studied in 8 male Sprague-Dawley rats. Six animals were exposed to 0.0124 mg/l (10 ppm) for 4 h; 3 rats each were sacrificed immediately after termination of exposure or 24 h later. Two rats remained unexposed (control). The nasal cavities of the rats were examined by scanning electron-microscopy.
In exposed rats, destruction of cilia, cell separation in both nasal cavity and maxillary sinus, cellular swelling and secretion of mucus of globlet cells was observed.
According to the authors, the severity of the nasal lesions due to formaldehyde were dependent on the localisation and on the cell type. The lesions observed in the nasal cavities of exposed rats which were sacrificed immediately after termination of exposure were more severe then the lesions found in rats sacrificed after 24 h of observation.

Histopathology confirmed the findings observed by electronmicroscopy (increase of cell volumina, separation of cells. and ciliar lesions).
Source: BASF AG Ludwigshafen
Test substance: formaldehyde; no data on purity of the compound
Reliability: (2) valid with restrictions

(146)

Type: other: RD50
Species: rat
Sex:
Number of Animals:
Vehicle:
Exposure time: 15 minute(s)
Value: = .017 mg/l
Method: other: sensory irritation according to Alarie, Y.; (no further data)
Year: 1966 **GLP:** no data
Test substance: no data
Remark: RD50 = 13.8 ppm; male CRL rats were used; RD50 = concentration of the test substance producing a 50% decrease in respiratory rate
Reliability: 2 (reliable with restrictions)
Source: BASF AG Ludwigshafen
Test substance: formaldehyde; no data on purity of the compound

(147)

Type: other: RD50
Species: rat
Sex:
Number of Animals:
Vehicle:
Exposure time: 10 minute(s)
Value: = .016 mg/l
Method: other: sensory irritation according to Alarie, Y.; (no further data)
Year: 1966 **GLP:** no
Test substance: no data
Remark: RD50 = 13.1 ppm; male Fischer 344 rats were used; RD50 = concentration of the test substance producing a 50% decrease in respiratory rate
Reliability: 2 (reliable with restrictions)
Source: BASF AG Ludwigshafen
Test substance: formaldehyde; no data on purity of the compound

(148)

Type: other: RD50
Species: rat
Sex:
Number of Animals:
Vehicle:
Exposure time: 10 minute(s)
Value: = .04 mg/l
Method: other: sensory irritation according to Alarie, Y.; (no further data)
Year: 1966 **GLP:** no
Test substance: no data
Remark: RD50 = 31.7 ppm; male Fischer 344 rats were used; RD50 = concentration of the test substance producing a 50% decreasein respiratory rate
Reliability: 2 (reliable with restrictions)
Source: BASF AG Ludwigshafen
Test substance: formaldehyde; no data on purity of the compound

(149)

Type: other: RD50
Species: rat
Sex:
Number of Animals:
Vehicle:
Exposure time:
Value: .012 mg/l
Method: other: no data
Year: **GLP:** no data
Test substance: no data
Remark: Reliability: 2 (reliable with restrictions)
Result: Sensory irritation of formaldehyde, acrolein, and acetaldehyde, was measured by Decrease in Breathing Frequency (DBF) in nose-only-exposed male Wistar rats using either the neat test substances or mixtures of them. A maximum DBF was observed withing 3 minutes of exposure followed by a marked desensitization during the next few minutes. During a 10-min. post-exposure period, the rats recovered partially.
In all groups exposed to mixtures, the DBF was more pronounced than in groups exposed to the neat test substances. However the DBF was significantly lower than the mean predicted by summation of the DBFs of single compounds. No desensitization occured. Both partial and full recovery was observed during the 10-min post-exposure period. The authors attributed the differences in the DBF of mixtures compared to the predicted DBF calculated by summation of the DBFs of single compounds as a result of competition for a common receptor (trigeminal nerve).
Source: BASF AG Ludwigshafen
Test substance: formaldehyde; no data on purity of the compound

(150)

Type: LC50
Species: mouse
Sex:
Number of Animals:
Vehicle:
Exposure time: 2 hour(s)
Value: = .9 mg/l
Method:
Year: **GLP:**
Test substance:
Source: ALDER S.p.A. TRIESTE

(141)

Type: LC50
Species: mouse
Sex:
Number of Animals:
Vehicle:
Exposure time: 4 hour(s)
Value: = .497 mg/l
Method: other: no data
Year: **GLP:** no
Test substance: no data
Remark: LC50 = 412 ppm
Reliability: 2 (reliable with restrictions)
Source: BASF AG Ludwigshafen
Test substance: formaldehyde; no data on purity of the compound

(143)

Type: LC50
Species: mouse
Sex:
Number of Animals:
Vehicle:
Exposure time: unspecified
Value: = .4 mg/l
Method: other: no data
Year: **GLP:** no
Test substance: no data
Remark: LC50 = 332 ppm
Reliability: 2 (reliable with restrictions)
Source: BASF AG Ludwigshafen
Test substance: formaldehyde; no data on purity of the compound

(151)

Type: other: RD50
Species: mouse
Sex:
Number of Animals:
Vehicle:
Exposure time: 10 minute(s)
Value: = .004 mg/l
Method: other: sensory irritation according to Alarie, Y.; (no further data)
Year: 1966 **GLP:** no
Test substance: no data
Remark: RD50 = 3.2 ppm; male Swiss Webster mice were used; RD50 = concentration of the test substance producing a 50% decrease in respiratory rate
Reliability: 2 (reliable with restrictions)
Source: BASF AG Ludwigshafen
Test substance: formaldehyde; no data on purity of the compound

(152)

Type: other: RD50
Species: mouse
Sex:
Number of Animals:
Vehicle:
Exposure time: 5 minute(s)
Value: = .007 mg/l
Method: other: sensory irritation according to Alarie, Y.; (no further data)
Year: 1966 **GLP:** no data
Test substance: no data
Remark: RD50 = 5.3 ppm; male OF1 mice were used; RD50 = concentration of the test substance producing a 50% decrease in respiratory rate
Reliability: 2 (reliable with restrictions)
Source: BASF AG Ludwigshafen
Test substance: formaldehyde; no data on purity of the compound

(153)

Type: other: RD50
Species: mouse
Sex:
Number of Animals:
Vehicle:
Exposure time: 10 minute(s)
Value: = .006 mg/l
Method: other: sensory irritation according to Alarie, Y.; (no further data)
Year: 1966 **GLP:** no data
Test substance: no data
Remark: RD50 = 4.9 ppm; male B6C3F1 mice were used; RD50 = concentration of the test substance producing a 50% decrease in respiratory rate
Reliability: 2 (reliable with restrictions)
Source: BASF AG Ludwigshafen

Test substance: formaldehyde; no data on purity of the compound

(148)

Type: LC0
Species: cat
Sex:
Number of Animals:
Vehicle:
Exposure time: 8 hour(s)
Value: = .82 mg/l
Method: other: aucune donnée
Year: **GLP:** no data
Test substance: no data
Source: PROTEX S.A LEVALLOIS PERRET

(154)

Type: LC50
Species: cat
Sex:
Number of Animals:
Vehicle:
Exposure time: 8 hour(s)
Value: = .82 mg/l
Method:
Year: **GLP:**
Test substance:
Source: ALDER S.p.A. TRIESTE

(141)

Type: LCLo
Species: cat
Sex:
Number of Animals:
Vehicle:
Exposure time: 2 hour(s)
Value: = .4 mg/l
Method:
Year: **GLP:**
Test substance:
Source: ALDER S.p.A. TRIESTE

(134)

5.1.3 Acute Dermal Toxicity

Type: LD50
Species: rabbit
Sex:
Number of Animals:
Vehicle:
Value: = 270 mg/kg bw
Method: other: aucune donnée
Year: **GLP:** no data
Test substance: no data
Source: PROTEX S.A LEVALLOIS PERRET
(155)

Type: LD50
Species: rabbit
Sex:
Number of Animals:
Vehicle:
Value: = 270 mg/kg bw
Method:
Year: **GLP:**
Test substance:
Source: ALDER S.p.A. TRIESTE
(134)

Type: LD50
Species: rabbit
Sex:
Number of Animals:
Vehicle:
Value: ca. 270 mg/kg bw
Method:
Year: 1980 **GLP:**
Test substance:
Source: STRATHCLYDE CHEMICAL COMPANY LIMITED JOHNSTONE
(156)

Type: LD50
Species: rabbit
Sex:
Number of Animals:
Vehicle:
Value: >= 2 mg/kg bw
Method:
Year: **GLP:**
Test substance:
Source: NORKEM LIMITED KNUTSFORD

Type: LD50
Species: rabbit
Sex:
Number of Animals:
Vehicle:
Value: ca. 270 mg/kg bw
Method: other: no data
Year: **GLP:** no data
Test substance: no data
Remark: Reliability: 2 (reliable with restrictions)
Value: = 270 ul/kg/bw
Source: BASF AG Ludwigshafen
Test substance: formaldehyde; no data on purity of the compound

(157)

5.1.4 Acute Toxicity, other Routes

Type: LDLo
Species: mouse
Sex:
Number of Animals:
Vehicle:
Route of admin.: i.p.
Value: = 16 mg/kg bw
Method:
Year: **GLP:**
Test substance: other TS
Source: BASF AG Ludwigshafen
Test substance: formaldehyde; no data on purity of the compound
Reliability: (2) valid with restrictions

(158)

Type: LD50
Species: rat
Sex:
Number of Animals:
Vehicle:
Route of admin.: s.c.
Value: ca. 420 mg/kg bw
Method:
Year: 1950 **GLP:**
Test substance:
Source: STRATHCLYDE CHEMICAL COMPANY LIMITED JOHNSTONE

(159)

Type: LD50
Species: rat
Sex:
Number of Animals:
Vehicle:
Route of admin.: s.c.
Value: = 420 mg/kg bw
Method: other: no data
Year: **GLP:** no
Test substance: no data
Remark: Reliability: 2 (reliable with restrictions)
Source: BASF AG Ludwigshafen
Test substance: formaldehyde; no data on purity of the compound

(142)

Type: LD50
Species: mouse
Sex:
Number of Animals:
Vehicle:
Route of admin.: s.c.
Value: = 300 mg/kg bw
Method: other: no data
Year: **GLP:** no
Test substance: no data
Remark: Reliability: 2 (reliable with restrictions)
Source: BASF AG Ludwigshafen
Test substance: formaldehyde; no data on purity of the compound

(142)

Type: LC50
Species: rat
Sex:
Number of Animals:
Vehicle:
Route of admin.: s.c.
Value: = 420 mg/kg bw
Method:
Year: **GLP:**
Test substance:
Source: ALDER S.p.A. TRIESTE

(160)

Type: LCLo
Species: rabbit
Sex:
Number of Animals:
Vehicle:
Route of admin.: s.c.
Value: = 240 mg/kg bw
Method:
Year: **GLP:**
Test substance:
Source: ALDER S.p.A. TRIESTE

(134)

Type: LDLo
Species: rabbit
Sex:
Number of Animals:
Vehicle:
Route of admin.: s.c.
Value: = 240 mg/kg bw
Method:
Year: **GLP:**
Test substance: other TS
Source: BASF AG Ludwigshafen
Test substance: formaldehyde; no data on purity of the compound
Reliability: (2) valid with restrictions

(161)

Type: LDLo
Species: dog
Sex:
Number of Animals:
Vehicle:
Route of admin.: s.c.
Value: = 350 mg/kg bw
Method:
Year: **GLP:**
Test substance: other TS
Source: BASF AG Ludwigshafen
Test substance: formaldehyde; no data on purity of the compound
Reliability: (2) valid with restrictions

(162)

Type: LD50
Species: rat
Sex:
Number of Animals:
Vehicle:
Route of admin.: i.v.
Value: = 87 mg/kg bw
Method: aucune donnée
Year: **GLP:** no data
Test substance: no data
Source: PROTEX S.A LEVALLOIS PERRET

(163)

Type: LD50
Species: mouse
Sex:
Number of Animals:
Vehicle:
Route of admin.: i.v.
Value: = 87 mg/kg bw
Method: other: no data
Year: **GLP:** no
Test substance: no data
Remark: Reliability: 2 (reliable with restrictions)
Source: BASF AG Ludwigshafen
Test substance: formaldehyde; no data on purity of the compound

(164)

Type: LCLo
Species: rabbit
Sex:
Number of Animals:
Vehicle:
Route of admin.: i.v.
Value: = 48 mg/kg bw
Method:
Year: **GLP:**
Test substance:
Source: ALDER S.p.A. TRIESTE

(134)

Type: LCLo
Species: cat
Sex:
Number of Animals:
Vehicle:
Route of admin.: i.v.
Value: = 30 mg/kg bw
Method:
Year: **GLP:**
Test substance:
Source: ALDER S.p.A. TRIESTE

(134)

Type: LDLo
Species: rabbit
Sex:
Number of Animals:
Vehicle:
Route of admin.: i.v.
Value: = 48 mg/kg bw
Method:
Year: **GLP:**
Test substance: other TS
Source: BASF AG Ludwigshafen
Test substance: formaldehyde; no data on purity of the compound
Reliability: (2) valid with restrictions

(165)

Type: LDLo
Species: cat
Sex:
Number of Animals:
Vehicle:
Route of admin.: i.v.
Value: = 30 mg/kg bw
Method:
Year: **GLP:**
Test substance: other TS
Source: BASF AG Ludwigshafen
Test substance: formaldehyde; no data on purity of the compound
Reliability: (2) valid with restrictions

(166)

Type: LDLo
Species: dog
Sex:
Number of Animals:
Vehicle:
Route of admin.: i.v.
Value: = 70 mg/kg bw
Method:
Year: **GLP:**
Test substance: other TS
Source: BASF AG Ludwigshafen
Test substance: formaldehyde; no data on purity of the compound
Reliability: (2) valid with restrictions

(162)

Type: LCLo
Species: cat
Sex:
Number of Animals:
Vehicle:
Route of admin.: other: inhalation
Value: = .4 mg/l
Method:
Year: **GLP:**
Test substance: other TS
Remark: 2 hours exposure
Source: BASF AG Ludwigshafen
Test substance: formaldehyde; no data on purity of the compound
Reliability: (2) valid with restrictions

(167)

5.2 Corrosiveness and Irritation

5.2.1 Skin Irritation

Species: rabbit
Concentration:

Exposure:
Exposure Time:
Number of Animals:
PDII:
Result: moderately irritating
EC classificat.: corrosive (causes burns)
Method: Estimation
Year: **GLP:**
Test substance:
Source: PROTEX S.A LEVALLOIS PERRET

Species: rabbit
Concentration:

Exposure:
Exposure Time:
Number of Animals:
PDII:
Result: highly irritating
EC classificat.: irritating
Method:
Year: **GLP:**
Test substance:
Source: STRATHCLYDE CHEMICAL COMPANY LIMITED JOHNSTONE

(168)

Species: rabbit
Concentration:

Exposure:
Exposure Time:
Number of Animals:
PDII:
Result: irritating
EC classificat.:
Method: other: no data
Year: **GLP:** no data
Test substance: no data
Remark: formaldehyde solutions (0.1-20%) were applied; according to the authors, the skin irritations were mild to moderate
Source: BASF AG Ludwigshafen
Test substance: formaldehyde; no data on purity of the compound
Reliability: (2) valid with restrictions

(169)

Species: guinea pig
Concentration:

Exposure:
Exposure Time:
Number of Animals:
PDII:
Result: irritating
EC classificat.:
Method: other: no data
Year: **GLP:** no data
Test substance: no data
Remark: application of 1% solution
Source: BASF AG Ludwigshafen
Test substance: formaldehyde; no data on purity of the compound
Reliability: (2) valid with restrictions

(170)

Species: human
Concentration:

Exposure:
Exposure Time:
Number of Animals:
PDII:
Result: irritating
EC classificat.: corrosive (causes burns)
Method:
Year: **GLP:**
Test substance:
Source: ALDER S.p.A. TRIESTE

5.2.2 Eye Irritation

Species: rabbit
Concentration:
Dose:
Exposure Time:
Comment:
Number of Animals:
Result: highly irritating
EC classificat.: risk of serious damage to eyes
Method: Draize Test
Year: **GLP:** no data
Test substance: other TS
Remark: Substance d'essai : formaldéhyde solution aqueuse à 10 %

-Dose 0,003 - 0,01 - 0,03 - 0,1 ml
-Durée du test =< 21 jours
Source: PROTEX S.A LEVALLOIS PERRET

(171)

Species: rabbit
Concentration:
Dose:
Exposure Time:
Comment:
Number of Animals:
Result: irritating
EC classificat.: irritating
Method:
Year: 1946 **GLP:**
Test substance:
Source: STRATHCLYDE CHEMICAL COMPANY LIMITED JOHNSTONE

(172)

Species: rabbit
Concentration:
Dose:
Exposure Time:
Comment:
Number of Animals:
Result: irritating
EC classificat.:
Method: other: no data
Year: **GLP:** no
Test substance: no data
Remark: application of 0.5 ml; the degree of eye irritation was up to a score of 8 (maximum score: 10)
Source: BASF AG Ludwigshafen
Test substance: formaldehyde; no data on purity of the compound
Reliability: (2) valid with restrictions
(173)

Species: human
Concentration:
Dose:
Exposure Time:
Comment:
Number of Animals:
Result: highly irritating
EC classificat.: irritating
Method:
Year: **GLP:**
Test substance:
Source: ALDER S.p.A. TRIESTE

5.3 Sensitization

Type: Buehler Test
Species: guinea pig
Number of Animals:
Vehicle:
Result: sensitizing
Classification:
Method:
Year: **GLP:** no data
Test substance: no data
Remark: challenge concentration might have been irritating
Result: Ten Dunkin–Hartley guinea pigs were topically induced by applying 5% formalin dissolved in the detergent ABS (aqueous solution of tetrapropylene benzene sulfonate) once a week for 6 weeks under occlusive conditions. After a resting period of another 2 weeks, the animals were challenged with 5% formalin. Sensitization rate was 3/10 (30%).
Source: BASF AG Ludwigshafen
Test substance: formalin; no data on purity or formaldehyde content
Reliability: (3) invalid

(174) (175)

Type: Buehler Test
Species: guinea pig
Number of Animals:
Vehicle:
Result: not sensitizing
Classification:
Method:
Year: **GLP:** no data
Test substance: as prescribed by 1.1 – 1.4
Remark: Reliability: 2 (reliable with restrictions)
Result: Three groups of 10 female Dunkin–Hartley guinea pigs were topically induced by applying 5% formalin dissolved in pysiological saline and were challenged with 1.25% formadehyde in saline. No sensitization was observed.
Source: BASF AG Ludwigshafen
Test substance: formalin; formaldehyde content 37%

(176)

Type: Buehler Test
Species: guinea pig
Number of Animals:
Vehicle:
Result: sensitizing
Classification:
Method:
Year: **GLP:** no data
Test substance: as prescribed by 1.1 – 1.4
Source: BASF AG Ludwigshafen
Reliability: (2) valid with restrictions

(177)

Type: Buehler Test
Species: guinea pig
Number of Animals:
Vehicle:
Result: sensitizing
Classification:
Method:
Year: **GLP:** no data
Test substance: other TS
Remark: strain: Dunkin–Hartley, animal nos. don’t meet OECD 406 requirements
Result: Induction: topical – occlusive 6h 5% in 0.9% NaCl (1x/week for three weeks).
Challenge: topical occlusive 6h, 1% in 0.9% NaCl (12–14 d later).
Number of animals with skin reactions: 7/10 (70%) no reactions in vehicle control animals after challenge.
Source: BASF AG Ludwigshafen
Test substance: formalin; formaldehyde content 37%
Reliability: (2) valid with restrictions

(178)

Type: Draize Test
Species: guinea pig
Number of Animals:
Vehicle:
Result: not sensitizing
Classification:
Method:
Year: **GLP:** no
Test substance: no data
Remark: Reliability: 2 (reliable with restrictions)
Result: The sensitizing potency of formalin was tested in 10 Dunkin-Hartley guinea pigs (males and females). For induction, the animals were injected with 1% formalin suspended in ABS (aqueous solution of tetrapropylene benzenesulfonate) 3 times per week for 3 weeks (totally 9 injections). After a resting period of 2 weeks, the animals were injected intradermally with 1% formalin forchallenge. Sensitization rate was 1/10 (10%).
Source: BASF AG Ludwigshafen
Test substance: formalin; no data on purity or formaldehyde content

(174)

Type: Draize Test
Species: guinea pig
Number of Animals:
Vehicle:
Result: not sensitizing
Classification:
Method:
Year: **GLP:** no
Test substance: no data
Remark: Reliability: 2 (reliable with restrictions)
Result: Twenty male Dunkin-Hartley guinea pigs were induced by intradermal injection of 0.1% formalin dissolved in saline 3 times per week for a total of 10 injections. Two weeks after the last induction dose, the animals were injected intradermally with 0.1% formalin for challenge. Sensitization rate was 1/20 (5%).
Source: BASF AG Ludwigshafen
Test substance: formalin; no data on purity or formaldehyde content

(179)

Type: Draize Test
Species: guinea pig
Number of Animals:
Vehicle:
Result: ambiguous
Classification: not sensitizing
Method:
Year: **GLP:** no
Test substance: as prescribed by 1.1 - 1.4
Remark: Reliability: 2 (reliable with restrictions)
Result: Groups of 20 female Dunkin-Hartley guinea pigs were induced by 7 intradermal injections of 0.1% formalin during 3 weeks.

Three weeks after the last induction dose, the animals were injected intradermally with 0.1% formalin for challenge. Two experimental runs were performed; readings were carried out after 24 h. Sensitization rates were 15% (3/20 animals) and 32% (5–6/20 animals) in the first and second tests, respectively. The degree of sensitization was evaluated by a grading system established by the authors. Mean reaction scores were given as 51 and 40 in the first and second experimental run, respectively. According to the authors, these results suggested that formaldehyde did not lead to sensitization in the first test and was not definitely sensitizing in the second test.

Source: BASF AG Ludwigshafen
Test substance: formalin; formaldehyde content 37%

(180)

Type: Draize Test
Species: guinea pig
Number of Animals:
Vehicle:
Result:
Classification:
Method:
Year: **GLP:** no data
Test substance: as prescribed by 1.1 – 1.4
Remark: challenge concentration might have been irritating
Result: Groups of 10 inbred DNCB–sensitive guinea pigs were induced by a single intradermal injection of 0.375% formalin. Challenge was performed by intradermal injection of 0.15% formalin and open topical application of 40% formalin 14 days later.
Solutions for injection were dissolved in physiological saline; solutions for topical application were prepared in distilled water. Two experimental runs were carried out. In the first test, 1/10 animals (10%) were sensitized; in the repeated test, 7/10 animals (70%) showed positive reactions. (According to the authors, these results indicated that formaldehyde was a moderate sensitizer.)
Source: BASF AG Ludwigshafen
Test substance: formalin; formaldehyde content 40%
Reliability: (3) invalid

(181)

Type: Draize Test
Species: guinea pig
Number of Animals:
Vehicle:
Result: sensitizing
Classification:
Method:
Year: **GLP:** no data
Test substance: as prescribed by 1.1 – 1.4
Remark: Reliability: 2 (reliable with restrictions)
Result: Groups of 10 female Dunkin–Hartley guinea pigs were used in the study. For induction, a 0.1% formalin solution was

injected 3 times per week (totally 10 injections). Challenge was performed by intradermal injection of 0.1% formalin two weeks after the last inducing dose. All solutions were prepared in physiological saline. Three experimental runs were carried out. Positive skin reaction was observed in 6/10, 1/10, and 3/10 animals in the first, second, and third experiment, respectively. The cumulative response was 10/30 (33%).

Source: BASF AG Ludwigshafen

Test substance: formalin; formaldehyde content 37%

(176)

Type: Freund's complete adjuvant test

Species: guinea pig

Number of Animals:

Vehicle:

Result: sensitizing

Classification: sensitizing

Method: other: aucune donnée

Year: **GLP:** no data

Test substance: no data

Remark: Occupational exposure formaldehyde (I) [50-00-0] most likely to cause sensitization and the potency of I as a sensitizing chem. were studied. Three routes of exposure were utilized; inhalation, dermal, and injection (with Freund's complete adjuvant). For inhalation exposure, guinea pigs were exposed to 6 ppm (group I) or &à ppm I (group II) for 6h/day or 8h/day (group III) on 5 consecutive days.
Animals were evaluated for skin sensitivity, prodn. of anti-I antibody, and respiratory sensitivity (both immediate-and delayed-onset to I. Of the animals receiving inhalation exposure, 2 of 4 animals in group III displayed dermal sensitivity. No antibodies or pulmonary sensivity were detected in any animals in any of th groups.
Animals exposed to I by dermal contact developed neither pulmonary sensitivity not antibodies to I. Howerver, all of these animals developed skin sensitivity. The severity of the contact sensitivity response, as well as the percentage of animals sensitized, increased with exposure dose. Apparently, I is a skin sensitizer in the guinea pig without causing delectable respiratory hypersensitivity.

Source: PROTEX S.A LEVALLOIS PERRET

(182)

Type: Freund's complete adjuvant test
Species: guinea pig
Number of Animals:
Vehicle:
Result:
Classification:
Method: other: no data
Year: **GLP:** yes
Test substance: as prescribed by 1.1 - 1.4
Remark: challenge concentration might have been irritating
Result: Groups of 10 Dunkin-Hartley guinea pigs were used in the study. Induction was initiated by injection of a 5% solution in Freund's Complete Adjuvant at days 0, 2, 4, 7, and 9. Challenge was carried out by topical application of the same concentration under occlusive conditions on days 21 or 35. Skin samples were taken for histopathological examination. Macroscopically, skin sensitization was observed in 3/10 animals challenged on day 21 and in 2/10 animals challenged on day 35. Doubtful results were observed in 4/10 animals challenged on day 35. Histopathology revealed incidences of 3/10 and 4/10 in the 21- and 35-day-group, respectively.
Source: BASF AG Ludwigshafen
Test substance: formalin; formaldehyde content 37%
Reliability: (3) invalid

(183) (184)

Type: Guinea pig maximization test
Species: guinea pig
Number of Animals:
Vehicle:
Result: sensitizing
Classification: sensitizing
Method: OECD Guide-line 406 "Skin Sensitization"
Year: 1983 **GLP:** yes
Test substance: other TS
Remark: formaldehyde; >37% aqueous solution (monitored)
Result: Female Pirbright-white guinea pigs were used.
The induction application was performed by 2 intradermal injections of 0.1 ml of a 5% solution in the presesnce and absence of Freund's Complete Adjuvant (FCA), followed by dermal application of 0.5 ml of a 5% solution for 48 h (days 9-11) under occlusive conditions. Challenge was performed dermally on days 22 and 36 (0.5 ml 2 and 4%; occlusively for 24 h)
According to the authors, the test substance was sensitizng at both concentrations: a challenge concentration of 4% resulted in 100% reaction at both challenges; a concentration of 2% resulted in 80 and 25% reaction at the first and second challenge, respectively.[2]
Source: BASF AG Ludwigshafen
Reliability: (2) valid with restrictions

(185)

Type: Guinea pig maximization test
Species: guinea pig
Number of Animals:
Vehicle:
Result: sensitizing
Classification:
Method: other
Year: **GLP:** no data
Test substance: no data
Remark: formaldehyde; no data on purity of the compound
Source: BASF AG Ludwigshafen
Reliability: (2) valid with restrictions

(186)

Type: Guinea pig maximization test
Species: guinea pig
Number of Animals:
Vehicle:
Result: sensitizing
Classification:
Method: other
Year: **GLP:** no data
Test substance: as prescribed by 1.1 - 1.4
Remark: Reliability: 2 (reliable with restrictions)
Source: BASF AG Ludwigshafen

(187)

Type: Guinea pig maximization test
Species: guinea pig
Number of Animals:
Vehicle:
Result: sensitizing
Classification:
Method: other
Year: **GLP:** no data
Test substance: as prescribed by 1.1 - 1.4
Remark: Reliability: 2 (reliable with restrictions)
Source: BASF AG Ludwigshafen

(188)

Type: Guinea pig maximization test
Species: guinea pig
Number of Animals:
Vehicle:
Result: sensitizing
Classification: sensitizing
Method:
Year: 1985 **GLP:**
Test substance:
Source: STRATHCLYDE CHEMICAL COMPANY LIMITED JOHNSTONE

(189)

Type: Guinea pig maximization test
Species: guinea pig
Number of Animals:
Vehicle:
Result: sensitizing
Classification:
Method:
Year: **GLP:** no
Test substance: no data
Remark: Reliability: 2 (reliable with restrictions)
Result: Twenty female Dunkin–Hartley guinea pigs were used. Induction was carried out by injecting 5% formaldehyde in petrolatum (emulsified in Freund's Complete Adjuvant) intradermally and, one week later by topical application of the same formalin solution under occlusive conditions. Challenge was carried out two weeks later by an application of 2% formalinunder occlusive conditions. Sensitization rate was 16/20 (80%).
Source: BASF AG Ludwigshafen
Test substance: formalin, dissolved in petrolatum; no data on formaldehyde content

(179)

Type: Guinea pig maximization test
Species: guinea pig
Number of Animals:
Vehicle:
Result: sensitizing
Classification:
Method:
Year: **GLP:** no data
Test substance: as prescribed by 1.1 – 1.4
Remark: Reliability: 2 (reliable with restrictions)
Result: Ten male and ten female Pirbright guinea pigs were used. Induction was carried out with 5% formalin (intradermal application followed by topical application); challenge was performed with 2% formalin under occlusive conditions 2 weeks after induction. Sensitization rate was 9/20 (45%). Physiological saline was used as solvent.
Source: BASF AG Ludwigshafen
Test substance: formalin; formaldehyde content 35%

(190)

Type: Guinea pig maximization test
Species: guinea pig
Number of Animals:
Vehicle:
Result: sensitizing
Classification:
Method:
Year: **GLP:** no data
Test substance: as prescribed by 1.1 – 1.4
Remark: challenge concentration might have been irritating
Result: Ten inbred DNCB–sensitive guinea pigs were induced by intradermal injection of 0.5% formalin (diluted with physiological saline) followed by topical application of 10% formalin. Challenge was performed topically with 5% formalin under occlusive conditions. Sensitization rate was 10/10 (100%). Mean test reaction score was 2.5; possible maximum score was 3.0.
Source: BASF AG Ludwigshafen
Test substance: formalin; formaldehyde content 40%
Reliability: (3) invalid

(181)

Type: Guinea pig maximization test
Species: guinea pig
Number of Animals:
Vehicle:
Result: not sensitizing
Classification:
Method:
Year: **GLP:** no data
Test substance: as prescribed by 1.1 – 1.4
Remark: challenge concentration might have been irritating
Result: Groups of 20 female Dunkin–Hartley guinea pigs were used. Induction was carried out by intradermal injection of 0.1 or 0.2% formalin dissolved in water followed by topical application of 5% formalin. Animals injected with 0.2% formalin were applied sodium lauryl sulfate 24 hours prior to the topical induction. Challenge was performed with 5% formalin under occlusive conditions. Sensitization rates were 0/20 (0%) among the animals injected with 0.1% and 5/20(25%) among the animals injected with 0.2%.
Source: BASF AG Ludwigshafen
Test substance: formalin; formaldehyde content 37%
Reliability: (3) invalid

(180)

Type: Guinea pig maximization test
Species: guinea pig
Number of Animals:
Vehicle:
Result: not sensitizing
Classification:
Method:
Year: **GLP:** no data
Test substance: as prescribed by 1.1 – 1.4
Remark: Reliability: 2 (reliable with restrictions)
Result: Three groups of 8, 10, and 10 female Dunkin–Hartley guinea pigs were used. Induction was carried out by intradermal injection of 5% formalin (37% aqueous formaldeyde solution, dissolved in physiologic saline) followed by topical application of 5% formalin; challenge was performed at a concentration of 1.25%. Sensitization rates were 2/8 (25%), 1/10 (10%), and 2/10 (20%); cumulative response was 5/28 (18%).
Source: BASF AG Ludwigshafen
Test substance: formalin; formaldehyde content 37%

(176)

Type: Guinea pig maximization test
Species: guinea pig
Number of Animals:
Vehicle:
Result: sensitizing
Classification:
Method:
Year: **GLP:** no data
Test substance: no data
Remark: challenge concentration might have been irritating
Result: Twenty female Dunkin–Hartley guinea pigs were used. Induction was carried out by intradermal injection of 5% formalin dissolved in de–ionized water followed by topical application of 5% formalin; challenge was performed with 5% formalin under occlusive conditions. Additionally, skin samples were examined histopathologically. Macroscopically, 20/20 animals showed positive skin reactions (sensitization rate 100%), however, histopathologically, allergic reaction was observed in only 14/20 animals (70%).
Source: BASF AG Ludwigshafen
Test substance: formalin; formaldehyde content 37%
Reliability: (3) invalid

(183) (184)

Type: Guinea pig maximization test
Species: guinea pig
Number of Animals:
Vehicle:
Result: sensitizing
Classification:
Method:
Year: **GLP:** no data
Test substance: no data
Remark: Reliability: 2 (reliable with restrictions)
Result: Groups of 20 female SSc:AL guinea pigs were used. Induction was carried out by intradermal injection of a 1% aqueous solution followed by topical application of a 5% solution; challenge was performed on day 21 by topical application of a 0.1, 0.5, and 1% solution. Sensitization rates were 0/20 (0%), 2/20 (10%), and 10/20 (50%) in the low, mid, and high challenge dose group, respectively, at the 48 h readings.
Source: BASF AG Ludwigshafen
Test substance: formaldehyde; no data on purity of the compound

(191)

Type: Guinea pig maximization test
Species: guinea pig
Number of Animals:
Vehicle:
Result: sensitizing
Classification:
Method:
Year: **GLP:** no data
Test substance: no data
Remark: Reliability: 2 (reliable with restrictions)
Result: Nineteen female Dunkin–Hatley guinea pigs were used. Induction was carried out by intradermal injection of a 0.1% aqueous solution followed by topical application of a 5% solution; challenge was performed on day 21 by topical application of a 1% solution. Sensitization rate was 17/19 (90%) at the 48 h reading.
Source: BASF AG Ludwigshafen
Test substance: formaldehyde; no data on purity of the compound

(191)

Type: Guinea pig maximization test
Species: guinea pig
Number of Animals:
Vehicle:
Result: sensitizing
Classification:
Method:
Year: **GLP:** no data
Test substance: as prescribed by 1.1 – 1.4
Remark: Reliability: 2 (reliable with restrictions)
Result: A dose–response study was performed with 18 groups of 6 SSc:AL guinea pigs each. On day 0, intradermal induction was performed by injection of solutions containing 0.01%

(groups 1–3), 0.03% (groups 4–6), 0.1% (groups 7–9), 0.3% (groups 10–12), 1.0% (groups 13–15), or 3.0% formaldehyde (groups 16–18). On day 7, topical induction was performed by application of 0.5% (groups 1, 7, 13), 1.0% (groups 4, 10, 16), 2.0% (groups 2, 8, 14), 5.0% (groups 5, 11, 17), 10.0% (groups 3, 9, 15), or 20.0% (groups 6, 12, 18). On day 21, challenge was performed topically with a concentration of 1%. Readings were carried out at 72 h. The sensitization rates differed between 0/6 and 6/6 and were dependent on the concentration of the intradermal induction mainly. No clear dose–response relationship was observed for topical induction. In some cases, the highest sensitization rates were found in animals that hadreceived low topical induction doses.
In a second dose–response experiment, guinea pigs of the Dunkin–Hartley strain were treated in the same manner. Again, no dose–response relationship was observed. The sensitization rates differed between 1/6 and 6/6 showing the same dependecies as observed in the SSC:AL strain. No inducation occurred at 0.01% i.d. in the SSc:AL strain,but Dunkin–Hartley guinea pigs showed some induction at that concentration. Intradermal concentrations
giving maximum response of ca. 80% was calculated as 0.46% (48 h) or 0.65% (72 h) for the SSc:AL guinea pigs; maximum response of ca. 85% was calculated as 0.45% (48 h) or 0.34% (72 h) for the Dunkin–Hartley guinea pigs.
According to the authors, these results demonstrated that the SSc:AL strain was less sensitive than the Dunkin–Hartley strain.

Source: BASF AG Ludwigshafen
Test substance: formaldehyde; 20% aqueous solution

(192)

Type: Guinea pig maximization test
Species: guinea pig
Number of Animals:
Vehicle:
Result: sensitizing
Classification:
Method:
Year: **GLP:** no data
Test substance: no data
Remark: Reliability: 2 (reliable with restrictions)
Result: A dose–response study was performed with 5 groups of 5 Dunkin–Hartley guinea pigs each. Intradermal induction was performed by injection of solutions containing 0.03, 0.1, 0.3, 1.0, or 3.0% of the test substance followed by topical induction which was performed by application of a 0.1% solution to the groups given 0.03, 0.3, or 3.0% intradermally or application of a 10% solution to the groups given 0.1 or 1.0% intradermally. Challenge was performed topically with a concentration of 1%. Readings were carried out at 72 h. The sensitization rates differed between 1/5 and 5/5; No dose–response relationship was observed; the sensitization was found to depend on the intradermal induction concentration. According to the

authors, the calculated maximum response concentration was 0.8% aqueous formaldehyde solution.
Source: BASF AG Ludwigshafen
Test substance: formaldehyde, dissolved in water; no data on formaldehyde content

(193)

Type: Guinea pig maximization test
Species: guinea pig
Number of Animals:
Vehicle:
Result: sensitizing
Classification:
Method:
Year: **GLP:** no data
Test substance: no data
Remark: Reliability: 2 (reliable with restrictions)
Result: The test substance (content not specified) was dissolved 4:1 with acetone/olive oil. For induction, the mixture was injected 0.25% intradermally in nine Dunkin–Hartley guinea pigs followed by a topical application of 10%. Challenge was carried out by topical application of 2% under occlusive conditions. Sensitization rate was 9/9.
Source: BASF AG Ludwigshafen
Test substance: formaldehyde; no data on purity of the compound

(194)

Type: Guinea pig maximization test
Species: guinea pig
Number of Animals:
Vehicle:
Result: sensitizing
Classification:
Method:
Year: **GLP:** no data
Test substance: no data
Remark: no details given
Result: The test substance (no further specifications) was injected intradermally at a concentration of 0.5% into Dunkin–Hartley guinea pigs (no data on number of animals) followed by a topical application of 10% (induction). Challenge was carried out by topical application of 2% under occlusive conditions. Sensitization rate was 90%.
Source: BASF AG Ludwigshafen
Test substance: formaldehyde; no data on purity of the compound
Reliability: (4) not assignable

(195)

Type: Guinea pig maximization test
Species: guinea pig
Number of Animals:
Vehicle:
Result: sensitizing
Classification:
Method:
Year: **GLP:** no data
Test substance: no data
Result: The effects of different challenge concentrations were studied groups of 10 female Dunkin–Hartley guinea pigs. The test substance was dissolved in distilled water. For induction, a 0.03% solution was injected intradermally followed by topical application of a 1% solution under occlusive conditions. Two challenges with an interval of 3 weeks were carried out by topical application of a solution containing the test substance at concentrations of 0.03, 0.1, or 0.3%. Readings were carried out 24, 48, and 72 h after each challenge application. After the first challenge, sensitization rates were 0/10–4/10, 6/10–9/10, and 10/10 in the low, mid, and high dose group, respectively. After the second challenge, sensitization rates were 0/10–3/10, 0/10–7/10, and 6/10–10/10 in the low, mid, and high dose group, respectively. According to the authors, sensitization rates showed a clear dose–response relationship, but the second challenge did not increase the incidences of sensitization.
Source: BASF AG Ludwigshafen
Test substance: formaldehyde; special grade, no further data
Reliability: (2) valid with restrictions

(196)

Type: Guinea pig maximization test
Species: guinea pig
Number of Animals:
Vehicle:
Result: sensitizing
Classification:
Method:
Year: **GLP:** no data
Test substance: no data
Remark: no details, challenge concentration might have been irritating
Result: Dunkin–Hartley guinea pigs were induced with the test substance intradermally at a concentration of 5% followed by topical induction at a concentration of 100%. Challenge was performed by topical application of the test substance at a concentration of 10%. According to the authors, the degree of sensitization was moderate to strong. No further data.
Source: BASF AG Ludwigshafen
Test substance: formaldehyde; no data on purity of the compound
Reliability: (3) invalid

(197)

Type: Guinea pig maximization test
Species: guinea pig
Number of Animals:
Vehicle:
Result: sensitizing
Classification:
Method:
Year: **GLP:**
Test substance: other TS
Remark: strain: Dunkin–Hartley, animal nos. don’t meet OECD 406 requirements
Result: Induction:
intradermal – 6 injections 0.25% in FCA in 0.9% NaCl
topical – occlusive 48h 10% in 0.9% NaCl
Challenge: occlusive 24h, 2% in 0.9% NaCl
Number of animals with skinreactions: 10/10 (100%) no reactions in vehicle control animals after challenge
Source: BASF AG Ludwigshafen
Test substance: formalin; formaldehyde content 37%
Reliability: (2) valid with restrictions

(178)

Type: Mouse ear swelling test
Species: mouse
Number of Animals:
Vehicle:
Result: ambiguous
Classification:
Method: other: no data
Year: **GLP:** no data
Test substance: as prescribed by 1.1 – 1.4
Remark: Reliability: 2 (reliable with restrictions)
Result: In this study, different varieties of the mouse–ear swelling test protocol were evaluated in male and female Balb/c mice.
In the first test, formalin was dissolved in 70% ethanol; 12 male mice were topially applied with a 10% solution onto the shaved abdomen for 4 consecutive days. Additionally, Freund’s Complete Adjuvant was injected intraperitoneally prior to each application. After a resting period, the animals were challenged by a topical application of a 10% solution onto the dorsum of the right ear at day 9; the vehicle was applied to the left ear.
In the second test, 7 mice received a repeated application twice weekly for 6 weeks prior to challenge using the same concentrations and procedures for induction and challenge as described in the protocol of the first test.
The third test was performed with 7 female mice which were initially applied a 15% solution without injection of Freund’s Complete Adjuvant for 2 consecutive days and challenged by topical application of 10% onto the ear at day 6; the vehicle was acetone.
In the fourth test, 7 female mice were treated as described in the protocol of the third test, additionally they were given a vitamin A acetate enriched diet for 4 weeks prior

to sensitizing and were maintained on this diet during the whole experimental period.
In every test, ear thickness was measured prior to challenge and 24, and 48 h after challenge.

In the first, second and third test, no increase in ear thickness was observed despite of the relatively high formalin concentrations applied. Only in the fourth test group which was given vitamin A enriched diet a statistically significant increase of the ear thickness was measured.

Source: BASF AG Ludwigshafen
Test substance: formalin; formaldehyde content 37%

(198)

Type: Mouse local lymphnode assay
Species: mouse
Number of Animals:
Vehicle:
Result: sensitizing
Classification: sensitizing
Method: other: no data
Year: **GLP:** no data
Test substance: no data
Remark: Reliability: 2 (reliable with restrictions)
Result: The local lymph node assay was performed in groups of 4 CBA/Ca mice by different working groups. Formalin was dissolved in a 4:1 mixture of acetone and olive oil. Concentrations of 5, 10, and 25% were topically applied onto the dorsum of the ear daily for 3 consecutive days. Four days after the initial treatment, the mice were injected with a buffered solution of 3H-methylthymidine into the tail vein and were sacrificed 5 hours later. The draining auricular lymph nodes were excised and pooled. Single cell suspension preparations of these lymph nodes were examined for incorporation of 3H-methylthymidine using a beta-scintillation counting technique.

Formalin was identified a contact sensitizer by all working groups. A no observed effect concentration (NOEC) was not evaluated. The incorporation of 3H-methylthymidine was increased showing a trend to dose-dependency, however, a clear dose-response relationsship could not be evaluated; the individual results varied 2-fold when expressed in disintegrations per minute (dpm) or calculated stimulation index (SI).

Source: BASF AG Ludwigshafen
Test substance: formalin; special grade, no further data on formaldehyde content

(195) (199) (194) (200)

Type: Mouse local lymphnode assay
Species: other: mouse and guinea pig
Number of Animals:
Vehicle:
Result:
Classification:
Method: other: no data
Year: **GLP:** no data
Test substance: no data
Remark: Reliability: 2 (reliable with restrictions)
Result: The local lymph node assay was performed in groups of CBA/Ca mice and Dunkin-Hartley guinea pigs (3 animals per group, each). Formalin was dissolved in a 4:1 mixture of acetone and olive oil. The test solutions were topically applied onto the dorsum of the ear daily for 3 consecutive days. The mice were treated with concentrations of 1 and 2%; additionally guinea pigs received 0.5 and 5%. Four days after the initial treatment, the animals were sacrificed. The draining auricular lymph nodes were excised, pooled, and single cell suspensions were prepared. The cell cultures were maintained for up to 48 h in the presence and absence of human recombinant interleukin-2 (IL-2), then 3H-methylthymidine was added for another 24 h. Thereafter, the cell cultures were examined for incorporation of 3H-methylthymidine using a beta-scintillation counting technique.

In mice, only the high dose (2%) caused an increase of the proliferation index and of the stimulation index. In guinea pigs, a positive reaction was observed at concentrations of 1% or more. However, no definite dose-response relationship was evaluated and addition of IL-2 had no effect. The mean lymph node weights indicated no substance-related effect at any concentration. According to the authors, formalin caused only slight reactions since even the highest doses caused only 2-fold increases in stimulating index and proliferation index in the positive animals.
Source: BASF AG Ludwigshafen
Test substance: formalin; special grade, no further data on formaldehyde content

(190)

Type: Open epicutaneous test
Species: guinea pig
Number of Animals:
Vehicle:
Result: sensitizing
Classification:
Method:
Year: **GLP:** no data
Test substance: as prescribed by 1.1 – 1.4
Remark: Reliability: 2 (reliable with restrictions)
Result: Fourteen groups of 6–8 guinea pigs (strain not specified) were used. Formalin was applied onto the uncovered skin at induction concentrations of 0.03, 0.1, 0.3, 1, 3, 10, and 30%. At the 24–h readings after the applications, slight skin irritation was observed in some animals even at the lowest concentration. Challenge was carried out on days 21 and 35 either at concentrations of both 0.03 and 1% (given to groups induced with 0.03 – 0.1%) 0.3 and 1% (given to groups induced with these concentratoins) and at concentrations of both 3 and 10% (given to groups induced with 3–30%). No skin reactions were observed in the groups induced or challenged with 1% or less. Induction or challenge with 3% or more resulted in sensitization: 3/8–7/8 animals were sensitized; the highest incidence of positive animals was observed at a concentration of 10% (induction and challenge). (Maibach, 1978).

In another test using a closed patch for application, 12 groups of 6–8 animals were used; one group each was induced with 0.03 or 0.1% (6 animals per group); two groups each were induced with 0.3 (6 animals per group), 1 (6 animals per group), 3 (8 animals per group), 10 (8 animals per group), or 30% (7 animals per group). The animals were challenged with 1% (the 2 groups induced with 0.03 and 0,1%, respectively), or with both 0.3 and 1% (groups induced with 0.3% and more). Sensitization was observed starting with induction concentrations of 0.3% (1/6 challenged with 0.3% and 2/6 challenged with 1%). (Maibach, 1978; Maibach, 1983).
However, according to the authors, no clear dose–response relationship could be observed in any experiment.
Source: BASF AG Ludwigshafen
Test substance: formalin; formaldehyde content 40%

(201) (202)

Type: Open epicutaneous test
Species: guinea pig
Number of Animals:
Vehicle:
Result: ambiguous
Classification:
Method:
Year: **GLP:** yes
Test substance: as prescribed by 1.1 – 1.4
Remark: Reliability: 2 (reliable with restrictions)
Result: Eight Dunkin–Hartley guinea pigs (males and females) were induced and challenged with a 5% formalin solution in de–ionized water. Additionally, skin samples were taken for histopathological examination. After the first challenge, no clear skin reaction was observed, however, 3/8 were scored as doubtful results. After the second challenge, 4/8 animals were clearly negative, while 4/8 showed doubtful reactions. In every case, histopathology revealed no signs of sensitization. Thus, according to the authors, these results suggested that formaldehyde was not sensitizing in the Open Epicutaneous Test.
Source: BASF AG Ludwigshafen
Test substance: formalin; formaldehyde content 37%

(183) (184)

Type: Split adjuvant test
Species: guinea pig
Number of Animals:
Vehicle:
Result: not sensitizing
Classification:
Method: other: no data
Year: **GLP:** no data
Test substance: as prescribed by 1.1 – 1.4
Remark: Reliability: 2 (reliable with restrictions)
Result: Groups of 10 female Dunkin–Hartley guinea pigs were used. Occluded patches containing the test solution were applied for 2 days followed by a second 2 day patch. On days 3 and 6 new patches were applied. On day 4 Freund’s Complete Adjuvant was injected intradermally. After a resting period of 2 weeks, the animals were challenged with an occluded patch. The induction concentration was 5%, the challenge concentrations was 1.25%; all solutions were prepared in physiological saline. Three experimental runs were carried out. In two tests, no animal was sensitized; in one test, 2/10 animals showed positive skin reaction. The cumulative sensitization rate was 2/30 (7%). Thus, according to the authors, the sensitizing potency was rather low.
Source: BASF AG Ludwigshafen
Test substance: formalin; formaldehyde content 37%

(176)

Type: Split adjuvant test
Species: guinea pig
Number of Animals:
Vehicle:
Result: ambiguous
Classification:
Method: other: no data
Year: **GLP:** yes
Test substance: as prescribed by 1.1 – 1.4
Remark: challenge concentration might have been irritating
Result: A modified Split Adjuvant Test protocol was used in groups of 10 Dunkin–Hartley guinea pigs of both sexes. Induction and challenge were performed at a concentration of 5%. Challenge was carried out 3 times (on days 21, 35, and 42). Skin samples were taken for histopathological examination. After the first challenge on day 21, none of the animals showed a clearly positive skin reaction, 7/10 were doubtful, and 3/10 were clearly negative. After the second challenge on day 35, 2/10 animals showed a clearly positive reaction, 3/10 were doubtful, and 5/10 were definitely negative. After the third challenge on day 42, none of the animals showed a clearly positive skin reaction, 3/10 were doubtful, and 7/10 were definitely negative. Histopathology confirmed postive results only for 1 animal each after the first and second challenge, respectively.
Source: BASF AG Ludwigshafen
Test substance: formalin; formaldehyde content 37%
Reliability: (4) not assignable

(183) (184)

Type: Split adjuvant test
Species: guinea pig
Number of Animals:
Vehicle:
Result: sensitizing
Classification:
Method: other: no data
Year: **GLP:** no data
Test substance: as prescribed by 1.1 – 1.4
Remark: challenge concentration might have been irritating
Result: The sensitizing potency of formaldehyde was studied in groups of 20 female Dunkin–Hartley guinea pigs using a modified Split Adjuvant Test protocol. Two tests were carried out. In the first experimental run, the initial induction concentration of 37% was reduced to 10%, challenge was performed at a concentration of 10%. In the second run, a concentration of 5% was used for both induction and challenge. In the first test, 85% of the animals (17/20) showed clearly positive skin reaction while in the second test only 5% (1/20) showed positive skin reaction.
Source: BASF AG Ludwigshafen
Test substance: formalin; formaldehyde content 37%
Reliability: (4) not assignable

(180)

Type: no data
Species: human
Number of Animals:
Vehicle:
Result: ambiguous
Classification: sensitizing
Method:
Year: **GLP:**
Test substance:
Source: ALDER S.p.A. TRIESTE

Type: other: AP2-test
Species: guinea pig
Number of Animals:
Vehicle:
Result: sensitizing
Classification: sensitizing
Method: other: new method
Year: **GLP:** no data
Test substance: no data
Remark: Reliability: 2 (reliable with restrictions)
Result: The aim of the study was to develop the Adjuvant and 24-h occlusive patch 2x test (abbreviated AP2 test), a new short-period method for delayed contact hypersensitivity in groups of 10 female Dunkin-Hartley guinea pigs. Formaldehyde was diluted with injectable distilled water. For induction, the protocol combined an intradermal injection of Freund's Complete Adjuvant and a 24 h occlussive patch test; this procedure was carried out twice with an interval of 4 days. The concentration for induction was 1%. The animals were challenged 3 times. The first challenge was performed 11 days after induction, the second challenge was performed 3 weeks after the first one, and the third challenge was carried out 1 week after the second one. For the first and second challenges, the test substance was administered by a non-occlusive topical application. The third challenge was applied with a 24 h occlusive patch. Challenge concentrations were 1% (1st and 2nd challenge) followed by 0.03 % (3rd challenge); 3% (1st and 2nd challenge) followed by 0.1% (3rd challenge); and 10% (1st and 2nd challenge) followed by 0.3% (3rd challenge). The skin reactions were examined 24, 48, and 72 h after each challenge.

Application of formaldehyde resulted in a dose-dependent skin sensitization; a no observed effect concentration (NOEC) was not obtained. No biologically relevant differences were observed after the first and second challenges, or at the different time-points of readings. The incidences of animals with positive skin reactions were 3-4/10, 4-7/10, and 8-9/10 in the groups challenged with 1, 3, and 10%, respectively at the first challenge. Only the animals that received a third challenge concentration of

0.03% (after 1% at the first and second challenge) showed no signs of sensitization.
Source: BASF AG Ludwigshafen
Test substance: formaldehyde; special grade, no further data

(203)

Type: other: CPA/FCA – Test
Species: guinea pig
Number of Animals:
Vehicle:
Result:
Classification:
Method: other: no data
Year: **GLP:** no data
Test substance: as prescribed by 1.1 – 1.4
Remark: large deviation of results
Result: The sensitizing potency of formaldehyde was studied in groups of 8 or 10 Dunkin–Hartley guinea pigs. Three days prior to induction, the animals received an intradermal injection of 150 mg/kg cyclophosphamide. Formalin was dissolved in physiological saline and was topically applied under occlusive conditions at a concentration of 5% on days 1, 2, 3, 4, and 9 (induction). On day 4, Freund's Complete Adjuvant was injected twice intradermally. Two weeks later, challenge was performed by topical application of 1.25% formalin under occlusive conditions. The test was carried out 3 times.
Positive skin reactions were observed in 4/8, 0/10, and 0/10 in the first, second, and third test runs, respectively. Thus, cumulative response was 4/28 (14%).
Source: BASF AG Ludwigshafen
Test substance: formalin; formaldehyde content 37%
Reliability: (3) invalid

(176)

Type: other: Cumulative contact enhancement test
Species: guinea pig
Number of Animals:
Vehicle:
Result: ambiguous
Classification:
Method: other: no data
Year: **GLP:** no data
Test substance: no data
Remark: Reliability: 2 (reliable with restrictions)
Result: The effects of several induction concentrations and several challenge concentration were studied in groups of 10 guinea pigs (males and females; no data on strain). The animals received 1–4 induction applications and 1 challenge application. For induction, the animals were applied solutions containing the test substance at concentrations of 0.2, 1, or 5% under occlusive conditions on days 0, 2, 7, and 9. On day 7, the guinea pigs received a single intradermal injection of Freund's Complete Adjuvant. Eleven days after the last induction application, challenge was

performed with closed patches containing 0.2, 1, 5, and 10% aqueous formalin.
The sensitization incidence was generally low; no clear dose-response relation was observed. According to the authors, the highest no observed effect concentrations (NOEC) were 5% for induction and 1% for challenge. However, even the challenge concentration of 5% caused only a low number of positive skin reactions up to 20%. Only challenge with 10% resulted in incidences above 20%. According to the authors,the results indicated that a higher sensitization incidence could be obtained by a higher application frequency. However, the overall conclusion was drawn, that formaldehyde was only slightly sensitzing in the Cumulative Contact Enhancement Test.

Source: BASF AG Ludwigshafen
Test substance: aqueous formalin; no data on formaldehyde content

(204)

Type: other: Cumulative contact enhancement test
Species: guinea pig
Number of Animals:
Vehicle:
Result: sensitizing
Classification: sensitizing
Method: other: no data
Year: **GLP:** no data
Test substance: no data
Remark: Reliability: 2 (reliable with restrictions)
Result: Three groups of 10 female guinea Dunkin-Hartley pigs were induced by topical occlusive application (2 x 4h on 4 days) of 1% formalin dissolved in distilled water. Two challenge procedures were performed by non-occlusive application of 1, 3, and 10% with an interval of 3 weeks. Readings were carried out 48 h after challenge application. No significant differences were observed when comparing the results after the first and the second challenge. After the second challenge, sensitization rates were 5/10, 10/10, and 10/10 in the groups challenged with 1, 3, and 10%, respectively. A dose-dependency was observed. NOEC (no observed effect concentration) could not be evaluated under the test conditions because the lowest challenge concentration (1%) already caused 50% sensitization.
Source: BASF AG Ludwigshafen
Test substance: formalin; no data on purity or formaldehyde content

(196)

Type: other: Cytokine production by draining mouse lymph node cells
Species: mouse
Number of Animals:
Vehicle:
Result: sensitizing
Classification: sensitizing
Method:
Year: **GLP:** no data
Test substance: other TS
Result: Induction: topical application on both shaved flanks, repitition at day 5, 10%, 25%, 50% in DMF, 10% Trimellitic Anhydride in acetone/olive oil (4:1)

Challenge: at day 10, topical application on the dorsum of the ears, daily repitition for three days, 10%, 25%, 50% in DMF, 10% in Trimellitic Anhydride in acetone/olive oil (4:1)

Determination of Interferon–gamma and IL–10 after 48 – 120h lymph–node cell culture; formaldehyde at 10% induced significant levels of IFN–gamma but not of IL–10, indicative for skin sensitization; Trimellitic Anhydride in acetone/olive oil (4:1) induced significant levels of IL–10 but only moderate level of IFN–gamma indicative, indicative for respiratory sensitization.
Source: BASF AG Ludwigshafen
Test substance: formalin; formaldehyde content 37%
Reliability: (2) valid with restrictions

(178)

Type: other: Dossou–Sicard test
Species: guinea pig
Number of Animals:
Vehicle:
Result: ambiguous
Classification:
Method: other: no data
Year: **GLP:** no data
Test substance: as prescribed by 1.1 – 1.4
Remark: challenge concentration might have been irritating
Result: The study procedure used two different induction methods. In any case, both induction and challenge was carried out with a 5% solution; 2 groups of 12 Dunkin–Hartley guinea pigs were used. In the first group, the animals received an intradermal injection of Freund’s Complete Adjuvant at day 0 and were induced by open topical application of the test solution at days 0, 2, and 4. In the second group, induction was performed by an intradermal injection of a 5% emulsion in Freund’s Complete Adjuvant. After a resting period of 6 days, challenge was carried out by an open topical application at day 15. Skin samples were taken for histopathological examination. Macroscopically, the intradermal induction caused skin sensitization was in 6/12 animals while none of the topically induced animals showed any skin reaction. Histpathology confirmed the positive macroscopic findings of only 2/12 animals.

Source: BASF AG Ludwigshafen
Test substance: formalin; formaldehyde content 37%
Reliability: (3) invalid
(183) (184)

Type: other: Guillot-Brulos test
Species: guinea pig
Number of Animals:
Vehicle:
Result: sensitizing
Classification:
Method: other: no data
Year: **GLP:** yes
Test substance: as prescribed by 1.1 - 1.4
Remark: challenge concentration might have been irritating
Result: Twenty Dunkin-Hartley guinea pigs were were given an intradermal injection of Freund's Complete Adjuvant at day 0 of the study. They were induced by 48 h occlusive topical application of a 5% aqueous solution at days 0, 2, 4, 7, 9, 11, and 14. After a resting period of 12 days, challenge was performed with by occlusive topical application of a 5% solution for 48 h. Skin samples were taken for histopathological examination. Macroscopically, a clearly positve skin reaction was observed in 7/20 animals, another 5/20 animals showed doubtful reactions. Histopathology only confirmed the clearly positive responses. Thus, according to the authors, a definite allergic reaction was observed in 7/20 (35%) of the animals.
Source: BASF AG Ludwigshafen
Test substance: formalin; formaldehyde content 37%
Reliability: (3) invalid
(183) (184)

Type: other: Guinea pig optimisation test
Species: guinea pig
Number of Animals:
Vehicle:
Result: sensitizing
Classification:
Method:
Year: **GLP:** no data
Test substance: as prescribed by 1.1 - 1.4
Remark: Reliability: 2 (reliable with restrictions)
Result: Ten male and 10 female Pirbright guinea pigs were given an intradermal induction concentration of 0.1% formaldehyde (35%) dissolved in saline in the first week; in the second and third week, the same amount of the test substance was administered as a solution in Freund's Complete Adjuvant. For challenge, the animals were injected intradermally with 0.1% formaldehyde solution; sensitization rate was 20/20 (100%). Two weeks after this intradermal challenge, the animals were challenged topically with 2% formaldehyde solution, and 10/20 (50%) showed a positive reaction.
Source: BASF AG Ludwigshafen
Test substance: formalin; formaldehyde content 35%

(205)

Type: other: Guinea pig optimisation test
Species: guinea pig
Number of Animals:
Vehicle:
Result: sensitizing
Classification:
Method:
Year: **GLP:** yes
Test substance: as prescribed by 1.1 – 1.4
Remark: challenge concentration might have been irritating
Result: Ten male and ten female Dunkin-Hartley guinea pigs were given a 5% dilution of formalin (37% formaldehyde) in de-ionized water. Intradermally induction was carried out at days 0, 2, and 4 using water as, and on days 7, 9, 11, 14,16, and 18 using a 50% mixture of Freund's Complete Adjuvants solvent. Intradermal challenge was performed on day 35 and topical challenge on day 49 with a 5% solution; additionally, skin amples were examined histopathologically after the second challenge. After the first challenge, sensitization rate was 20/20 (100%); all animals showed positive skin reaction. However, after the second challenge, only 2/20 animals (10%) showed a clearly positive skin reaction, 16/20 animals (80%) had a questionable reaction, and 2/10 animals (10%) were not sensitized. Histopathology revealed no allergic reaction.
Source: BASF AG Ludwigshafen
Test substance: formalin; formaldehyde content 37%
Reliability: (4) not assignable

(183) (184)

Type: other: Local lymph node assay
Species: mouse
Number of Animals:
Vehicle:
Result: sensitizing
Classification:
Method:
Year: **GLP:** no data
Test substance: other TS
Remark: strain: BALB/c
Result: Induction: topical application on the dorsum of the ears, daily for three days, 10%, 25%, 50% in DMF, DMF control, 1% Dinitrochlorobenzene (DNCB) as positive control dissolved in Acetone/olive oil (4:1)

Challenge: no challenge

Comments: at 10% increase in [3H]-methyl-thymidine incorporation in lymph node cells (4 animals/group), indicative for a clear sensitizing response, 3 fold less than DNCB induced increase in [3H]-thymidine incorporation in lymph

node cells (3 animals/group)
Source: BASF AG Ludwigshafen
Test substance: formalin; formaldehyde content 37%
Reliability: (2) valid with restrictions

(178)

Type: other: Mouse immuno globuline E test
Species: mouse
Number of Animals:
Vehicle:
Result: sensitizing
Classification:
Method:
Year: **GLP:** no data
Test substance: other TS
Remark: strain: BALB/c
Result: Induction: single topical application on both shaved flanks, 10%, 25%, 50% in DMF, DMF and acetone/olve oil (4:1) and 1% Dinitrochlorobenzene as negative control, 25% Trimellitic Anhydride as positive control in acetone/olve oil (4:1)

Challenge: at day 7 topical application on the dorsum of the ears, 5%, 12.5%, 25% in DMF, DMF and acetone/olve oil (4:1) and 0.5% Dinitrochlorobenzene as negative control, 12.5% Trimellitic Anhydride as positive control in acetone/olive oil (4:1)

Comments: at day 14 immuno globuline E measurement (6 animals/group), formaldehyde and Dinitrochlorobenzene: no increase in immuno globuline E conc.
Trimellitic Anhydride: stat. sig. increase in immuno globuline E conc.

Immuno globulin E: increase is indicative for respiratory sensitization

Conclusion formaldehde has no potential to cause respiratory sensitization
Source: BASF AG Ludwigshafen
Test substance: formalin; formaldehyde content 37%
Reliability: (2) valid with restrictions

(178)

Type: other: Single injection adjuvant test
Species: guinea pig
Number of Animals:
Vehicle:
Result: sensitizing
Classification:
Method: other: no data
Year: **GLP:** no data
Test substance: as prescribed by 1.1 – 1.4
Remark: challenge concentration might have been irritating
Result: Ten inbred DNCB-sensitive guinea pigs were induced by intradermal injection of 0.5% formalin mixed with Freund's

Complete Adjuvant. Challenge was performed 12 to 14 days later by open topical application of 10%. The challenge procedure was repeated weekly up to a total of 3-4 applications. Solutions for injection were dissolved in physiological saline; solutions for topical application were prepared in distilled water. All 10 animals (100%) showed positive skin reaction; the mean patch test reaction score was 1.85 (possible maximum score: 3.0). Thus, according to the authors, formaldehyde was assessed as moderately sensitizing.

Source: BASF AG Ludwigshafen
Test substance: formalin; formaldehyde content 40%
Reliability: (3) invalid

(181)

Type: other: specially designed study
Species: guinea pig
Number of Animals:
Vehicle:
Result:
Classification:
Method: other: no data
Year: **GLP:** no data
Test substance: no data
Remark: Reliability: 2 (reliable with restrictions)
The aim of the study was to evaluate the most likely route to cause sensitization and the potency of formaldehyde as a sensitizing agent. Thus, groups of male English smooth-haired guinea pigs were exposed to the test substance by inhalation, dermally, or by intradermal injection.
The different groups were treated as follows:
- Group 1 (4 shaved and depilated animals): induction by inhalation of 6 ppm (ca. 0.007 mg/l) 6 h/day for 5 consecutive days; challenge: dermally by topical application of 2% (20 ul) on day 9 and pulmonary by inhalation of 2 ppm (ca. 0.002 mg/l) on day 7 for 1 h; blood samples were taken on days 14 and 22.
- Group 2 (4 shaved and depilated animals): induction by inhaling 10 ppm (ca. 0.012mg/l) 6 h/day for 5 consecutive days; challenge: dermally by topical application of 2% (20 ul) on day 9 and pulmonary by inhalation of 4 ppm (ca. 0.005 mg/l) on day 7 for 1 h; blood samples were taken on days 14 and 22.
- Group 3 (4 animals): induction by inhalation of 10 ppm (ca. 0.012 mg/l) 8 h/day on 5 consecutive days; challenge: dermally by topical application of 2% (20 ul) on day 31 and pulmonary by inhalation of 4 ppm (ca. 0.005 mg/l) on days 7, 22, and 29 for 4 h; blood samples were taken on days 22 and 29.
- Group 4 (8 animals): dermal induction by topical application of 0.1 ml of 37% solution on days 1 and 3 (total dose: 74 mg); challenge: dermally by topical application of 2% (20 ul) on day 7 and pulmonary by inhalation of 4 ppm (ca. 0.005 mg/l) on day 22 for 1 h; blood samples were taken on day 14.
- Group 5 (8 animals): dermal induction by topical

application of 0.012 mg on day 1; challenge: dermally by topical application of 2% (20 ul) on day 7.
- Group 6 (8 animals): dermal induction by topical application of 0.12 mg on day 1; challenge: dermally by topical application of 2% (20 ul) on day 7.
- Group 7 (8 animals): dermal induction by topical application of 1.2 mg on day 1; challenge: dermally by topial application of 2% (20 ul) on day 7.
- Group 8 (8 animals): dermal induction by topical application of 5.1 mg on day 1; challenge: dermally by topical application of 2% (20 ul) on day 7.
- Group 9 (8 animals): dermal induction by topical application of 9.3 mg in day 1; challenge: dermally by topical application of 2% (20 ul) on day 7.
- Group 10 (4 animals): intradermal induction by injection of 0.2 ml of a 27% solution in Freund's Complete Adjuvant (total dose: 37 mg); challenge: dermally by topical application of 2% (20 ul) and pulmonary by inhalation of 4 ppm (ca. 0.005 mg/l) on day 19 for 1 h; blood samples were taken on day 14.

Skin sites were examined for erythema 1, 6, 24, and 48 h after challenge; respiratory rates were monitored continuously prior to challenge and during 24 h post challenge; the animals were exposed to vapors of the test substance. Blood samples were examined serologically.

Result: The animals induced inhalationally with 10 ppm (groups 2 and 3) revealed a depression in respiratory rates (up to 45%) with 2 different patterns indicating sensory irritation followed by pulmonary irritation. Brochial provocation failed to elicit either immediate or delayed respiratory reaction in groups 1–3. After skin testing, no contact sensitivity was observed in groups 1 and 2; while in group 3, 2/4 animals showed mild skin reactions. No antibodies were found in the blood samples.
After topical application, no respiratory response by inhalation challenge was seen (group 4), however, all animals showed extensive skin reactions after dermal challenge. No antibodies were found in the blood samples.
The animals treated only dermally (groups 5–9) showed dose–dependent contact sensitivity. Sensitization rates were 1/8, 3/8, 4/8, 5/8, and 7/8 in groups 5, 6, 7, 8, and 9, respectively. The severity of the skin reaction ranged from grade 1 (groups 5 and 6) to grade 1–4 (group 9).
All animals which were injected with the test substance (group 10) showed extensive positive skin reaction after dermal challenge but no signs of allergy were observed after pulmonary challenge. In the blood samples of 2/4 animals, low titer cytophilic antibodies were detected on day 14. However, the antibodies reacted only after a special preparation of the formaldehyde serum with a reducing
agent (sodium cyanoborohydride); without this agent, no antibodies could be detected. Thus, the detection of antibodies was rather questionable. Preimmunization sera were negative.

According to the authors, these results indicated that

formaldehyde was a skin sensitizer but did not induce respiratory hypersensitivity in the studied guinea pigs. The immunogenic activity of the test substance was assessed to be very low or questionable because of the detecting procedure.

Source: BASF AG Ludwigshafen

Test substance: formaldehyde; no data on purity of the compound

(206)

5.4 Repeated Dose Toxicity

Species: rat **Sex:**
Strain:
Route of admin.: inhalation
Exposure period: 26 WEEKS
Frequency of treatment: 22 HOURS/DAY 7 DAYS/WEEK
Post. obs. period: UNKNOWN
Doses: 3.6 MG/M3
Control Group: no data specified
Method:
Year: 1983 **GLP:**
Test substance:
Source: STRATHCLYDE CHEMICAL COMPANY LIMITED JOHNSTONE

(207)

Species: rat **Sex:** male
Strain: Wistar
Route of admin.: inhalation
Exposure period: 3 days
Frequency of treatment: 22 h/d
Post. obs. period: none
Doses: ca. 0.0001, 0.0012, 0.0037 mg/l (0.1, 1, 3 ppm)
Control Group: yes, concurrent no treatment
NOAEL: = .0012 mg/l
LOAEL: = .0037 mg/l
Method: other: no data
Year: **GLP:** no data
Test substance: no data
Remark: Reliability: 2 (reliable with restrictions)
Result: Ten rats were used per dose group. Examinations on general health state and nasal histopathology were carried out. Additionally, cell proliferation (the percentage of labelled cells in the nasoturbinales after a single injection of 3H-thymidine) was measured in 5 animals per group.
In the highest dose group, disarrangement and both hyperplasia and metaplasia of the respiratory epithelium in the nasal levels II and III were recorded. Cell proliferation was statistically significantly increased at nasal level II but not at nasal level III. Coexposure to ozone did not lead to any change of the lesions observed.
In the mid and low dose group, no findings were recorded.
Source: BASF AG Ludwigshafen

Test substance: formaldehyde; no data on purity of the compound

(208)

Species: rat **Sex:** male
Strain: Fischer 344
Route of admin.: inhalation
Exposure period: up to 4 days
Frequency of treatment: 6 h/d
Post. obs. period: none
Doses: ca. 0.0006, 0.0027, 0.0073, 0.0184 mg/l (0.5, 2.2, 5.9, 14.8 ppm)
Control Group: yes, concurrent no treatment
NOAEL: = .0027 mg/l
LOAEL: = .0073 mg/l
Method: other: no data
Year: **GLP:** no data
Test substance: no data
Remark: Reliability: 2 (reliable with restrictions)
Result: The ultrastructural chances of nasal epithelium caused by inhalational exposure to the test substance were studied in groups of 3-5 rats. After exposure, nasal epithelium was examined by transmission electron microscopy.
In the 2 high dose groups (14.8 and 5.9 ppm), degenerative changes differentially expressed in various cell types indicating squamous metaplasia and inflammatory processes were observed. In the 2 low dose groups (2.2 and 0.5 ppm), blebbing of the membranes in some cilia of the respiratory epithelial cells were found. According to the authors, the findings of the 2 groups exposed to 0.5 and 2.2 ppm were not considered as epithelial injury. Thus, NOAEL was given as 2.2 ppm.
Source: BASF AG Ludwigshafen
Test substance: formaldehyde; no data on purity of the compound

(209)

Species: rat **Sex:** male
Strain: Wistar
Route of admin.: inhalation
Exposure period: 4 weeks
Frequency of treatment: 5 d/w
Post. obs. period: none
Doses: ca. 0.006, 0.012, 0.024 mg/l (5, 10, 20 ppm)
Control Group: yes, concurrent no treatment
NOAEL: < .006 mg/l
Method: other: no data
Year: **GLP:** no data
Test substance: no data
Remark: Reliability: 2 (reliable with restrictions)
Result: The aim of the study was to find out whether treatment-related effects were determined by the total dose or by the exposure concentration. Thus, the cytotoxic effects of inhalational exposure to the test substance on the nasal epithelium were studied in groups of 10 rats. Two

groups were exposed continuously to 5 or 10 ppm 8 hours/day 5 days/week for 4 weeks; another 2 groups were exposed to 10 or 20 ppm 4 hours/day in intervals of 30 minutes interrupted by 30 minutes without exposure for 4 weeks (5 days/week); control rats remained untreated. After 4 weeks of treatment, autopsy and nasal histopathology were performedwith 4 rats per group, the remaining 6 rats per group were examined for nasal cell proliferation.

In the group continuously exposed to 10 ppm (total daily dose 80 ppmh/d), rhinitis and focal thinning were observed in a few rats; squamous metaplasia and basal hyperplasia of the respiratory epithelium were found in most of the animals. In the group intermittently exposed to 20 ppm (total daily dose 80 ppmh/d, too), rhinitis, focal thinning,squamous metaplasia and basal hyperplasia of the respiratory epithelium were found in all or most of the animals. The lesions found in this group were more severe than those found in rats continuously exposed to 10 ppm.

In the group continuously exposed to 5 ppm (total daily dose 40 ppmh/d), rhinitis, squamous metaplasia and basal hyperplasia of respiratory epithelium was found in some rats. In the group intermittently exposed to 10 ppm (total daily dose 40 ppmh/d, too), rhinitis, focal thinning and disarrangement was observed in few rats, squamous metaplasia and basal hyperplasia of respiratory epithelium were present in most of the animals. The lesions found in this group weremore severe than those observed in rats continuously exposed to 5 ppm.

According to the authors, these results suggested that the severity of cytotoxic effects to the nasal epithelium was rather determined by the exposure concentration than by the total dose.

Source: BASF AG Ludwigshafen

Test substance: formaldehyde; no data on purity of the compound

(210)

Species: rat **Sex:** male
Strain: Fischer 344
Route of admin.: inhalation
Exposure period: up to 6 weeks
Frequency of treatment: 5 d/w, 5 h/d
Post. obs. period: none
Doses: ca. 0.0009, 0.0025, 0.0077, 0.0123, 0.0.0184 mg/l (0.69, 2.0, 6.2, 9.9, 14.8 ppm)
Control Group: yes, concurrent no treatment
NOAEL: = .0025 mg/l
LOAEL: = .0077 mg/l
Method: other: no data
Year: **GLP:** no data
Test substance: no data
Remark: Reliability: 2 (reliable with restrictions)
Result: The effects of the test substance on the respiratory tract were studied in groups of 36 rats. In each group, rats were sacrificed after 1, 4, and 9 days and after 6 weeks of exposure. The respiratory tracts were examined histopathologically.
At the two highest dose levels (9.9 and 14.8 ppm), epithelial cell vacuolar degeneration, individual cell necrosis, epithelial exfoliation, multifocal erosion, ulceration, epithelial hyperplasia, sqamous metaplasia, and mixed inflammatory cell infiltrates were observed. The lesions were more severe at 14.8 ppm than at 9.9 ppm; the occurrence of increasing severity and distal expansion down to the nasopharynx of the lesions were exposure-time dependent. At the dose-level of 6.2 ppm, the lesions were much less severe that at the higher doses and were confined to the anterior part of the nose (level II) without exposure-time dependent increase in severity or local expansion. Mild individual cell necrosis, epithelial hyperplasia and squamous metaplasia were observed in the rats of this group. No substance-related lesions were found in rats exposed to 2 ppm or less.
Source: BASF AG Ludwigshafen
Test substance: formaldehyde; no data on purity of the compound

(211) (212)

Species: rat **Sex:** male
Strain: other: albino
Route of admin.: inhalation
Exposure period: 6 weeks to 3 months
Frequency of treatment: no data specified
Post. obs. period: none
Doses: ca. 0.002, 0.006, 0.1 mg/l (1.6, 4.6, 8.1 ppm)
Control Group: yes, concurrent vehicle
NOAEL: = .002 mg/l
LOAEL: = .006 mg/l
Method: other: no data
Year: **GLP:** no data
Test substance: no data
Remark: Reliability: 3 (not reliable)
Result: Seventy-five rats were exposed to the test-substance (no data on number of rats per treatment group), 75 controls remained untreated. Data on general health state, selected organ weights and number and activity of lavaged macrophages were determined.
In the highest dose group, clinical irritation of the eyes and of the upper respiratory tract, reduced food consumption and reduced body weight gains, decreased relativeliver weights, and reduction of alveolar macrophages and their phagocytic capacity were observed. In the mid dose group, exposure to formaldehyde resulted in reduced body weight gains. In the low dose group, no substance-related effects were found.
Source: BASF AG Ludwigshafen
Test substance: formaldehyde; no data on purity of the compound

(213)

Species: rat **Sex:** male
Strain: Fischer 344
Route of admin.: inhalation
Exposure period: 12 weeks (whole body exposure) plus 3 hours (nose-only exposure)
Frequency of treatment: 5 d/w, 6 h/d
Post. obs. period: none
Doses: ca. 0.0009, 0.0026, 0.0073, 0.0124, 0.0.018 mg/l (0.7, 2.1, 5.9, 10.0, 14.5 ppm)
Control Group: yes, concurrent vehicle
NOAEL: = .0026 mg/l
LOAEL: = .0073 mg/l
Method: other: no data
Year: **GLP:** no data
Test substance: no data
Remark: Another aim of the study was to evaluate protein DNA cross links in unexposed and subchronically preexposed rats.
Reliability: 2 (reliable with restrictions)
Result: Several groups of 10 rats per concentration were exposed to the test substance for 12 weeks followed by a 3-hours nose-only exposure to the 14C- or unlabelled formaldehyde. After termination of the treatment, gross inspection of the

nasal cavity and histopathologic examination of the nose were carried out in 1 or 2 animals per group.
Grossly, keratinizing epithelial plaques were observed in the highest dose group. No grossly visible lesions were recorded in the other groups.
At 14.5 ppm, histopathology revealed generalized and severe epithelial lesions extending to the nasopharyngeal meatus, lateral meatus (high tumor site); epithelial erosion, transitional epithelial hyperplasia, squamous metaplasia, intraluminal and mucosal inflammatory infiltration, keratinizing plaques with subepithelial inflammation, thickening of underlying periosteum, and edema and hyperemia of lamina propria were recorded. At 10 ppm, squamous metaplasia of the lateral meatus and the medial maxilloturbinate, epithelial hyperplasia and inflammatory cell infiltration of the midseptum were observed. At 5.9 ppm, multifocal epithelial hypertrophy, hyperplasia and squamous metaplasia of the lateral meatus were present. No histopathologic lesions were found at 2.1 and 0.7 ppm.

Source: BASF AG Ludwigshafen

Test substance: formaldehyde; no data on purity of the compound

(214)

Species: rat **Sex:** male/female
Strain: Wistar
Route of admin.: inhalation
Exposure period: 13 weeks
Frequency of treatment: 5 d/w, 6 h/d
Post. obs. period: none
Doses: ca. 0.0004, 0.0012, 0.0037 mg/l (0.3, 1, 3 ppm)
Control Group: yes, concurrent no treatment
NOAEL: = .0012 mg/l
LOAEL: = .0037 mg/l
Method: other: no data
Year: **GLP:** no data
Test substance: no data
Remark: Reliability: 2 (reliable with restrictions)
Result: Twenty–five rats of each sex were used per dose group. Studies on general health state, nasal histopathology and electronmicroscopical examinations were carried out. Histopathology revealed changes in about 50% of the animals of both sexes exposed to 3 ppm; squamous metaplasia at the nasal level II were present at 3 ppm only, disarrangement orslight hyperplasia of the respiratory epithelium in the anterior part of the nose (transitional zone) were found in all groups. Electron microscopy revealed ultrastructural changes at 3 ppm comprising loss of cilia, indented and disarranged nuclei, glandularization of globlet cells, foci of keratinized squamous epithelium. No distinct differences to control were found at 1 and 0.3 ppm.
Source: BASF AG Ludwigshafen
Test substance: formaldehyde; no data on purity of the compound

(215)

Species: rat **Sex:** male
Strain: Wistar
Route of admin.: inhalation
Exposure period: 13 weeks
Frequency of treatment: 5 d/w
Post. obs. period: none
Doses: ca. 0.0012, 0.0025, 0.005 mg/l (1, 2, 4 ppm)
Control Group: yes, concurrent no treatment
NOAEL: = .0012 mg/l
LOAEL: = .0025 mg/l
Method: other: no data
Year: **GLP:** no data
Test substance: no data
Remark: Reliability: 2 (reliable with restrictions)
Result: The aim of the study was to find out whether treatment-related effects were determined by the total dose or by the exposure concentration. Thus, the cytotoxic effects of inhalational exposure to the test substance on the nasal epithelium were studied in groups of 25 rats. Two groups were exposed continuously to 1 or 2 ppm 8 hours/day 5days/week for 13 weeks; another 2 groups were exposed to 2 or 4 ppm 4 hours/day in intervals of 30 minutes interrupted by 30 minutes without exposure for 13 weeks (5 days/week); control rats remained untreated. After 13 weeks of treatment, autopsy and nasal histopathology (with special regard to cell proliferation) were performed; alterations in general health state were recorded.

In the group continuously exposed to 2 ppm (total daily dose 16 ppmh/d), no difference to controls were observed in any item. In the group intermittently exposed to 4 ppm (total daily dose 16 ppmh/d, too), disarrangement and squamous metaplasia were observed in about 50% of the animals.

In the group continuously exposed to 1 ppm (total daily dose 8 ppmh/d), no differences to controls were observed. In the group intermittently exposed to 2 ppm (total daily dose 8 ppmh/d, too), rhinitis, disarrangement squamous metaplasia and nest-like infolds of the respiratory epithelium were observed; globlet cell hyperplasia was present in about 50% of the animals.

For detection of cell proliferation, 3H-tymidine was injected intraperitoneally after 3 exposures and at the end of the study. Cell proliferation was observed only in rats which were intermittently exposed to 4 ppm; the percentage of labelled cells was about 3-fold increased after 13 weeks, however, this change was not statistically significant.

According to the authors, these results suggested that the severity of cytotoxic effects to the nasal epithelium was rather determinted by the exposure concentration than by the total dose.

Source: BASF AG Ludwigshafen
Test substance: formaldehyde; no data on purity of the compound

(216)

Species: rat **Sex:** male/female
Strain: Wistar
Route of admin.: inhalation
Exposure period: 13 weeks
Frequency of treatment: 5 d/w, 6 h/d
Post. obs. period: none
Doses: ca. 0.0012, 0.012, 0.025 mg/l (1, 9.7, 19.8 ppm)
Control Group: yes, concurrent no treatment
NOAEL: <= .0012 mg/l
Method: other: no data
Year: **GLP:** no data
Test substance: no data
Remark: Reliability: 2 (reliable with restrictions)
Result: The effects of inhalational exposure to the test substance on the respiratory tract were studied in 10 rats/sex/group. After 13 weeks of treatment, autopsy and nasal histopathology were performed; alterations in general health state were recorded.

In the high dose group, impairment of general health accompanied by unspecific findings in clinical pathology; rhinitis; diffuse squamous metaplasia, focal hyperplasia, disarrangement and keratinization of the respiratory epithelium; focal thinning, squamous metaplasia and keratinization of the olfactory epithelium were observed in males and females. Additionally, squamous metaplasia of the lanryx epithelium was found in males, but not in females.

In the mid dose group, rhinitis, focal squamous metaplasia, hyperplasia, disarrangement and keratinization of the respiratory epithelium were observed.

In the low dose group, rhinitis was observed in 2 males; minimal hyperplasia and squamous metaplasia was found in 2 males and 1 female. However, according to the authors, the substance-relation of these findings was questionable.
Source: BASF AG Ludwigshafen
Test substance: formaldehyde; no data on purity of the compound

(217)

Species: rat **Sex:** male
Strain: other: albino
Route of admin.: inhalation
Exposure period: up to 22 weeks
Frequency of treatment: no data
Post. obs. period: none
Doses: no data specified
Control Group: yes, concurrent no treatment
Method: other: no data
Year: **GLP:** no data
Test substance: other TS
Remark: Reliability: 4 (not assignable)
Result: Groups of rats were inhalationally exposed to a "vaporizing" 10% formalin solution; anayltical monitoring of the inhalation atmosphere was not carried out. Three treated and 1 control rat each were sacrificed after 2, 4, 8, 17, and 22 weeks of exposure. Data on general health were recorded, histopathology of the trachea was performed.
Three of the rats died during 22 weeks of exposure. Morphological alterations of the tracheal epithelium and submucosa were observed. No further data.
Source: BASF AG Ludwigshafen
Test substance: 10% formalin solution

(218)

Species: rat **Sex:** male/female
Strain: Fischer 344
Route of admin.: inhalation
Exposure period: 26 weeks
Frequency of treatment: 7 d/w, 22 h/d
Post. obs. period: none
Doses: ca. 0.0002, 0.0012, 0.0037 mg/l (0.19, 0.98, 2.95 ppm)
Control Group: yes, concurrent no treatment
NOAEL: .0012 mg/l
LOAEL: .0037 mg/l
Method: other: no data
Year: **GLP:** no data
Test substance: no data
Remark: Reliability: 3 (not reliable)
Result: Five groups of 20 rats of each sex were used in the study; 2 control groups remained untreated. After termination of exposure, the animals were examined macroscopically and electronmicroscopically; histopathological investigation of the nose, trachea and lung were performed.

In the high dose group, decreased body weight gains and decreased absolute and relative liver weight were observed. Histopathology revealed basal cell hyperplasia of the respiratory epithelium which was most pronounced in the middle region of the nasotubinate.

According to the authors, randomly distributed rhinitis was observed in all 5 groups.

Source: BASF AG Ludwigshafen
Test substance: formaldehyde; no data on purity of the compound

(219)

Species: rat **Sex:** male
Strain: Wistar
Route of admin.: inhalation
Exposure period: 13 and 52 weeks
Frequency of treatment: 5 d/w, 6 h/d
Post. obs. period: up to 1 week
Doses: ca. 0.0001, 0.0012, 0.012 mg/l (0.1, 1.0, 9.4 ppm)
Control Group: yes, concurrent no treatment
NOAEL: .0012 mg/l
LOAEL: .012 mg/l
Method: other: no data
Year: **GLP:** no data
Test substance: no data
Remark: Reliability: 2 (reliable with restrictions)
Result: The different effects of inhaled formaldehyde on damaged and undamaged nose was studied in 16 groups of 10 rats. Four groups were used per concentration level: 0 (control), 0.1, 1.0, and 9.4 ppm, respectively. In each concentration level, 1 group with nose damage and 1 group without nose damage each was exposed to either 13 or 52 weeks. Nose damage was set by bilateral electro-coagulation of the anterior nasal cavity ca. 20 h prior to the first exposure. After termination of the exposure, investigations on general health, clinical pathology, autopsy, measurement of organ weights, and histopathology of the respiratory tract and other organs were performed.

The electro-coagulation without exposure resulted in necrosis, hemorrhages, perforation of the nasal septum, and loss of turbinates; epithelial repair followed the pattern of wound healing. Residues found 14 weeks after damaging were rhinitis, nest-like infolds and basal cell hyperplasia and squamous metaplasia of the respiratory epithelium. In week 53 after damaging, rhinitis and basal cell hyperplasia of the respiratory epithelium were still present.

Exposure to 9.4 ppm for 13 weeks resulted in growth retardation, focal rhinits, and squamous metaplasia and basal cell hyperplasia of the respiratory epithelium in rats with undamaged noses. In rats with damaged noses, the same histopathological lesions were found, however, these lesions were more severe. Additionally, thinning and disarrangement and basal cell hyperplasia of the olfactory epithelium were found. Growth retardation and decreased liver protein and glutathione content due to exceptional high control values were recorded.

Exposure to 9.4 ppm for 52 weeks resulted in growth retardation, oliguria, focal rhinitis, squamous metaplasia and basal cell hyperplasia of the respiratory epithelium, and low incidence of thinning and disarrangement and basal

cell hyperplasia of the olfactory epithelium in rats with undamaged noses. In rats with damaged noses, the same histopathological lesions were found, however, the alterations of the olfactory epithelium were more pronounced.

According to the authors, no substance-related lesions were found in the mid and low dose groups.

Source: BASF AG Ludwigshafen
Test substance: formaldehyde; no data on purity of the compound

(220)

Species: rat **Sex:** male
Strain: Wistar
Route of admin.: inhalation
Exposure period: up to 13 weeks
Frequency of treatment: 5 d/w, 6 h/d
Post. obs. period: none or up to week 131 of the study
Doses: ca. 0.012, 0.025 mg/l (10, 20 ppm)
Control Group: yes, concurrent no treatment
NOAEL: < .012 mg/l
Method: other: no data
Year: **GLP:** no data
Test substance: no data
Remark: Reliability: 2 (reliable with restrictions)
Result: The effects of inhalation exposure to the test substance on the nasal epithelium was studied in groups of 50-55 rats. The rats were exposed for 4, 8, and 13 weeks with sacrifices immediately after termination of exposure and after an observation period up to study week 131. Control rats remained untreated. Investigations on general health, autopsy and histopathology of the nose were performed.

In all treated groups, decreased body weight gains were observed, except the group exposed to 10 ppm for 4 weeks. The depression of body weight gain was mostly reversible during the observation period and had no influence on the mortality rates.

In rats exposed to 20 ppm and sacrificed immediately after termination of treatment, rhinitis, hyperplasia and squamous metaplasia of the respiratory epithelium and dissarrangement, thinning, cuboidal, or squamous metaplasia of the olfactory epithelium were observed. The intensity of the lesions increased with duration of exposure. Among the rats exposed to 20 ppm and sacrificed after the observation period, increased incidences of rhinitis, focal hyperplasia and stratified metaplasia were found in all exposure groups;alterations of the olfactory epithelium were present after 8 and 13 weeks of exposure.

In rats exposed to 10 ppm for 13 weeks and sacrificed immediately after treatment, rhinitis was found; lesions of the respiratory epithelium were more focal and less pronounced than at 20 ppm; no alterations of the olfactory

epithelium were observed. In rats exposed to 10 ppm for 13 weeks and sacrificed after the observation period, increased incidences of focal hyperplasia and stratified metaplasia were observed.

According to the authors, no statisitically significant increased incidence of nasal epithelial lesions was observed at all other exposure times.

Increased numbers of tumors were observed in the groups exposed to 20 ppm (for further data see chapter 5.7 Carcinogenicity).

Source: BASF AG Ludwigshafen
Test substance: formaldehyde; no data on purity of the compound

(221)

Species: rat **Sex:** male/female
Strain: Fischer 344
Route of admin.: inhalation
Exposure period: 28 months
Frequency of treatment: 5 d/w, 6 h/d
Post. obs. period: none
Doses: ca. 0.0001, 0.0012, 0.011 mg/l (0.1, 1.0, 9.2 ppm)
Control Group: yes, concurrent no treatment
NOAEL: .0012 mg/l
LOAEL: .011 mg/l
Method: other: no data
Year: **GLP:** no data
Test substance: no data
Remark: Reliability: 2 (reliable with restrictions)
Result: The different effects of inhaled formaldehyde on the intact or damaged nasal epithelium were studied. Groups of 30 rats with intact noses and groups of 60 rats with damaged noses were used. Nose damage was set by electro-coagulation of the nasal cavity. After termination of the exposure, investigations on general health, autopsy, measurement of organ weights, and histopathology of the nose were performed.

The electro-coagulation without exposure resulted in perforation of the nasal septum, loss of turbinates, high incidence of squamous metaplasia (increase of up to 46%), hyperplasia of the respiratory epithelium (11%), and rhinitis (50%).

Exposure to 9.2 ppm for 28 months resulted in growth retardation, focal rhinits (69%), squamous metaplasia (increase of up to 96%) and basal cell hyperplasia (54%) of the respiratory epithelium, and degeneration of the olfactory epithelium (27%) in the anterior nose in rats with undamaged noses. In rats with damaged noses, the same histopathological lesions were found, however, these lesions were more severe. Exposure to 9.2 ppm after nasal damage caused squamous metaplasia (increase of up to 82%) and basal cell hyperplasia (41%) of the respiratory epithelium,

degeneration (31%), squamous metaplasia (19%) and basal cell hyperplasia (21%) of the olfactory epithelium, and rhinitis (71%). In rats exposed to 1.0 ppm after nose damaging squamous metaplasia (increaseof up to 57%) and basal cell hyperplasia (29%) of the respiratory epithelium, and rhinitis (70%) were observed. After exposure to 0.1 ppm, squamous metaplasia (maximum increase of 66%) and basal cell hyperplasia (14%) of the respiratory epithelium, and rhinitis (78%) were found in rats with damaged noses. No significant influence of exposure to 1.0 or 0.1 ppm of the test substance on electro-coagulation damage was found. According to the authors, the NOAEL was 1 ppm for rats with intact nasal epithelium.

Source: BASF AG Ludwigshafen

Test substance: formaldehyde; no data on purity of the compound

(217)

Species: rat **Sex:** male/female
Strain: Fischer 344
Route of admin.: inhalation
Exposure period: 3 months
Frequency of treatment: 5 d/w, 6 h/d
Post. obs. period: 25 months
Doses: ca. 0.0001, 0.0012, 0.012 mg/l (0.1, 1.0, 9.4 ppm)
Control Group: yes, concurrent no treatment
NOAEL: .0012 mg/l
LOAEL: .012 mg/l
Method: other: no data
Year: **GLP:** no data
Test substance: no data
Remark: Reliability: 2 (reliable with restrictions)
Result: The different effects of inhaled formaldehyde on the intact or damaged nasal epithelium were studied. Groups of 30 rats with intact noses and groups of 60 rats with damaged noses were used. Nose damage was set by electro-coagulation of the nasal cavity. After termination of both exposure and postobservation period, investigations on general health, autopsy, measurement of organ weights, and histopathology ofthe nose were performed.

The electro-coagulation without exposure resulted in perforation of the nasal septum, loss of turbinates, high incidence of squamous metaplasia (increase of up to 46%), hyperplasia of the respiratory epithelium (11%), and rhinitis (50%).

Exposure to 9.4 ppm for 3 months followed by 25-months observation resulted in growth retardation, rhinits (50%), squamous metaplasia (increase of up to 65%) and basal cell hyperplasia (15%) of the respiratory epithelium in the anterior nose in rats with undamaged noses. Exposure to 9.2ppm after nasal damage caused growth retardation, squamous metaplasia (increase of up to 81%) and basal cell hyperplasia (33%) of the respiratory epithelium, degeneration of the olfactory epithelium (15%), and

rhinitis(80%). In rats exposed to 1.0 ppm after nose damaging squamous metaplasia (increase of up to 58%) and basal cell hyperplasia (9%) of the respiratory epithelium, and rhinitis(45%) were observed. After exposure to 0.1 ppm, squamous metaplasia (maximum increase of 47%) and basal cell hyperplasia (15%) of the respiratory epithelium, and rhinitis (67%) were found in rats with damaged noses.
No significant influence of exposure to 1.0 or 0.1 ppm of the test substance on electro-coagulation damage was found.
According to the authors, the NOAEL was 1 ppm for rats with intact nasal epithelium.

Source: BASF AG Ludwigshafen
Test substance: formaldehyde; no data on purity of the compound

(217)

Species: rat **Sex:** male
Strain: Fischer 344
Route of admin.: inhalation
Exposure period: up to 18 months
Frequency of treatment: 5 d/w, 6 h/d
Post. obs. period: none
Doses: ca. 0.0009, 0.0025, 0.0075, 0.012, 0.019 mg/l (0.7, 2.0, 6.0, 9.9, 14.9 ppm)
Control Group: yes, concurrent no treatment
NOAEL: = .0025 mg/l
LOAEL: = .0075 mg/l
Method: other: no data
Year: **GLP:** no data
Test substance: no data
Remark: Reliability: 2 (reliable with restrictions)
Result: The effects of inhalation exposure to the test substance with special regard to nasal proliferation was studied in 6 groups of 24 rats (5 treated and 1 control group). Six rats each per group were sacrificed after 3, 6, 12, and 18 months of exposure and examined nasal-histopathologically.
At 14.9 ppm, hyperplasia, squamous metaplasia and hyperplasia of the nasal epithelium, individual cell necrosis, exfoliation and neutrophilic infiltration were observed. After exposure for 12 months and more, neutrophilic exudate, turbinate-to-turbinate or turbinate-to-wall adhesions, mucosal folding, and both degeneration and atrophy of the olfactory epithelium were found. An anterior posterior gradient of these lesions were determined; 71 putative preneoplastic lesions were recorded.
After exposure to 9.9 ppm, hyperplasia, squamous metaplasia and hyperplasia of the nasal epitelium, individual cell necrosis, exfoliation, neutrophilic infiltrate were observed, however, these findings were less pronounced than in the 14.9 ppm groups. One putative preneoplasic lesion was recorded.
Exposure to 6.0 ppm resulted in subtle individual nasal epithelial cell necrosis and incidental small foci of squamous cell metaplasia. Generally, no significant lesions were observed.
Nasal tumors were found in the rats exposed to 14.9 and 9.9

ppm. Locations of non-neoplastic lesions correlated with tumor sites. Thelack of marked lesions in the 6 ppm group was interpreted as an adaptive response. A steep non-linear increase of putative preneoplastic lesions comparable to tumor incidence was determined. According to the authors, the preneoplastic lesions could be differentated from adaptive squamous metaplasia and exhibited much higher cell proliferation.

Source: BASF AG Ludwigshafen
Test substance: formaldehyde; no data on purity of the compound

(222) (223) (224) (225) (212)

Species: rat **Sex:** female
Strain: Sprague-Dawley
Route of admin.: inhalation
Exposure period: no data specified
Frequency of treatment: no data specified
Post. obs. period: no data
Doses: ca. 0.015 mg/l (12.4 ppm alone or 12.7 ppm in combination with 25 mg/m3 wood dust)
Control Group: yes, concurrent no treatment
Method: other: no data
Year: **GLP:** no data
Test substance: no data
Remark: Reliability: 2 (reliable with restrictions)
Result: The histological changes in the nasal mucosa after long term exposure to formaldehyde and wood dust were studied in groups of 15-16 rats. Sixteen rats were exposed to 12.4 ppm of formaldehyde; 15 animals were exposed to 12.7 ppm of formaldehyde combined with 25 mg/m3 of wood dust. Controls remained untreated; additionally, another group was exposed to 25 mg/m3 wood dust only. Data on general health were recorded; after termination of the exposure, nose and lungs were examined histopathologically.
In 10/16 (63%) rats exposed to formaldehyde only, squamous metaplasia partly with keratinization or dysplasia was observed; the same lesions were found in 12/15 (80%) rats exposed to the combination of formaldehyde and wood dust. In 1/16 (6%) of the group exposed to formaldehyde, nasal tumors were observed (see chapter 5.7). Exposure to wood dust alone did not lead to pronounced nasal lesions but increased the incidence of emphysema. According to the authors, higher incidences of nasal lesions were observed n coexposed animals, this could be interpreted as an additive effect.
Source: BASF AG Ludwigshafen
Test substance: formaldehyde; no data on purity of the compound

(226)

Species: rat **Sex:** male
Strain: Sprague–Dawley
Route of admin.: inhalation
Exposure period: lifetime
Frequency of treatment: 5 d/w, 6 h/d
Post. obs. period: none
Doses: ca. 0.018 mg/l (14.7 ppm) combined with ca. 0.016 mg/l (10.6 ppm) HCl
Control Group: yes, concurrent no treatment
Method: other: no data
Year: **GLP:** no data
Test substance: other TS
Remark: Reliability: 2 (reliable with restrictions)
Result: The effects of a mixture of formaldehyde (FA) and hydrogen chloride (HCl) was studied. Groups of 50 (untreated), 50 (sham–controls) and 99 FA + HCL exposed rats were used. Studies on general health, autopsy, and histopathology of nose, larynx, trachea, lung. liver, bladder, kidneys, and spleen were conducted.
Exposure to the gases resulted in increased mortality and reduced body weight gains compared to controls. Increased incidences in rhinitis, epithelial hyperplasia and hyperplasia with atypia (72% in the treated groups versus 16% in unexposed controls), and squamous metaplasia (65% in the treated groups versus 0% in unexposed controls) were observed. For tumor incidence see chapter 5.7.
According to the authors, this experiment was a preliminary study.
Source: BASF AG Ludwigshafen
Test substance: formaldehyde–hydrogen chloride premix; no data on purity of the compounds

(227)

Species: rat **Sex:** male
Strain: Fischer 344
Route of admin.: inhalation
Exposure period: up to 28 months
Frequency of treatment: 5 d/w, 6 h/d
Post. obs. period: none
Doses: ca. 0.0004, 0.003, 0.018 mg/l (0.3, 2.2, 14.9 ppm)
Control Group: yes, concurrent no treatment
Method: other: no data
Year: **GLP:** no data
Test substance: no data
Remark: Reliability: 2 (reliable with restrictions)
Result: The inhalation toxicity of formaldehyde was studied in 5 groups of 32 rats. Three groups were exposed to the test substance at dose levels of 0.3, 2.2 and 14.9 ppm, one group remained unexposed (control), and one group was exposed to 3.3 ppm (ca. 0.004 mg/l) of methanol, correspondig to the methanol level present at the high concentration. Interim sacrifices (5 animals/group/ sacrifice) were carried out after 12, 18,and 24 months.

Studies on general health, clinicalpathology, autopsy and histopathology of several tissues were conducted.
In the high dose group, clinical irritation during the first minutes of exposure was observed, however, this irritation vanished during the onset of exposure. Exposure to 14.9 ppm of the test substance further resulted in increased mortality, reduction of both body weight gain and food consumption, increased incidence of rhinitis (100%), squamous metaplasia (100%), epithelial cell hyperplasia (90%), epithelial cell hyperkeratosis (80%), and papillary hyperplasia (6%).
In the mid dose group, low incidence of squamous metaplasia (6%) and epithelial cell hyperplasia (28%) was observed after 24 months of exposure and more; these findings were not present in controls. The incidence of rhinitis was not significantly different from controls.
In the low dose group, low incidence of squamous metaplasia (9%) and epithelial cell hyperplasia (13%) was observed after 24 and 28 months of exposure. Rhinitis was comparable to controls.
According to the authors, the non-neoplastic lesions observed in these groups could not be attributed clearly to the test substance, since there did not exist a clear concentration relation. (For tumor incidences see chapter 5.7)

Source: BASF AG Ludwigshafen
Test substance: formaldehyde, dissolved in methanol; no data on purity of the compound

(228) (229)

Species: rat **Sex:** male/female
Strain: Fischer 344
Route of admin.: inhalation
Exposure period: up to 24 months
Frequency of treatment: 5 d/w, 6 h/d
Post. obs. period: up to 6 months
Doses: ca. 0.002, 0.007, 0.018 mg/l (2.0, 5.6, 14.3 ppm)
Control Group: yes, concurrent no treatment
NOAEL: < .002 mg/l
Method: other: no data
Year: **GLP:** no data
Test substance: no data
Remark: Reliability: 2 (reliable with restrictions)
Result: The inhalation toxicity of formaldehyde was studied in 4 groups of 120 rats/sex. Interim sacrifices were carried out after 6, 12, 18, 27, and 30 months. Studies on general health (including neurofunction and opthalmoscopy), clinicalpathology, autopsy, unrinalysis, and histopathology of ca. 50 tissues were conducted.
Exposure to 14.3 ppm resulted in increased mortality, reduction of body weight gain during the exposure period, dyspnea, rhinitis, epithelial dysplasia and squamous metaplasia (partly papillary or with cellular atypia) in all nasal levels but most pronounced in the anterior part of the nose, as well as mild hyperplasia, dysplasia, or

squamous metaplasia of the proximal tracheal epithelium. In the mid dose group, increased mortality and slightly decreased body weight gains during the exposure period (males only), rhinitis, epithelial dysplasia and squamous metaplasia in the anterior part of the nose (levels I-III) were observed. The incidence and severity of the lesions increased with exposure duration and showed a trend for recovery during the postexposure period.
In the low dose group, rhinitis, epithelial dysplasia and squamous metaplasia in the most anterior part of the nose (level I) were observed. The incidence and severity of the lesions were exposure-duration dependent; however, there was recovery during the post exposure period.

Source: BASF AG Ludwigshafen
Test substance: formaldehyde; no data on purity of the compound

(230) (231)

Species: rat **Sex:** male
Strain: Wistar
Route of admin.: inhalation
Exposure period: 3 days
Frequency of treatment: 6 h/d
Post. obs. period: none
Doses: ca. 0.0012, 0.0124, 0.0245 mg/l (1, 10, 20 ppm)
Control Group: yes, concurrent no treatment
Method: other: cell proliferation measurement
Year: **GLP:** no data
Test substance: no data
Remark: Reliability: 2 (reliable with restrictions)
Result: Cell proliferation in nasoturbinates after inhalation of formaldehyde (whole body exposure) was studied. Two rats per group were exposed to the test substance; the nasoturbinates were removed after exposure and incubated with 3H-thymidine.Cell proliferation was measured as % labelled cells. Doubling of labelled cells was observed in light microscopically unaffected regions of the respiratory epithelium; a ca. 20-fold increase was measured in regions of squamous metaplasia in material obtained from rats exposed to 10 or 20 ppm. No increase in cell turnover was found at 1 ppm.
Source: BASF AG Ludwigshafen
Test substance: formaldehyde; no data on purity of the compound

(217)

Species: rat **Sex:** male
Strain: Wistar
Route of admin.: inhalation
Exposure period: 3 days
Frequency of treatment: 22 h/d
Post. obs. period: none
Doses: ca. 0.001, 0.0012, 0.0037 mg/l (0.1, 1, 3 ppm)
Control Group: yes, concurrent no treatment
Method: other: cell proliferation measurement
Year: **GLP:** no data
Test substance: no data
Remark: Reliability: 2 (reliable with restrictions)
Result: Cell proliferation in nasoturbinates after inhalation of formaldehyde (whole body exposure) was studied in groups of 10 rats. Cell proliferation was measured as % labelled cells in nasoturbinates after a single intraperitoneal injection of 3H-thymidine following the exposure to the test substance. At 3 ppm, a statistically significantly increase in cell proliferation was observed atnasal level II but not at nasal level III.

Data presented in graphical form only; low labelling index in controls.
Source: BASF AG Ludwigshafen
Test substance: formaldehyde; no data on purity of the compound

(208)

Species: rat **Sex:** male
Strain: Wistar
Route of admin.: inhalation
Exposure period: 3 days or 4 weeks (5 d/w)
Frequency of treatment: 4 or 8 h/d
Post. obs. period: none
Doses: 0.006, 0.012, 0.025 mg/l (5, 10, 20 ppm)
Control Group: yes, concurrent no treatment
Method: other: cell proliferation measurement
Year: **GLP:** no data
Test substance: no data
Remark: Reliability: 2 (reliable with restrictions)
Result: The aim of the study was to find out whether treatment-related effects were determined by the total dose or by the exposure concentration. Thus, cell proliferation was measured after continuous and intermittent inhalation exposure of 10 rats/group to the test substance. Two groups were exposed continuously to 5 or 10 ppm 8 hours/day for 3 days or 5 days/week for 4 weeks; another 2 groups were exposed to 10 or 20 ppm 4 hours/day in intervals of 30 minutes interrupted by 30 minutes without exposure for 3 days or 4 weeks (5 days/week); control rats remained untreated. Cell proliferation (% labelled cells) was measured in nasoturbinates following a single intraperitoneal injection of 3H-thymidine either after 3 exposures or at the end of the study.

In the group continuously exposed to 10 ppm (dose 80 ppmh/d), ca. 10-fold increase was found after both exposure periods. In the group intermittently exposed to 20 ppm (dose 80 ppmh/d, too), ca. 20-fold increase was observed after both exposure periods.
In the group continuously exposed to 5 ppm (dose 40 ppmh/d), ca. 3-fold increase was found after 3 exposures and doubling was observed at the end of the study. In the group intermittently exposed to 10 ppm (dose 40 ppmh/d, too), ca. 10-fold increase were found after 3 exposures and ca. 5-fold increase was determined at the end of the study.

According to the authors, these results suggest that the cell proliferation effect was concentration-related rather than "total dose"-related. A tendency of decreasing proliferation rate with duration of exposure was pointed out; however, no differentiation between histopathologicallyaffected and unaffected regions was worked out.

Source: BASF AG Ludwigshafen
Test substance: formaldehyde; no data on purity of the compound

(210)

Species: rat **Sex:** male
Strain: Fischer 344
Route of admin.: inhalation
Exposure period: 6 weeks
Frequency of treatment: 5 d/w, 6 h/d
Post. obs. period: none
Doses: ca. 0.0008, 0.0025, 0.0077, 0.012, 0.018 mg/l (0.69, 2.0, 6.2, 9.9, 14.8 ppm)
Control Group: yes, concurrent no treatment
Method: other: cell proliferation measurement
Year: **GLP:** no data
Test substance: no data
Remark: Reliability: 2 (reliable with restrictions)
Result: Cell proliferation in nasoturbinates after inhalation of formaldehyde (whole body exposure) was studied in groups of 36 rats. The rats were sacrificed after 1, 4, 9 days and after 6 weeks. Cell proliferation was measured in nasoturbinates after a single intraperitoneal injection of 3H-thymidine after the different exposure times; the unit lenght labelling index (ULLI) of 5 different locations was determined; 4-6 animals were evaluated for each time point and exposure concentration.
ULLI was increased at concentrations of 6.2 ppm and more at most locations investigated and already after the first exposure. An anterior-posterior gradient was found at 6.2 ppm, but not at higher concentrations. No clearcut response was determined within the same exposure time groups except in posterior locations between 6.2 and 9.9 ppm. No clearcut effects on duration of exposure on the degree of cell proliferation was observed.
Source: BASF AG Ludwigshafen
Test substance: formaldehyde; no data on purity of the compound

(211) (212)

Species: rat **Sex:** male
Strain: Fischer 344
Route of admin.: inhalation
Exposure period: 12 weeks
Frequency of treatment: 5 d/w, 5 h/d
Post. obs. period: none
Doses: ca. 0.0008, 0.0026, 0.0073, 0.018 mg/l (0.7, 2.1, 5.9, 14.5 ppm)
Control Group: yes, concurrent no treatment
Method: other: cell proliferation measurement
Year: **GLP:** no data
Test substance: no data
Remark: Reliability: 2 (reliable with restrictions)
Result: Cell proliferation in nasoturbinates after inhalation of formaldehyde was studied in groups of 10 rats. Cell proliferation was measured by determination of incorporation of 14C from 14C-formaldehyde into DNA. The animals were exposed (whole body exposure) to the test substance for 12 weeks followed by a 3-h head nose exposure to 14C-formaldehyde.
In the 5.9 ppm group, an increase of 14C incorporation was observed in the lateral but not in the medial and the posterior meatus. In the 14.5 ppm group, an increase was found in lateral, medial, and posterior meatus.
Source: BASF AG Ludwigshafen
Test substance: formaldehyde; no data on purity of the compound

(214)

Species: rat **Sex:** male
Strain: Wistar
Route of admin.: inhalation
Exposure period: 13 weeks
Frequency of treatment: 5 d/w, 4 or 8 h/d
Post. obs. period: none
Doses: ca. 0.0012, 0.0025, 0.0050 mg/l (1, 2, 4 ppm)
Control Group: yes, concurrent no treatment
Method: other: cell proliferation measurement
Year: **GLP:** no data
Test substance: no data
Remark: Reliability: 2 (reliable with restrictions)
Result: The aim of the study was to find out whether treatment-related effects were determined by the "dose" or by the exposure concentration. Thus, cell proliferation was measured after continuous and intermittent inhalational exposure of 5 rats/group to the test substance. Two groups were exposed continuously to 1 or 2 ppm 8 hours/day 5 days/week for 13 weeks; another 2 groups were exposed to 2 or 4 ppm 4 hours/day in intervals of 30 minutes interrupted by 30 minutes without exposure for 13 weeks (5 days/week); control rats remained untreated. Cell proliferation (% labelled cells) was measured in nasoturbinates following a

single intraperitoneal injection of 3H-thymidine either after 3 exposures or at the end of the study.

In the group intermittently exposed to 4 ppm (daily dose 16 ppmh/d), ca. 3-fold increase was found after 13 weeks, however, this change was not statistically significantly. In the group continuously exposed to 2 ppm (daily dose 16 ppmh/d, too), no change was observed. In the groups exposed intermittently to 2 ppm or continuously to 1 ppm (both dose 8 ppmh/d), no change was observed. No differentiation between histopathologicallyaffected and unaffected regions was worked out. According tothe authors, an increase in cell proliferation after 13 weeks but not after 3 days was unusual.

Source: BASF AG Ludwigshafen
Test substance: formaldehyde; no data on purity of the compound

(216)

Species: rat **Sex:** male
Strain: Wistar
Route of admin.: inhalation
Exposure period: 13 weeks
Frequency of treatment: 5 d/w, 6 h/d
Post. obs. period: none
Doses: ca. 0.0004, 0.0012, 0.0037 mg/l (0.3, 1, 3 ppm)
Control Group: yes, concurrent no treatment
Method: other: cell proliferation measurement
Year: **GLP:** no data
Test substance: no data
Remark: Reliability: 2 (reliable with restrictions)
Result: Cell proliferation due to exposure to formaldehyde was measured as incorporation of 3H-thymidine into DNA (% labelled cells) in nasoturbinates following a single intraperitoneal injection of 3H-thymidine after 3 exposures and after termination of the 13-week exposure. Groups of 5 rats/sex were used.
At the high dose level, histological changes (squamous metaplasia) were found in level II; additionally, slight hyperplasia of the respiratory of respiratory epithelium of the nasal level III were observed after 3 days, but not after 13 weeks. Proliferation was observed in locations showing histological changes (ca. 10-fold increase), no increase was found at nasal level III after 13 weeks. In both the mid and low dose group, a statistical trend for concentration response relation was recorded at level III after 3-d exposure.
No differentiation was made between histopathologically affected and unaffected regions; a very low labelling index was observed in controls, large variations of individual cell proliferation response were present; thus, according to the authors differencies of individual susceptibility were concluded. Data were presented in graphical form only.
Source: BASF AG Ludwigshafen
Test substance: formaldehyde; no data on purity of the compound

(215)

Species: rat **Sex:** male
Strain: Fischer 344
Route of admin.: inhalation
Exposure period: up to 18 months
Frequency of treatment: 5 d/w, 6 h/d
Post. obs. period: none
Doses: ca. 0.0009, 0.0025, 0.0075, 0.0123, 0.0185 mg/l (0.7, 2.0, 6.0, 9.9, 14.9 ppm)
Control Group: yes, concurrent no treatment
Method: other: cell proliferation measurement
Year: **GLP:** no data
Test substance: no data
Remark: Reliability: 2 (reliable with restrictions)
Result: Cell proliferation due to exposure to formaldehyde was determined via measurement of unit length labelling index (ULLI). Six male rats/group each were sacrificed after 3, 6, 12, and 18 months of exposure and after osmotic pump infusion of 3H-thymidine for 5 days before the sacrifices. Scoring of inflammation by intraepithelial neutrophil counts was carried out.
A significant increase of cell proliferation was observed at ca. 10 and 15 ppm (max ca. 11 and 16 fold increase, respectively). Cell proliferation was enhanced in metaplastic lesions and most pronounced in preneoplastic lesions. Additionally an increase of inflammation scores was observed at these dose levels. Nasal tumors were observed (see chapter 5.7). The authors concluded that sustained enhanced cell proliferation in the target organ was associated with nasal carcinogenesis.
Source: BASF AG Ludwigshafen
Test substance: formaldehyde; no data on purity of the compound

(222) (223) (224) (211) (225) (232) (212)

Species: rat **Sex:** no data
Strain: Fischer 344
Route of admin.: inhalation
Exposure period: 1,3 and 5 or 3 and 10 days for C x T study
Frequency of treatment: 6h/d or 36 ppm h/d as 3 ppm x 12 h, 6 ppm x 6 h, 12 ppm x 3 h for C x T study
Post. obs. period: none
Doses: 0, 0.5, 2, 6, 15 ppm or 3, 6 and 12 ppm
Control Group: other: yes, concurrent
Method: other: cell proliferation measurement
Year: **GLP:** no data
Test substance: no data
Remark: no clearcut concentration time response relation; data for mice in seperate entry - LI of control groups [%]
level B:
pulse 2 h post exp.: 0.22; 0.26
pulse 18 h post exp. 0.54; 0.43, 0.54, 0.26
level A:
3.0
Result: Examinations:

measurements of cell proliferation (% labeled cells) in nasoturbinate levels A (anterior) and B (mid–anterior) single i.p. injection of H–thymidine 2 or 18 h after end of exposure

Findings:

	fold increase of LI in level B
1 d/15 ppm:	about 13
1 d/6 ppm:	about 5
3 d/15 ppm:	about 13
3 d/6 ppm:	about 25
3 d/6 ppm:	about 6 from C x T study
5 d/15 ppm:	about 23
10 d/6 ppm:	about 2 from C x T study

no increase at 2 and 0.5 ppm labelling 18 h after end of exposure yielded higher fractions of labeled cells in controls and exposed animals (authors: circadian variations)

C x T study
level A: about 5–fold increase of proliferation independent from exposure regimen.
level B: concentration dependent about 3, 6 and 17 fold increase of proliferation after 3 days and about 2, 2 and 7 fold after 10 days

Source: BASF AG Ludwigshafen
Test substance: formaldehyde; no data on purity of the compound
Reliability: (2) valid with restrictions

(233)

Species: rat **Sex:** no data
Strain: Sprague–Dawley
Route of admin.: inhalation
Exposure period: lifetime
Frequency of treatment: 5 d/w, 6 h/d
Post. obs. period: none
Doses: 14.8 ppm FA only, 15.2 ppm FA + 9.9 HCL ppm premix 14.9 ppm FA + 9.7 ppm HCl non–premix and 10.0 ppm HCl only
Control Group: other: yes, concurrent no treatment and sham exposed
Method: other: no data
Year: **GLP:** no data
Test substance: other TS
Result: Findings – increased mortality and reduced body weight development in all groups (100 male rats per group) exposed to FA

nasal lesions:
incidences of rhinitis and epithelial or squamous hyperplasia about 70% and 50% resp. in all groups but more severe in FA treated groups, especially in naso–maxillary turbinate and nasal septum independent from coexposure, squamous metaplasia about 60% in FA treated groups versus about 7% in others

larynx:
epithelial hyperplasia in about 20% of substance treated

animals versus about 2% in controls and squamous metaplasia in about 10% FA treated animals versus 0% in HCl treated or controls

trachea:
epithelial hyperplasia in about 25% of substance treated animals versus about 4% in controls and squamous metaplasia in about 8% of FA treated animals versus 0% in HCl treated or controls

Source: BASF AG Ludwigshafen
Test substance: formaldehyde-hydrogen chloride; no data on purity of the compounds
Reliability: (2) valid with restrictions

(234)

Species: rat **Sex:** male
Strain: Wistar
Route of admin.: inhalation
Exposure period: 4 weeks
Frequency of treatment: 6h/d, 5d/w
Post. obs. period:
Doses: 0, 0.35, 1.09, 3.1 ppm
Control Group:
NOAEL: 1.09 ppm
Method:
Year: **GLP:** no data
Test substance: other TS
Remark: Examinations:
5 males per group, clinical examination, clinical pathology, pathology

Findings:
3.1 ppm: hyperplasia of respiratory epithelium in the nose, no systemic toxicity
1.09 ppm: NOAEL

no details on pathology; study was intended to investigate combination toxicity of 9 chemicals (oral exposure with a mixture of 7 plus inhalation exposure with a mixture of 2) combined treatment at the NOAEL of each compound (FA=1.09 ppm) showed some transitional epithelial hyperplasia, which was not present with FA alone, the authors conclude that simultaneous exposure at or below individual NOAELs does not constitute an evidently increased hazard
Source: BASF AG Ludwigshafen
Test substance: formaldehyde; no data on purity of the compound
Reliability: (2) valid with restrictions

(235) (236) (237)

Species: rat **Sex:** male/female
Strain: Wistar
Route of admin.: drinking water
Exposure period: 24 mesi
Frequency of treatment: giornaliero
Post. obs. period: 24 mesi
Doses: 0, 1.2, 15, 82 mg/kg/giorno
Control Group: yes
NOAEL: = 15 mg/kg bw
Method:
Year: **GLP:**
Test substance:
Source: ALDER S.p.A. TRIESTE

(238)

Species: rat **Sex:** male/female
Strain: Wistar
Route of admin.: drinking water
Exposure period: 4 weeks
Frequency of treatment: continuously in the drinking water
Post. obs. period: none
Doses: 5, 25, 125 mg/kg/d
Control Group: yes, concurrent no treatment
NOAEL: = 25 mg/kg bw
Method: other: no data
Year: **GLP:** no data
Test substance: no data
Remark: Reliability: 2 (reliable with restrictions)
Result: The effects of orally administered formaldehyde was studied in rats: 3 groups of 10 rats/sex were given the test substance in the drinking water (concentration in the drinking water was not given) and 20 rats/sex remained untreated. In another group of 10 rats/sex, water was restricted. Examinations on general health, clinical pathology, autopsy, and histopathology of the nose, upper gastrointestinal tract, liver, and kidneys were performed.

No systemic toxicity was observed. In the high dose group, a decrease in water and food consumption and in body weight gain was observed. A decrease of plasma protein, hyperkeratosis, incidental hyperplasia of the forestomach epithelium, and focal atrophic gastritis in the glandular stomach was found. Water restriction resulted in a decrease in body weight gain and in changes in several hematological and clinicochemical parameters. No substance–related effects were observed in animals treated with 25 and 5 mg/kg/d. Thus, NOAEL was given as 25 mg/kg/d.
Source: BASF AG Ludwigshafen
Test substance: formaldehyde; no data on purity of the compound

(239)

Species: rat **Sex:** male/female
Strain: Sprague–Dawley
Route of admin.: drinking water
Exposure period: 91 days
Frequency of treatment: continuously in the drinking water
Post. obs. period: none
Doses: 50, 100, 150 mg/kg/d
Control Group: yes, concurrent no treatment
Method: other: no data
Year: **GLP:** no data
Test substance: no data
Remark: In preliminary two week studies gavage of 37.5, 75, 150 and 225 mg/kg body weight reduced weight development above 75 mg/kg whereas administration of 500, 1000 and 1500 ppm (i.e. 75, 150 and 225 mg/kg body weight) did only reduce water consumption.
Reliability: 3 (not reliable)
Result: The effects of orally administered formaldehyde was studied in 4 groups of 15 rats/sex (3 treated groups, 1 control group; concentration in the drinking water was not given). Examinations on general health, clinical pathology, autopsy,and histopathology of several organs were performed.

Administration of the high dose resulted in reduction of both water consumption and body weight gain in males and females. In the mid dose group, reduction of waterconsumption and body weight gain was observed in males only.In the low dose group, decrease in water consumption was recorded.
Source: BASF AG Ludwigshafen
Test substance: formaldehyde; no data on purity of the compound

(240)

Species: rat **Sex:** male
Strain: Wistar
Route of admin.: drinking water
Exposure period: 32 weeks
Frequency of treatment: continuously in the drinking water
Post. obs. period: none
Doses: ca. 450 mg/kg/d (5000 ppm)
Control Group: yes
Method: other: no data
Year: **GLP:** no data
Test substance: no data
Remark: Reliability: 2 (reliable with restrictions)
Result: The study was part of an initiation–promotion study; 10 rats were administered the test substance, 10 rats remained untreated. Examinations on general health, autopsy, and histopathology of stomach and duodenum were performed.

Administration of the test substance resulted in reduction of body weight gain. Diffuse proliferative changes in the superficial epithelium of the glandular stomach, erosions

and ulcers along the liming ridge of fundic mucosa was observed. For carcinogenic effects see chapter 5.7.
Source: BASF AG Ludwigshafen
Test substance: formaldehyde; no data on purity of the compound

(241)

Species: rat **Sex:** male
Strain: Wistar
Route of admin.: drinking water
Exposure period: 104 weeks
Frequency of treatment: continuously in the drinking water
Post. obs. period: none
Doses: 10, 50, 300 mg/kg/d (200, 1000, 5000 ppm in the drinking water)
Control Group: yes
NOAEL: = 10 mg/kg bw
Method: other: no data
Year: **GLP:** no data
Test substance: no data
Remark: Reliability: 2 (reliable with restrictions)
Result: The effects of orally administered formaldehyde was studied in 4 groups of 20 rats/sex (3 treated groups, 1 control group). Interim sacrifices were carried out with 6 animals/sex/group after 12 and 18 months. Examinations on general health, clinical pathology, autopsy, and histopathology of several organs were performed.

In the high dose group (5000 ppm), poor general state, reduction of body weight gain and both food and water consumption (ca. 50%), increased mortality (ca. 50% after 12 months), and changes in various clinical parameters were recorded. Lesions of the stomach were most pronounced after 12 months of exposure: squamous and basal cell hyperplasia and hyperkeratosis (70–100%), erosions/ulcers and submucosal cell infiltration (20–30%) in the forestomach; glandular hyperplasia, erosions/ulcers (70–100%) and submucosal cell infiltration (30–50%) in the glandular stomach were found.
Administration of 1000 ppm resulted in forestomach hyperkeratosis in several animals after 18 and 24 months. According to the authors, NOAEL was 10 mg/kg/d; for carcinogenicity see chapter 5.7.
Source: BASF AG Ludwigshafen
Test substance: formaldehyde; no data on purity of the compound

(242)

Species: rat **Sex:** male
Strain: Wistar
Route of admin.: drinking water
Exposure period: 104 weeks
Frequency of treatment: continuously in the drinking water
Post. obs. period: none
Doses: 1.2, 15, 82 mg/kg/d (males), 1.8, 21, 109 mg/kg/d (females); i.e. average concentration of 20, 260, 1900 mg/l in the drinking water
Control Group: yes
NOAEL: ca. 260 mg/l
Method: other: no data
Year: **GLP:** no data
Test substance: no data
Remark: Reliability: 2 (reliable with restrictions)
Result: The effects of orally administered formaldehyde was studied in 4 groups of 70 rats/sex (3 treated groups, 1 control group). The concentration of the test substance in the drinking water was adjusted for body weight and liquid consumption up to week 52; average concentrations were 20, 260, and 1900 mg/l. Thus, the doses were calculated as 1.2, 15, and 82 mg/kg/d for males and 1.8, 21, and 109 mg/kg/d for females. Interim sacrifices were carried out with 10 animals/sex/group after 12 and 18 months. Examinations on general health, clinical pathology, autopsy, and histopathology of about 50 organs and tissues were performed.

In the high dose group (1900 mg/l; 82 and 109 mg/kg/d for males and females, respectively), decreased water (40%) and food consumption, depressed body weight gain, and minor changes in urinary densitiy and volume were recorded. Increased incidence of papillary epithelial hyperplasia in the forestomach (60-90%) and chronic atrophic gastritis in the glandular stomach (100%) were observed. After 24 months of exposure, additionally hyperkeratosis (50-70%) and ulceration (15%) in the forestomach, focal ulceration (20%) and glandular hyperplasia in the glandular stomach (30-40%),and renal papillary necrosis (40%) were found. The forestomach lesions were mostly located in the vicinty of the limiting ridge; according to the authors, the renal papillary necrosis was due to decreased water consumption.

In the mid dose group, (260 mg/l; 15 and 21 mg/kg/d for males and females, respectively), a slight reduction of water consumption was observed. Thus, according to the authors, a concentration of 260 mg/l drinking water was considered to be the NOAEL. No evidence of carcinogenicity was found (see chapter 5.7).
Source: BASF AG Ludwigshafen
Test substance: formaldehyde; no data on purity of the compound

(239)

Species: rat **Sex:** no data
Strain: other: no data
Route of admin.: i.p.
Exposure period: single or 4 daily doses
Frequency of treatment:
Post. obs. period: no data
Doses: 0.02 ml of a 2% solution (ca. 0.4 mg/dose)
Control Group: no data specified
Method: other: no data
Year: **GLP:** no
Test substance: no data
Result: A single intraperitoneal injection to neonatal rats resulted in a decrease of cellular activity in some regions of the hypothalamus and in an accumulation of granula in neural cytoplasm. Furthermore, the nuclear volumina of adrenal cells were incresed. The latter finding was also observed after 4 treatments of the same kind. Additionally, in rats treated 4 times, pronounced degeneration and cellular atrophy of the hypothalamus was observed. Only secondary literature; no further data.
Source: BASF AG Ludwigshafen
Test substance: formaldehyde; no data on purity of the compound
Reliability: (3) invalid

(243)

Species: mouse **Sex:** female
Strain: Swiss
Route of admin.: inhalation
Exposure period: 4 days
Frequency of treatment: 4 h/d
Post. obs. period: none
Doses: ca. 0.006 mg/l (5 ppm)
Control Group: yes, concurrent no treatment
Method: other: no data
Year: **GLP:** no data
Test substance: no data
Remark: Reliability: 3 (not reliable)
The results are biologically not plausible, no clear description and explanations were given by the author.
Result: The effect of formaldehyde inhalation on alveolar macrophage Fc-mediated phagocytosis was studied. According to the authors, exposure to 5 ppm formaldeyde alone had no effect on phagocytosis.

Coexposure with 0.01 mg/l (10 mg/m3) carbon black reversibly decreased phagocytosis but did not alter bacterial elimination in the lung. Four-hour single exposure to 15, but not to <=10 ppm decreased phagocytosis; 18-h exposure to 1 but not to 0.5 ppm followed by bacterial challenge and 4-h exposure to decreased bacterial elimination in the lung.
Source: BASF AG Ludwigshafen
Test substance: formaldehyde; no data on purity of the compound

(244)

Species: mouse **Sex:** female
Strain: B6C3F1
Route of admin.: inhalation
Exposure period: 3 weeks
Frequency of treatment: 5 d/w, 6 h/d
Post. obs. period: none
Doses: ca. 0.018 mg/l (14.8 – 15.0 ppm)
Control Group: yes, concurrent no treatment
Method: other: no data
Year: **GLP:** no data
Test substance: no data
Remark: Reliability: 2 (reliable with restrictions)
Result: The effects of formaldehyde were studied in a total of 255 mice. Three experimental runs were carried aout at dose levels of 14.8, 14.8, and 15.0 ppm. Examinations on general health, thymus and spleen weights, hematology, spleen and bone marrow cellularity and colony-forming activity, cell mediated immunity by 4 different lymphocyte function tests, function tests with peritoneal macrophages and host susceptibility studies with Listeria monocytogenes and 2 lines of transplantable tumor cells were carried out. According to the authors, enhanced resistance to Listeria monocytogenes, and increased competence of peritoneal macrophages for release of hydrogen peroxide were observed.
Source: BASF AG Ludwigshafen
Test substance: formaldehyde; no data on purity of the compound

(245) (246)

Species: mouse **Sex:** male/female
Strain: B6C3F1
Route of admin.: inhalation
Exposure period: 13 weeks
Frequency of treatment: 5 d/w, 6 h/d
Post. obs. period: none
Doses: ca. 0.002, 0.005, 0.012, 0.025, 0.050 mg/l (1.96, 4.1, 10.1, 20.4, 40.3 ppm)
Control Group: yes, concurrent no treatment
NOAEL: = .002 mg/l
LOAEL: = .005 mg/l
Method: other: no data
Year: **GLP:** no data
Test substance: no data
Remark: Reliability: 2 (reliable with restrictions)
Result: The effects of formaldehyde were studied in groups of 10 mice/sex/group. Examinations on general health, autopsy, and histopathology of several organs and tissues were performed.
At the highest dose level (40.3 ppm), 80% lethality was observed from exposure week 5–6 onwards. Impairment of general health was recorded. In all animals, rhinitis, and squamous metaplasia of the nose, the larynx, and the

trachea was observed. Some animals showed epithelial hyperplasia, purulent inflammation, and submucosal fibrosis of the trachea; bronchial squamous metaplasia, inflammation, and submucosal fibrosis were found in the lungs of some animals. Hyperplasia of ovaries and uterus was observed.
Exposure to 20.4 ppm resulted in an impairment of general health, rhinitis, and squamous metaplasia of the nose in alle animals; squamous metaplasia of the larynx and trachea and epithelial hyperplasia of the larynx was observed in some animals of this group.
In the 10.1 ppm group, squamous metaplasia was observed in in all animals; some males showed rhinitis.
Squamous metaplasia was observed in one male exposed to 4.1 ppm.
Exposure to 1.96 ppm did not result in any abnormalities.
According to the authors, death, impairment of general health, and findings in the female genital tract were related to severe local damage of the respiratory tract.

Source: BASF AG Ludwigshafen
Test substance: formaldehyde; no data on purity of the compound

(247)

Species: mouse **Sex:** male/female
Strain: B6C3F1
Route of admin.: inhalation
Exposure period: up to 24 months
Frequency of treatment: 5 d/w, 6 h/d
Post. obs. period: up to 6 months
Doses: ca. 0.0025, 0.007, 0.018 mg/l (2.0, 5.6, 14.3 ppm)
Control Group: yes, concurrent no treatment
NOAEL: = .0025 mg/l
LOAEL: = .007 mg/l
Method: other: no data
Year: **GLP:** no data
Test substance: no data
Remark: Reliability: 2 (reliable with restrictions)
Result: The effects of formaldehyde were studied in groups of ca. 120 mice/sex/group. Mice were sacrificed after month 6, 12, 18, 24, 27, and 30 of the study. Examinations on general health (including neurofunction and ophthalmoscopy), clinical pathology, urinalysis, autopsy, and histopathology of about 50 tissues were performed. An exposure-independent increase in mortality due to infections of the genitourinary tract was observed in males.
At the highest dose level (14.3 ppm), a trend to decreased body weight gains was noted in the last third of exposure. Rhinitis, epithelial dysplasia and squamous metaplasia was observed from month 12 onwards. Increased incidence and severity of the findings with exposure duration and a tendency for recovery during the postexposure period was recorded.
In the mid dose group (5.6 ppm), epithelial dysplasia was observed in a few animals.
No substance-related effects were observed in mice exposed

to 2.0 ppm.
For carcinogenic effects see chapter 5.7.
Source: BASF AG Ludwigshafen
Test substance: formaldehyde; no data on purity of the compound

(230)

Species: mouse **Sex:** no data
Strain: B6C3F1
Route of admin.: inhalation
Exposure period: up to 10 days
Frequency of treatment: 6 h/d, 1, 3 and 5 d; 36 ppmh/d, 3 ppm x 12 h, 6 ppm x 6h, 12 ppm x 3h for 10 days
Post. obs. period: none
Doses: 0, 0.5, 2, 6, 15 ppm or 3, 6 and 12ppm
Control Group: other: yes, concurrent
Method: other: cell proliferation measurement
Year: **GLP:** no data
Test substance: no data
Remark: Examinations:
measurements of cell proliferation (% labeled cells) in nasoturbinate levels A (anterior) and B (mid anterior)
single i.p. injection of H-thymidine 2 or 18 h after end of exposure

Findings:
fold increase of LI in level B
1 d/15 ppm: about 8
3 d/15 ppm: about 8
5 d/15 ppm: about 13
no increase at 6, 2 and 0.5 ppm labelling; 18 h after end of exposure yielded higher fractions of labeled cells in controls and exposed animals (authors: circadian variations)

C x T study
level A: concentration dependent about 8, 4 and 1.4 fold increase of proliferation after 10 days
level B: no increase in proliferation rate

Authors try to explain inverse proportionality of proliferation versus concentration by high suceptibility of mice to sensory irritation; LI of control groups [%]
level B:
pulse 2 h post exp.: 0.12
pulse 18 h post exp.: 0.27
level A:
1.24
data for rats in seperate entry
Source: BASF AG Ludwigshafen
Test substance: formaldehyde; no data on purity of the compound
Reliability: (2) valid with restrictions

(248) (231) (233)

Species: mouse **Sex:** male
Strain: B6C3F1
Route of admin.: gavage
Exposure period: 5 days
Frequency of treatment: daily
Post. obs. period: 5 weeks
Doses: 100, 250, 500 mg/kg/d
Control Group: yes, concurrent vehicle
Method: other: no data
Year: **GLP:** no data
Test substance: no data
Remark: Reliability: 2 (reliable with restrictions)
These experiments were part of a sperm morphology study.
Result: Formalin (37% formaldehyde, 10% methanol in water) was administered to groups of 10 mice for 5 consecutive days; 5 control mice were given distilled water. Five weeks after treatment, the mice were sacrificed.
According to the authors, application of the mid and high dose was lethal to all mice treated.
Source: BASF AG Ludwigshafen
Test substance: formalin; 37% formaldehyde; no data on purity of the compound

(249)

Species: mouse **Sex:** female
Strain: CD–1
Route of admin.: dermal
Exposure period: 2–3 weeks
Frequency of treatment: daily
Post. obs. period: none
Doses: 3 – 300 mg/kg
Control Group: no data specified
Method: other: no data
Year: **GLP:** no data
Test substance: no data
Remark: Reliability: 2 (reliable with restrictions)
Result: The effects of dermally administered formaldehyde was studied in 30 mice; the test substance was dissolved in acetone/water 50:50; 100 ul of 0.1, 0.5, 1, 2, 5, and 10% solutions (i.e. 0.1–10 mg/animal, i.e. 3–300 mg/kg) were applied for 2–3 weeks. Examinations on general health with special regard for skin irritation were performed.

No systemic toxicity was observed. Administration of a 10% solution resulted in fissuring, sloughing and papules at the application site (moderate irritation) after 2–4 treatments. In mice exposed to 5 and 2%, mild to moderate irritation occurred after 4–5 treatments. A solution of 1% caused mild irritation beginning during the second week. A concentration of 0.5% caused slight irritation which was reversible during weekends.

This study was a pre–test for an initiation–promotion

study. No further data.
Source: BASF AG Ludwigshafen
Test substance: formaldehyde; no data on purity of the compound

(250)

Species: mouse **Sex:** male/female
Strain: other: hairless (hr/hr, Oslo)
Route of admin.: dermal
Exposure period: 60 weeks
Frequency of treatment: twice a week
Post. obs. period: none
Doses: 2, 20 mg/animal
Control Group: no data specified
Method: other: no data
Year: **GLP:** no data
Test substance: no data
Remark: Reliability: 2 (reliable with restrictions)
Result: The effects of dermally administered formaldehyde was studied in 16 mice/sex; 200 ul of a 1 or 10% aqueous solution of the test substance (i.e. ca. 2 and 20 mg/animal,respectively) were applied. Examinations on general health, autopsy, and histopathology of brain, nasal mucosa, lungs, and skin and other tumors were performed.

Application of the 10% solution resulted in slight hyperplasia of the epidermis; skin ulcers were observed in few animals. No systemic toxicity was reported.

This study was part of an initiation-promotion study.
Source: BASF AG Ludwigshafen
Test substance: formaldehyde; no data on purity of the compound

(251)

Species: mouse **Sex:** male/female
Strain: other
Route of admin.: dermal
Exposure period: 26 weeks
Frequency of treatment: 3 times per week
Post. obs. period: 26 weeks
Doses: 125 mg/kg (single dose) followed by 2.5, 12.5, 25 mg/kg/application
Control Group: no data specified
Method: other: no data
Year: **GLP:** no data
Test substance: no data
Remark: Reliability: 2 (reliable with restrictions)
Result: The effects of dermally administered formaldehyde was studied in 30 mice; the test substance was dissolved in acetone/water 50:50. At the beginning of the study, 50 ul of a 10% solution (5 mg/animal = 125 mg/kg) was applied. Thereafter, 100 ul of a solution containing 0.1, 0.5, or 1% (2.5, 12.5, or 25 mg/kg, respectively) was applied 3 times a week for 26 weeks. After termination of exposure, the

mice were post-observed for additional 26 weeks.
Examinationson general health and skin nodules were performed.
No influence on mortality and body weight was found; minimal irritation of skin was observed.
This study was part of an initiation-promotion study (see chapter 5.7).

Source: BASF AG Ludwigshafen
Test substance: formaldehyde; no data on purity of the compound

(250)

Species: mouse **Sex:** male
Strain: B6C3F1
Route of admin.: i.p.
Exposure period: 5 days
Frequency of treatment: daily
Post. obs. period: 5 weeks
Doses: 100 mg/kg/d
Control Group: yes, concurrent vehicle
Method: other: no data
Year: **GLP:** no data
Test substance: no data
Remark: Reliability: 2 (reliable with restrictions)
These experiments were part of a sperm count study.
Result: Formalin (37% formaldehyde, 10% methanol in water) was administered to 10 mice for 5 consecutive days; 5 control mice were given distilled water.
According to the authors, i.p. application of the test substance was lethal to all mice treated.
Source: BASF AG Ludwigshafen
Test substance: formalin; 37% formaldehyde; no data on purity of the compound

(249)

Species: rabbit **Sex:** no data
Strain: other: no data
Route of admin.: other: topical application to oral mucosa ("oral tank")
Exposure period: 10 months
Frequency of treatment: 5 times a weeks for 90 min
Post. obs. period: 1 month
Doses: 3% aqueous solution
Control Group: yes, concurrent vehicle
Method: other: no data
Year: **GLP:** no data
Test substance: no data
Remark: According to the authors, "oral tank" was a stomatological device to hold viscose sponges in close contact to oral mucosa over prolonged periods of time.
Reliability: 3 (not reliable)
Result: The effects of topical administration of the test substance to oral mucosa using "oral tanks" was investigated using 20 rabbits (10 untreated controls, 4 "oral tank" controls = vehicle controls, 6 treated). A 3% aqueous solution was

applied; histopathology of oral mucosa was performed. Treatment with the test substance resulted in severe epithelial hyperplasia; visible leukoplakia was found in 2/6 animals and was histologicallly characterized by "preneoplasic unrest". According to the authors, one lesion was classified as "carcinoma in situ". In "oral tank" controls, moderate hyperplasia with parakeratosis by mechanical irritation was observed.

Source: BASF AG Ludwigshafen

Test substance: formaldehyde; no data on purity of the compound

(252)

Species: Syrian hamster **Sex:** male

Strain:

Route of admin.: inhalation

Exposure period: 26 weeks

Frequency of treatment: 7 d/w, 22 h/d

Post. obs. period: none

Doses: ca. 0.0002, 0.0012, 0.0037 mg/l (0.19, 0.98, 2.95 ppm)

Control Group: yes, concurrent no treatment

NOAEL: > .0037 mg/l

Method: other: no data

Year: **GLP:** no data

Test substance: no data

Result: The effects of formaldehyde were studied in 5 groups of 10 hamsters/sex (3 treated groups and 2 untreated control groups). Examinations on general health, autopsy, measurements of organ weights (heart, kidneys, liver, adrenals) and histopathology of the nose, trachea and lungs were performed.
No substance-related findings were recorded.

Source: BASF AG Ludwigshafen

Test substance: formaldehyde; no data on purity of the compound

Reliability: (2) valid with restrictions

(219)

Species: Syrian hamster **Sex:** male
Strain: other: no data
Route of admin.: inhalation
Exposure period: lifetime
Frequency of treatment: 5 h/d, 5 d/w (10 ppm) or 5 h/d, 1 d/w (30 ppm)
Post. obs. period: none
Doses: ca. 0.012 mg/l (10 ppm) or 0.037 mg/l (30 ppm)
Control Group: yes, concurrent no treatment
Method: other: no data
Year: **GLP:** no data
Test substance: no data
Result: The effects of formaldehyde on the respiratory tract were studied in 88 animals exposed to 10 ppm and 50 animals exposed to 30 ppm, 132 and 50 control animals remained untreated.Autopsy and histopathology or subgross stereomicroscopical examination of the respiratory tract was performed. At 10 ppm a reduced survival time (50% mortality between 80 and 90 weeks of age) was recorded. A 5% incidence of nasal epithelial hyperplasia and metaplasia was observed. No changes were found in the control group. At 30 ppm fifty percent mortality between 70 or 80 weeks of age was observed in both control and treated group.

The analytical concentration of the test substance was not reported.
Source: BASF AG Ludwigshafen
Test substance: formaldehyde; no data on purity of the compound
Reliability: (2) valid with restrictions

(253)

Species: dog **Sex:** male/female
Strain: Beagle
Route of admin.: drinking water
Exposure period: 91 days
Frequency of treatment:
Post. obs. period:
Doses: 0, 50, 75, 100 mg/kg/bw
Control Group:
Method:
Year: **GLP:** no data
Test substance: other TS
Remark: In prelimary studies food containing concentrations resulting in higher dosages than 100 mg/kg were not applicable (food rejection or regurgitation)
Result: Examinations:
General health, clinical pathology, autopsy, histopathology of several organs (digestive tract not mentioned)

Findings:
100 mg/kg – decrease in drinking water and food consumption and reduced body weight development

75 mg/kg – decrease in drinking water and food consumption

50 mg/kg – decrease in drinking water and food consumption
Source: BASF AG Ludwigshafen
Test substance: formaldehyde; no data on purity of the compound
Reliability: (2) valid with restrictions

(240)

Species: guinea pig **Sex:** male
Strain: Hartley
Route of admin.: inhalation
Exposure period: 8 weeks
Frequency of treatment: no data specified
Post. obs. period: none or 4 weeks
Doses: ca. 0.001, 0.011 mg/l (0.9, 8.8 ppm)
Control Group: yes, concurrent no treatment
NOAEL: < .001 mg/l
LOAEL: = .001 mg/l
Method: other: no data
Year: **GLP:** no data
Test substance: no data
Result: The effects of formaldehyde were studied in groups of 20 animals. The guinea pigs were sacrificed either immediately after termination of exposure or 4 weeks later. Examinations on general health, nasal and tracheal mucosal clearance velocities, biochemical parameters of lung lavage fluid and lung homogenate, and histopathology of nasal cavitiy, trachea, lung and 12 other tissues were performed.
In the high dose group, behaviour indicating eye and nose irritation, a tendency to increased mucous clearance during exposure and decreased tracheal mucosal clearance during exposure which reversed to increased velocities after the end of the exposure period was recorded. Hyperkeratosis of squamous epithelium and focal squamous metaplasia of the respiratory epithelium in the anterior half of the nasal cavity which resolved to slight hyperkeratosis at the end of the recovery period.
In the low dose group, hyperkeratosis of squamous epithelium was observed.
Source: BASF AG Ludwigshafen
Test substance: formaldehyde; no data on purity of the compound
Reliability: (2) valid with restrictions

(254)

Species: monkey **Sex:** male
Strain: other: Rhesus
Route of admin.: inhalation
Exposure period: 1 or 6 weeks
Frequency of treatment: 5 d/w, 5 h/d
Post. obs. period: none
Doses: ca. 0.007 mg/l (6 ppm)
Control Group: yes, concurrent no treatment
Method: other: no data
Year: **GLP:** no data
Test substance: no data
Remark: Reliability: 2 (reliable with restrictions)
Result: Three animals were used per group. Examinations on general health, autopsy, and histopathology of the respiratory tract (including the maxillar sinuses) and other organs were performed.
Exposure to the test substance resulted in ocular irritation and altered breathing pattern. In animals exposed for 1 week, loss of cilia and globlet cells, mild epithelial hyperplasia and squamous metaplasia, inflammation with a clear anterior-posterior gradient was observed in the respiratory epithelium of the nose; in larynx, trachea , andcarina, loss of cilia was found. In animals exposed for 6 weeks, mild hyperkeratosis of the squamous epithelium of thenose, and erosions, epithelial hyperplasia, and inflammationof the transitional epithelium of the nose was observed. In the respiratory epithelium of the nose, the same lesions were found after 1 week of exposure, however, these lesions were more extensive and found also in the posterior parts of the nasal cavity. The lesions were most pronounced in the middle turbinate. In larynx, trachea, and carina, loss of cilia and globlet cells, mild epithelial hyperplasia, and early squamous metaplasia were observed; these lesions were of a higher extent than in the 1-week group. No substance-related lesions were found int the maxillar sinuses or in organs outside the respiratory tract.

The results of concentration measurement of the inhalation atmosphere were not reported; no tabulation or grading of the histopathological findings.
Source: BASF AG Ludwigshafen
Test substance: formaldehyde; no data on purity of the compound

(255) (212)

Species: monkey **Sex:** male
Strain: other: Cynomolgus
Route of admin.: inhalation
Exposure period: 26 weeks
Frequency of treatment: 7 d/w, 22 h/d
Post. obs. period: none
Doses: ca. 0.0002, 0.0012, 0.0037 mg/l (0.19, 0.98, 2.95 ppm)
Control Group: yes, concurrent no treatment
NOAEL: = .0012 mg/l
LOAEL: = .0037 mg/l
Method: other: no data
Year: **GLP:** no data
Test substance: no data
Remark: Reliability: 2 (reliable with restrictions)
Result: The effects of formaldehyde were studied in 5 groups of 6 monkeys (3 treated groups and 2 untreated control groups). Examinations on general health, autopsy, measurements of organ weights (heart, kidneys, liver, adrenals) and histopathology of the nose, trachea and lungs were performed.
In the high dose group, increased incidence of hoarseness, congestion, nasal discharge, and squamous metaplasia of the respiratory epithelium was observed; the lesions were most pronounced in the middle region of the nasoturbinate. Rhinits was randomly distributed in all 5 groups. No datailed tabulation of data.
Source: BASF AG Ludwigshafen
Test substance: formaldehyde; no data on purity of the compound

(219)

Species: monkey **Sex:** male
Strain: other: Rhesus
Route of admin.: inhalation
Exposure period: 1 or 6 weeks
Frequency of treatment: 5 d/w, 5 h/d
Post. obs. period: none
Doses: ca. 0.007 mg/l (6 ppm)
Control Group: yes, concurrent no treatment
Method: other: cell proliferation measurement
Year: **GLP:** no data
Test substance: no data
Remark: Reliability: 2 (reliable with restrictions)
Result: Cell proliferation due to exposure to formaldehyde was determined via measurement of unit length labelling index (ULLI) in nasoturbinates, larynx, trachea, and carina and measurement of the Labelling Index (LI) of the terminal bronchioles. Three animals/group each were exposed to 6 ppm of the test substance for 1 or 6 weeks, then a single dose of 3H-thymidine was injected intraperitoneally.
After exposure for 1 week, an increase in proliferation of transitional and respiratory epithelium of the nose was observed; the degree of the increase was dependent on the localisation (max. 14-fold); a clear anterior-posterior

gradient of labelling was recorded. A ca. 2-3 fold increase was found in the larynx, trachea, and carina.
After 6 weeks of exposure, an increase of proliferation of transitional, respiratory, and olfactory epithelium of the nose was observed (depending on the location; max. 16-fold). A 7-9 fold increase was found in the larynx, trachea, and carina, however these alterations were not statistically significant due to huge variations.
No increase in proliferation was found in maxillary sinuses and terminal bronchioles.

Source: BASF AG Ludwigshafen
Test substance: formaldehyde; no data on purity of the compound

(255) (212)

Species: **Sex:**
Strain:
Route of admin.:
Exposure period:
Frequency of treatment:
Post. obs. period:
Doses:
Control Group:
Method:
Year: **GLP:**
Test substance:
Remark: Pas de données disponibles
Source: PROTEX S.A LEVALLOIS PERRET

5.5 Genetic Toxicity 'in Vitro'

Type: Gene mutation in Saccharomyces cerevisiae
System of testing:
Concentration: 5 g/L
Metabolic activation:
Result: positive
Method:
Year: **GLP:**
Test substance:
Source: ALDER S.p.A. TRIESTE

(134)

Type: other: ex vivo (in vitro/in vivo) DNA damage – prokaryotes (bacteria)
System of testing: other: male NMRI mice and Escherichia coli K–12/343/636 (uvrB+/recA+), K–12/343/591 (uvrB–/recA–)
Concentration: (a) 17, 50 mg/kg (oral); (b) 10, 30 mg/kg (i.v.)
Metabolic activation: with
Result: positive
Method: other: host–mediated assay
Year: **GLP:** no data
Test substance: no data
Remark: Reliability: 2 (reliable with restrictions)
Result: Seven male NMRI mice per dose were used. The bacterial mix was injected in the lateral vein. The lowest effective dose was 17 mg/kg after oral administration and 10 mg/kg after intravenous administration of formaldehyde. Preferential reduction of DNA repair deficient strain was observed in blood and lungs.
Source: BASF AG Ludwigshafen
Test substance: formaldehyde; no data on purity of the compound

(256) (257)

Type: other: in vitro DNA damage – eukaryotes (mammalian cells)
System of testing: CHO cells AA8 (wild type), EM9, UV4, UV5 (repair–deficient)
Concentration: 5.6 mg/l
Metabolic activation: without
Result: positive
Method: other: differential cell killing (DNA damage)
Year: **GLP:** no data
Test substance: no data
Remark: Differential cytotoxicity was observed with the mutant cells UV4 and UV5 compared to the wild–type; differential cell killing (based on colony–forming ability) was interpreted as a measure of lethal, potentially repairable damage to DNA
Reliability: 2 (reliable with restrictions)
Source: BASF AG Ludwigshafen
Test substance: formaldehyde; no data on purity of the compound

(258)

Type: other: in vitro DNA damage – eukaryotes (mammalian cells/DNA strand breaks)
System of testing: human fibroblasts
Concentration: 0.1, 1 mM (ca. 3, 30 mg/l)
Metabolic activation: without
Result: positive
Method: other: Nick translation assay (DNA strand breaks)
Year: **GLP:** no data
Test substance: no data
Remark: induction of DNA damage (DNA strand breaks) as measured by the incorporation of dCTP into the DNA; little or no reduction of long–patch repair

Reliability: 2 (reliable with restrictions)
Source: BASF AG Ludwigshafen
Test substance: formaldehyde; no data on purity of the compound

(259)

Type: other: in vitro DNA damage – eukaryotes (mammalian cells/DNA strand breaks)
System of testing: human fibroblasts
Concentration: 0.1 – 10 mM (ca. 3 – 300 mg/l)
Metabolic activation: without
Result: positive
Method: other: Nick translation assay (DNA strand breaks)other: in vitro DNA damage – eukaryotes (mammalian cells/DNA strand breaks)
Year: **GLP:** no data
Test substance: no data
Remark: induction of DNA damage (DNA strand breaks) as measured by the incorporation of dNTPs into the DNA; higher doses (>= 1mM) were inhibitory in this assay
Reliability: 2 (reliable with restrictions)
Source: BASF AG Ludwigshafen
Test substance: formaldehyde; no data on purity of the compound

(260)

Type: other: in vitro DNA damage – eukaryotes (mammalian cells/DNA strand breaks)
System of testing: F344 rat tracheal epithel cell line, C18
Concentration: 100 – 400 uM (ca. 3 – 12 mg/l)
Metabolic activation: without
Result: positive
Method: other: alkaline elution assay (DNA strand break)
Year: **GLP:** no data
Test substance: no data
Remark: dose-related increase in single strand breaks (SSB) up to 400 uM; SSB were repaired within 2 h; treatment for 90 min. reduced the Colony-Forming Efficiency (CFE) at 400 uM (25% of control)
Reliability: 2 (reliable with restrictions)
Source: BASF AG Ludwigshafen
Test substance: formaldehyde; no data on purity of the compound

(261)

Type: other: in vitro DNA damage – eukaryotes (mammalian cells/DNA strand breaks)
System of testing: mouse leukemia L1210 cells
Concentration: up to 300 uM (ca. 9 mg/l)
Metabolic activation: without
Result: positive
Method: other: alkaline elution assay (DNA strand break)
Year: **GLP:** no data
Test substance: no data
Remark: A small number of single strand breaks (SSB) occurred at 200 uM with an increase up to 300 uM. According to the authors, DNA damage was accompanied by inhibition of DNA synthesis. Extensive DNA-protein crosslinks (DPC) which were repaired after removal of the test substance were observed.
Reliability: 2 (reliable with restrictions)
Source: BASF AG Ludwigshafen
Test substance: formaldehyde; no data on purity of the compound

(262)

Type: other: in vitro DNA damage – eukaryotes (mammalian cells/DNA strand breaks)
System of testing: human bronchial epithelial cells
Concentration: 0.1 mM (ca. 3 mg/l)
Metabolic activation: without
Result: positive
Method: other: alkaline elution assay (DNA strand break)
Year: **GLP:** no data
Test substance: no data
Remark: induction of a significant level of single strand breaks (SSB); according to the authors, formaldehyde caused substantially higher levels of DNA-Protein cross links (DPC) than SSB
Reliability: 2 (reliable with restrictions)
Source: BASF AG Ludwigshafen
Test substance: formaldehyde; no data on purity of the compound

(263)

Type: other: in vitro DNA damage – eukaryotes (mammalian cells/DNA strand breaks)
System of testing: primary rat hepatocytes, SV-40 transformed CHO cells CO631
Concentration: no data
Metabolic activation: without
Result: positive
Method: other: alkaline elution assay (DNA strand break)
Year: **GLP:** no data
Test substance: no data
Remark: Reliability: 2 (reliable with restrictions)
slight increase in single strand breaks (2-3-fold) in both cell lines; induction of DNA amplification (SDA) in CHO cells; no further data
Source: BASF AG Ludwigshafen

Test substance: formaldehyde; no data on purity of the compound

(264)

Type: other: in vitro DNA damage – eukaryotes (mammalian cells/DNA strand breaks)
System of testing: Yoshida lymphosarcoma cells
Concentration: 250 uM (ca. 7.5 mg/l)
Metabolic activation: without
Result: positive
Method: other: alkaline elution assay (DNA strand break)
Year: **GLP:** no data
Test substance: no data
Remark: induction of a small number of single strand breaks; according to the authors, formaldehyde caused several-fold higher levels of DNA-Protein Crosslinks
Reliability: 2 (reliable with restrictions)
Source: BASF AG Ludwigshafen
Test substance: formaldehyde; no data on purity of the compound

(265)

Type: other: in vitro DNA damage – eukaryotes (mammalian cells/DNA strand breaks)
System of testing: primary rat tracheal cells, rat tracheal epithelial cell line C18
Concentration: 200 uM (ca. 6 mg/l)
Metabolic activation: without
Result: positive
Method: other: alkaline elution assay (DNA strand break)
Year: **GLP:** no data
Test substance: no data
Remark: induction of a few single strand breaks in both C18 and primary cells; only abstract available; no further data
Reliability: 2 (reliable with restrictions)
Source: BASF AG Ludwigshafen
Test substance: formaldehyde; no data on purity of the compound

(266)

Type: other: in vitro DNA damage – eukaryotes (mammalian cells/DNA strand breaks)
System of testing: primary rat tracheal cells
Concentration: 200 uM (ca. 6 mg/l)
Metabolic activation: without
Result: positive
Method: other: alkaline elution assay (DNA strand break)
Year: **GLP:** no data
Test substance: no data
Remark: induction of single strand breaks (SSB), SSB were removed within 2 h; only abstract available; no further data
Reliability: 2 (reliable with restrictions)
Source: BASF AG Ludwigshafen
Test substance: formaldehyde; no data on purity of the compound

(267)

Type: other: in vitro DNA damage – eukaryotes (mammalian cells/DNA strand breaks)
System of testing: human cells: bronchial epithelial cells
Concentration: 100 uM (ca. 3 mg/l)
Metabolic activation: without
Result: positive
Method: other: alkaline elution assay (DNA strand break)
Year: **GLP:** no data
Test substance: no data
Remark: induction of single strand breaks (SSB); according to the authors, formaldehyde caused 7-fold higher levels of DNA-Protein Crosslinks (DPC) than SSB.
Reliability: 2 (reliable with restrictions)
Source: BASF AG Ludwigshafen
Test substance: formaldehyde; no data on purity of the compound

(268)

Type: other: in vitro DNA damage – eukaryotes (mammalian cells/DNA strand breaks)
System of testing: human cells: bronchial epithelial cells, bronchial fibroblasts
Concentration: 0.8 mM (ca. 24 mg/l)
Metabolic activation: without
Result: negative
Method: other: alkaline elution assay (DNA strand break)
Year: **GLP:** no data
Test substance: no data
Remark: no increase in single strand breaks (SSB); according to the authors, a significant accumulation of SSB was observed after treatment with formaldehyde combined with polymerase inhibitors
Reliability: 2 (reliable with restrictions)
Source: BASF AG Ludwigshafen
Test substance: formaldehyde; no data on purity of the compound

(269)

Type: other: in vitro DNA damage – eukaryotes (mammalian cells/DNA strand breaks)
System of testing: human cells: bronchial epithelial cells, bronchial fibroblasts
Concentration: up to 500 uM (ca. 15 mg/l)
Metabolic activation: without
Result: positive
Method: other: alkaline elution assay (DNA strand break)
Year: **GLP:** no data
Test substance: no data
Remark: dose-dependent increase in single strand breaks (SSB) in both cell types; according to the authors, formaldehyde inhibited DNA-repair (resealing of SSB and inhibition of UDS)
Reliability: 2 (reliable with restrictions)

Source: BASF AG Ludwigshafen
Test substance: formaldehyde; no data on purity of the compound
(270)

Type: other: in vitro DNA damage – eukaryotes (mammalian cells/DNA strand breaks)
System of testing: human cells: bronchial epithelial cells
Concentration: 0.1 mM (ca. 3000 mg/l)
Metabolic activation: without
Result: positive
Method: other: alkaline elution assay (DNA strand break)
Year: **GLP:** no data
Test substance: no data
Remark: Reliability: 2 (reliable with restrictions)
slight increase in single strand breaks (SSB); according to the authors, formaldehyde caused several-fold higher levels of DNA-Protein Crosslinks (DPC); the effect occurred at moderate levels of cytotoxicity.
Source: BASF AG Ludwigshafen
Test substance: formaldehyde; no data on purity of the compound
(271)

Type: other: in vitro DNA damage – eukaryotes (mammalian cells/DNA strand breaks)
System of testing: human cells: bronchial epithelial cells
Concentration: 0.4 mM (ca. 12 mg/l)
Metabolic activation: without
Result: positive
Method: other: alkaline elution assay (DNA strand break)
Year: **GLP:** no data
Test substance: no data
Remark: Reliability: 2 (reliable with restrictions)
slight increase in single strand breaks (SSB); according to the authors, formaldehyde dose that inhibited Colony-Forming Efficiency (CFE) to 50% was used.
Source: BASF AG Ludwigshafen
Test substance: formaldehyde; no data on purity of the compound
(272)

Type: other: in vitro DNA damage – eukaryotes (mammalian cells/DNA strand breaks)
System of testing: B6C3F1 mouse hepatocytes
Concentration: 0.25, 0.5 mM (ca. 7.5, 15 mg/l)
Metabolic activation: without
Result: positive
Method: other: alkaline elution assay (DNA strand break)
Year: **GLP:** no data
Test substance: no data
Remark: Reliability: 2 (reliable with restrictions)
significant and dose-related increase in single strand breaks (SSB) at doses >= 0.25 mM

Source: BASF AG Ludwigshafen
Test substance: formaldehyde; no data on purity of the compound (273) (274)

Type: other: in vitro DNA damage – eukaryotes (mammalian cells/DNA strand breaks)
System of testing: AP rat hepatocytes
Concentration: 1 – 5 mM (ca. 30 – 150 mg/l)
Metabolic activation: without
Result: positive
Method: other: alkaline elution assay (DNA strand break)
Year: **GLP:** no data
Test substance: no data
Remark: Reliability: 2 (reliable with restrictions) significant and dose-related increase in single strand breaks (SSB) at doses >= 1 mM
Source: BASF AG Ludwigshafen
Test substance: formaldehyde; no data on purity of the compound (273) (274)

Type: other: in vitro DNA damage – eukaryotes (mammalian cells/DNA strand breaks)
System of testing: CHO cells
Concentration: 0.125 – 0.5 mM (ca. 3.75 – 15 mg/l) (-S-9); 2.0 – 4.0 mM (ca. 60 – 120 mg/l) (+S-9)
Metabolic activation: with and without
Result: positive
Method: other: alkaline elution assay (DNA strand break)
Year: **GLP:** no data
Test substance: no data
Remark: Reliability: 2 (reliable with restrictions) significant and dose-related increase in single strand breaks (SSB) with and without mouse liver S-9; in the presence of S-9, higher concentrations of the test substance were needed to induce DNA damage
Source: BASF AG Ludwigshafen
Test substance: formaldehyde; no data on purity of the compound (273) (274)

Type: other: in vitro DNA damage – eukaryotes (mammalian cells/DNA strand breaks)
System of testing: F344 rat hepatocytes
Concentration: 0.5 – 4.0 mM (ca. 15 – 120 mg/l)
Metabolic activation: without
Result: positive
Method: other: alkaline elution assay (DNA strand break)
Year: **GLP:** no data
Test substance: no data
Remark: dose-related induction of single strand breaks (SSB) at doses of 0.75-1.5 mM (ca. 22.5-45 mg/l); no induction of double strand breaks (DSB) was observed up to 4.0 mM; 2 mM

formaldehyde decreased intracellular glutathione content (60% of control)
Reliability: 2 (reliable with restrictions)
Source: BASF AG Ludwigshafen
Test substance: formaldehyde; no data on purity of the compound
(275)

Type: other: in vitro DNA damage – eukaryotes (mammalian cells/DNA strand breaks)
System of testing: human cells: skin fibroblasts, bronchial fibroblasts, bronchial epithelial cells, XP skin fibroblasts
Concentration: 0.1 – 1.0 mM (ca. 3 – 30 mg/l)
Metabolic activation: without
Result: positive
Method: other: alkaline elution assay (DNA strand break)
Year: **GLP:** no data
Test substance: no data
Remark: dose-related increase in single strand breaks (SSB) in all cell types; formaldehyde caused more SSB in normal cell types than in the xeroderma pigmentosum (XP) cells; formaldehyde was only moderately toxic to normal cells at DNA damaging concentrations.
Reliability: 2 (reliable with restrictions)
Source: BASF AG Ludwigshafen
Test substance: formaldehyde; no data on purity of the compound
(276)

Type: other: in vitro DNA damage – eukaryotes (mammalian cells/DNA strand breaks)
System of testing: human fibroblasts N1, N2, XP1, XP2
Concentration: 0.8 mM (ca. 24 mg/l)
Metabolic activation: without
Result: negative
Method: other: alkaline elution assay (DNA strand break)
Year: **GLP:** no data
Test substance: no data
Remark: no appreciable level of single strand breaks (SSB); in the presence of a polymerase inhibitor, a signifcant level of SSB accumulated in normal cells (N1, N2) but not in excision-deficient xeroderma pigmentosum cells was found.
Reliability: 2 (reliable with restrictions)
Source: BASF AG Ludwigshafen
Test substance: formaldehyde; no data on purity of the compound
(277)

Type: other: in vitro DNA damage – eukaryotes (mammalian cells/DNA strand breaks)
System of testing: Sprague-Dawley rat hepatocytes; SV-40 transformed Chinese hamster embryo cells CO631, CO60
Concentration: 0.002- 0.016 umoles (ca. 6x10E-6 – 4.8x10E-4 mg)
Metabolic activation: with and without
Result: positive
Method: other: alkaline elution assay (DNA strand break)
Year: **GLP:** no data
Test substance: no data
Remark: Reliability: 2 (reliable with restrictions)
The hepatocytes were testes without metabolic activation; the CHO cells were testes with and without metabolic activation. The test substance was a weak inducer of single strand breaks (SSB) in hepatocytes and in CO631 cells. DNA amplification (SDA) was not detected in CHO cells (C0631 and CO60).
Source: BASF AG Ludwigshafen
Test substance: formaldehyde; no data on purity of the compound

(278)

Type: other: in vitro DNA damage – eukaryotes (mammalian cells/DNA strand breaks)
System of testing: F344 rat tracheal epithel cells
Concentration: 100 – 400 uM (ca. 3 – 12 mg/l)
Metabolic activation: without
Result: positive
Method: other: alkaline elution assay (DNA strand breaks)
Year: **GLP:** no data
Test substance: no data
Remark: dose-related increase in single strand breaks (SSB) up to 400 uM; SSB were repaired within 2 h; rapid and complete removal of SSB within 2 h
Reliability: 2 (reliable with restrictions)
Source: BASF AG Ludwigshafen
Test substance: formaldehyde; no data on purity of the compound

(279)

Type: other: in vitro DNA damage – eukaryotes (mammalian cells/DNA strand breaks)
System of testing: human fibroblasts
Concentration: 100 – 500 uM (ca. 3 – 15 mg/l)
Metabolic activation: without
Result: negative
Method: other: alkaline sucrose sedimentation assay (DNA strand breaks)
Year: **GLP:** no data
Test substance: no data
Remark: no DNA strand breaks up to 250 uM (ca. 7.5 mg/l); doses >=250 uM caused sedimentation anomalies
Reliability: 2 (reliable with restrictions)

Source: BASF AG Ludwigshafen
Test substance: formaldehyde; no data on purity of the compound
(260)

Type: other: in vitro DNA damage – eukaryotes (mammalian cells/DNA strand breaks)
System of testing: mouse lymphoma cells
Concentration: no data
Metabolic activation: without
Result: positive
Method: other: alkaline unwinding assay (DNA strand breaks)
Year: **GLP:** no data
Test substance: no data
Remark: Reliability: 2 (reliable with restrictions)
single strand breaks were observed; only abstract available;no further data
Source: BASF AG Ludwigshafen
Test substance: formaldehyde; no data on purity of the compound
(280)

Type: other: in vitro DNA damage – eukaryotes (mammalian cells/DNA strand breaks)
System of testing: mouse lymphoma cells
Concentration: 0.03 – 1.1 mmoles/l (ca. 0.9 – 33 mg/l)
Metabolic activation: without
Result: negative
Method: other: alkaline unwinding assay (DNA strand breaks)
Year: **GLP:** no data
Test substance: no data
Remark: No induction of double and single strand breaks was observed; only abstract available; no further data
Source: BASF AG Ludwigshafen
Test substance: formaldehyde; no data on purity of the compound
Reliability: (2) valid with restrictions
(281)

Type: other: in vitro DNA damage – eukaryotes (mammalian cells/DNA–protein crosslinks)
System of testing: CHO cells
Concentration: 0.02 – 2.0 mM (ca. 0.6 – 60 mg/l)
Metabolic activation: without
Result: positive
Method: other: K–SDS precipitation assay (DNA–protein crosslinks)
Year: **GLP:** no data
Test substance: no data
Remark: dose–dependent formation of DNA–Protein Crosslinks (DPC); exposure to 0.02 mM resulted in a 10–fold increase of DPC
Reliability: 2 (reliable with restrictions)
Source: BASF AG Ludwigshafen
Test substance: formaldehyde; no data on purity of the compound
(282)

Type: other: in vitro DNA damage – eukaryotes (mammalian cells/DNA-protein crosslinks)
System of testing: F344 rat tracheal epithelial cells
Concentration: 0.05 – 0.4 mM (ca. 1.5 – 12 mg/l)
Metabolic activation: without
Result: positive
Method: other: alkaline elution assay (DNA-protein crosslinks)
Year: **GLP:** no data
Test substance: no data
Remark: dose-dependent formation of DNA-Protein Crosslinks (DPC) up to 0.4 mM; after 16 h, most of the DPC were eliminated
Reliability: 2 (reliable with restrictions)
Source: BASF AG Ludwigshafen
Test substance: formaldehyde; no data on purity of the compound

(279)

Type: other: in vitro DNA damage – eukaryotes (mammalian cells/DNA-protein crosslinks)
System of testing: rat tracheal epithelial cell line, C18
Concentration: 0.1 – 0.4 mM (ca. 3 – 12 mg/l)
Metabolic activation: without
Result: positive
Method: other: alkaline elution assay (DNA-protein crosslinks)
Year: **GLP:** no data
Test substance: no data
Remark: formation of DNA-Protein Crosslinks (DPC) linear up to 0.4 mM; treatment for 90 min reduced the Colony-Forming Efficiency (CFE) at 0.4 mM (25% of control)
Reliability: 2 (reliable with restrictions)
Source: BASF AG Ludwigshafen
Test substance: formaldehyde; no data on purity of the compound

(261)

Type: other: in vitro DNA damage – eukaryotes (mammalian cells/DNA-protein crosslinks)
System of testing: primary rat tracheal cells
Concentration: 0.2 mM (ca. 6 mg/l)
Metabolic activation: without
Result: positive
Method: other: alkaline elution assay (DNA-protein crosslinks)
Year: **GLP:** no data
Test substance: no data
Remark: formation of DNA-Protein Crosslinks (DPC); complete repair of DPC took 24 h; only abstract available, no further data
Source: BASF AG Ludwigshafen
Test substance: formaldehyde; no data on purity of the compound
Reliability: (2) valid with restrictions

(267)

Type: other: in vitro DNA damage – eukaryotes (mammalian cells/DNA–protein crosslinks)
System of testing: primary rat tracheal cells, rat tracheal epithelial cell line C18
Concentration: 200 uM (ca. 6 mg/l)
Metabolic activation: without
Result: positive
Method: other: alkaline elution assay (DNA–protein crosslinks)
Year: **GLP:** no data
Test substance: no data
Remark: Reliability: 2 (reliable with restrictions)
significant production of DNA–Protein Crosslinks (DPC) in both cell types; similar removal rates of DPC in both cell lines; only abstract available; no further data
Source: BASF AG Ludwigshafen
Test substance: formaldehyde; no data on purity of the compound

(266)

Type: other: in vitro DNA damage – eukaryotes (mammalian cells/DNA–protein crosslinks)
System of testing: human cells: bronchial epithelial cells
Concentration: 0.4 mM (ca. 12 mg/l)
Metabolic activation: without
Result: positive
Method: other: alkaline elution assay (DNA–protein crosslinks)
Year: **GLP:** no data
Test substance: no data
Remark: Reliability: 2 (reliable with restrictions)
significant production of DNA–Protein Croslinks (DPC); DPC were formed at ca. 10–fold higher amounts than single strand breaks (SSB) at doses that decreased Colony–Forming Efficiency (CFE) to 50%.
Source: BASF AG Ludwigshafen
Test substance: formaldehyde; no data on purity of the compound

(272)

Type: other: in vitro DNA damage – eukaryotes (mammalian cells/DNA–protein crosslinks)
System of testing: human cells: bronchial epithelial cells, bronchial fibroblasts
Concentration: 0.1 mM (ca. 3 mg/l)
Metabolic activation: without
Result: positive
Method: other: alkaline elution assay (DNA–protein crosslinks)
Year: **GLP:** no data
Test substance: no data
Remark: formation of DNA–Protein Crosslinks (DPC) to a similar extent in both cells types; the half–time of removal was ca. 2 h for both cell types
Reliability: 2 (reliable with restrictions)
Source: BASF AG Ludwigshafen
Test substance: formaldehyde; no data on purity of the compound

(270)

Type: other: in vitro DNA damage – eukaryotes (mammalian cells/DNA–protein crosslinks)
System of testing: human cells: skin fibroblasts, bronchial fibroblasts, bronchial epithelial cells, XP skin fibroblasts
Concentration: 0.2 – 0.8 mM (ca. 6 – 24 mg/l)
Metabolic activation: without
Result: positive
Method: other: alkaline elution assay (DNA–protein crosslinks)
Year: **GLP:** no data
Test substance: no data
Remark: Reliability: 2 (reliable with restrictions)
test substance–related formation of DNA–Protein Crosslinks (DPC) at similar levels in all cell types; the half–life of DPC was ca. 2–3 h in all cell types
Source: BASF AG Ludwigshafen
Test substance: formaldehyde; no data on purity of the compound

(276)

Type: other: in vitro DNA damage – eukaryotes (mammalian cells/DNA–protein crosslinks)
System of testing: human cells: bronchial epithelial cells
Concentration: 0.1 m uM (ca. 3 mg/l)
Metabolic activation: without
Result: positive
Method: other: alkaline elution assay (DNA–protein crosslinks)
Year: **GLP:** no data
Test substance: no data
Remark: Reliability: 2 (reliable with restrictions)
significant production of DNA–Protein Crosslinks (DPC); the effect occurred at moderate levels of cytotoxicity.
Source: BASF AG Ludwigshafen
Test substance: formaldehyde; no data on purity of the compound

(271)

Type: other: in vitro DNA damage – eukaryotes (mammalian cells/DNA–protein crosslinks)
System of testing: CHO cells
Concentration: 0.125 – 0.5 mM (ca. 3.75 – 15 mg/l) (–S–9); 2.0 – 4.0 mM (ca. 60 – 120 mg/l) (+S–9)
Metabolic activation: with and without
Result: positive
Method: other: alkaline elution assay (DNA–protein crosslinks)
Year: **GLP:** no data
Test substance: no data
Remark: dose–dependent formation of DNA–Protein Crosslinks (DPC) with and without mouse liver S–9; in the presence of S–9, higher concentrations of the test substance were needed to induce DNA damage
Reliability: 2 (reliable with restrictions)

Source: BASF AG Ludwigshafen
Test substance: formaldehyde; no data on purity of the compound (273) (274)

Type: other: in vitro DNA damage – eukaryotes (mammalian cells/DNA-protein crosslinks)
System of testing: human cells: bronchial epithelial cells
Concentration: 100 mM (ca. 3000 mg/l)
Metabolic activation: without
Result: positive
Method: other: alkaline elution assay (DNA-protein crosslinks)
Year: **GLP:** no data
Test substance: no data
Remark: Reliability: 2 (reliable with restrictions)
significant production of DNA-Protein Crosslinks (DPC) (ca. 7-fold higher than single strand break level)
Source: BASF AG Ludwigshafen
Test substance: formaldehyde; no data on purity of the compound (268)

Type: other: in vitro DNA damage – eukaryotes (mammalian cells/DNA-protein crosslinks)
System of testing: Yoshida lymphosarcoma cells
Concentration: 250 uM (ca. 7.5 mg/l)
Metabolic activation: without
Result: positive
Method: other: alkaline elution assay (DNA-protein crosslinks)
Year: **GLP:** no data
Test substance: no data
Remark: production of DNA-Protein Crosslinks; the concentration caused 50% inhibition of cell growth
Reliability: 2 (reliable with restrictions)
Source: BASF AG Ludwigshafen
Test substance: formaldehyde; no data on purity of the compound (265)

Type: other: in vitro DNA damage – eukaryotes (mammalian cells/DNA-protein crosslinks)
System of testing: mouse leukemia L1210 cells
Concentration: 0.01 – 0.3 mM (ca. 0.3 – 9 mg/l)
Metabolic activation: without
Result: positive
Method: other: alkaline elution assay (DNA-protein crosslinks)
Year: **GLP:** no data
Test substance: no data
Remark: Reliability: 2 (reliable with restrictions)
significant production of DNA-Protein Crosslinks (DPC); DPC formation occurred at relatively nontoxic doses (i.e. <0.2 mM); DPC were repaired after removal of the test substance
Source: BASF AG Ludwigshafen
Test substance: formaldehyde; no data on purity of the compound

(262)

Type: other: in vitro DNA damage – eukaryotes (mammalian cells/DNA–protein crosslinks)
System of testing: human bronchial epithelial cells
Concentration: 0.1 mM (ca. 3 mg/l)
Metabolic activation: without
Result: positive
Method: other: alkaline elution assay (DNA–protein crosslinks)
Year: **GLP:** no data
Test substance: no data
Remark: Reliability: 2 (reliable with restrictions)
significant production of DNA–Protein cross links (DPC); reduction of cell growth rate to 50% at 0.21 mM (6.3 mg/l)
Source: BASF AG Ludwigshafen
Test substance: formaldehyde; no data on purity of the compound

(263)

Type: other: in vitro DNA damage – eukaryotes (mammalian cells/DNA–protein crosslinks)
System of testing: F344 rat nasal epithelial cells (nasal– and maxillar turbinates)
Concentration: up to 1.0 mM (ca. 30 mg/l)
Metabolic activation: without
Result: positive
Method: other: alkaline elution assay (DNA–protein crosslinks)
Year: **GLP:** no data
Test substance: no data
Remark: DNA–Protein cross links (DPC) were found at 0.5 and 1.0 mM; only abstract available, no further data
Source: BASF AG Ludwigshafen
Test substance: formaldehyde; no data on purity of the compound
Reliability: (2) valid with restrictions

(283)

Type: other: in vitro DNA damage – eukaryotes (mammalian cells/DNA–protein crosslinks)
System of testing: human cells: bronchial epithelial cells, bronchial fibroblasts
Concentration: 0.8 mM (ca. 24 mg/l)
Metabolic activation: without
Result: positive
Method: other: alkaline elution assay (DNA–protein crosslinks)
Year: **GLP:** no data
Test substance: no data
Remark: formation of DNA–Protein Crosslinks (DPC); DPC were rapidly removed in both cell types
Reliability: 2 (reliable with restrictions)
Source: BASF AG Ludwigshafen
Test substance: formaldehyde; no data on purity of the compound

(277)

Type: other: in vitro DNA damage – eukaryotes (mammalian cells/DNA–protein crosslinks)
System of testing: human lymphocytes
Concentration: 0.015 – 0.6 mM (ca. 0.45 – 18 mg/l)
Metabolic activation: without
Result: positive
Method: other: alkaline elution assay (DNA–protein crosslinks)
Year: **GLP:** no data
Test substance: no data
Remark: dose–related production of DNA–Protein Crosslinks (DPC) at 0.05–0.6 mM; rapid removal of DPC; only abstract available; no further data.
Source: BASF AG Ludwigshafen
Test substance: formaldehyde; no data on purity of the compound
Reliability: (2) valid with restrictions

(284)

Type: other: in vitro DNA damage – eukaryotes (mammalian cells/DNA–protein crosslinks)
System of testing: human lymphoblasts
Concentration: up to 0.6 mM (ca. 18 mg/l)
Metabolic activation: without
Result: positive
Method: other: alkaline elution assay (DNA–protein crosslinks)
Year: **GLP:** no data
Test substance: no data
Remark: Reliability: 2 (reliable with restrictions)
significant nonlinear increase in DNA–Protein Crosslinks (DPC) at 0.05–0.6 mM for 2 h; holding the culture for 24 h resulted in complete removal of DPC
Source: BASF AG Ludwigshafen
Test substance: formaldehyde; no data on purity of the compound

(285)

Type: other: in vitro DNA damage – eukaryotes (mammalian cells/DNA–protein crosslinks)
System of testing: Yoshida sarcoma cells
Concentration: 0.25 mM (ca. 7.5 mg/l)
Metabolic activation: without
Result: positive
Method: other: alkaline elution assay (DNA–protein crosslinks)
Year: **GLP:** no data
Test substance: no data
Remark: formation of DNA–Protein Crosslinks (DPC); removal of the DPC revealed the presence of a small amount of single strand breaks
Reliability: 2 (reliable with restrictions)
Source: BASF AG Ludwigshafen
Test substance: formaldehyde; no data on purity of the compound

(286)

Type: other: in vitro DNA damage – eukaryotes (mammalian cells/DNA–protein crosslinks)
System of testing: CHO cells
Concentration: up to 13 mM (ca. 39 mg/l)
Metabolic activation: without
Result: positive
Method: other: two–dimensional gel electrophoresis, immunoblotting (DNA–protein crosslinks)
Year: **GLP:** no data
Test substance: no data
Remark: formation of DNA–Protein Crosslinks (DPC); exposure to 1.45 mM for 90 min. resulted in a 50% reduction in colonies; at 3 mM, histone DNA crosslinks were observed.
Reliability: 2 (reliable with restrictions)
Source: BASF AG Ludwigshafen
Test substance: formaldehyde; no data on purity of the compound
(287) (288) (289)

Type: other: in vitro DNA damage – eukaryotes (mammalian cells/SCE)
System of testing: V79 cells
Concentration: 0.033 – 0.54 mM (ca. 1 – 16.2 mg/l)
Metabolic activation: with and without
Result: positive
Method: other: Sister chromatid exchange assay
Year: **GLP:** no data
Test substance: no data
Remark: A dose– and exposure–dependent (1, 2, 3, or 28 h) frequency with a 3– to 4–fold increase was found at non–toxic doses without S–9 mix; S–9 mix (prepared from liver homogenate of Aroclor pretreated Wistar rats) as well as primary hepatocytes (prepared from Aroclor pretreated Wistar rats) reduced the SCE frequency to nearly control value. According to the authors, the decrease in genotoxicity was due to a rapid metabolism and not to an unspecific binding to the macromolecules of the S–9 mix or hepatocytes; toxicity was reduced after adding a metabolizing system.
Reliability: 2 (reliable with restrictions)
Source: BASF AG Ludwigshafen
Test substance: formaldehyde; no data on purity of the compound
(290) (291)

Type: other: in vitro DNA damage – eukaryotes (mammalian cells/SCE)
System of testing: CHO cells
Concentration: 1 – 4 mg/l (–S–9), 0.5 – 3 mg/l (+S–9)
Metabolic activation: with and without
Result: positive
Method: other: Sister chromatid exchange assay
Year: **GLP:** no data
Test substance: no data
Remark: Induction of SCE both with and without S–9 mix prepared fromliver homogenate of Aroclor pretreated Wistar rats, but without any dose–related effect; S–9 activation lowered the minimum effective concentration for SCE induction. Reliability: 2 (reliable with restrictions)
Source: BASF AG Ludwigshafen
Test substance: formaldehyde; no data on purity of the compound

(292)

Type: other: in vitro DNA damage – eukaryotes (mammalian cells/SCE)
System of testing: CHO cells
Concentration: no data
Metabolic activation: with and without
Result: positive
Method: other: Sister chromatid exchange assay
Year: **GLP:** no data
Test substance: no data
Remark: dose–related increase with and without S–9 mix; only abstract available, no further data
Source: BASF AG Ludwigshafen
Test substance: formaldehyde; no data on purity of the compound
Reliability: (3) invalid

(293)

Type: other: in vitro DNA damage – eukaryotes (mammalian cells/SCE)
System of testing: CHO cells
Concentration: (a) 0.5–5.0 mg/l (–S–9); (b) 1.6–16 mg/l (+S–9); (c) 0.37–3.7 mg/l (–S–9); (d) 6.0–11.0 mg/l (–S–9); (e) 0.37–3.7 (+S–9); (f) 6.0–11.0 mg/l (+S–9)
Metabolic activation: with and without
Result: positive
Method: other: Sister chromatid exchange assay
Year: **GLP:** no data
Test substance: no data
Remark: (a): negative result
(b), (e): positive result at only 1 dose
(c), (d), (f): positive result
S–9 prepared from liver homogenate of Aroclor pretreated Wistar rats
The tests were performed by 2 different laboratories (lab. 1: protocols (a) and (b), Lab. 2: protocols (c) – (f)).
Reliability: 2 (reliable with restrictions)
Source: BASF AG Ludwigshafen

Test substance: formaldehyde; no data on purity of the compound

(294)

Type: other: in vitro DNA damage – eukaryotes (mammalian cells/SCE)
System of testing: human lymphocytes
Concentration: 0.05 – 100 mg/l
Metabolic activation: without
Result: positive
Method: other: Sister chromatid exchange assay
Year: **GLP:** no data
Test substance: no data
Remark: elevated SCE/cell at a dose range of 1 – 10 mg/l; cytotoxicity (30% decrease in viability) at already 0.05 mg/l (Abstract, no further details)
Reliability: 2 (reliable with restrictions)
Source: BASF AG Ludwigshafen
Test substance: formaldehyde; no data on purity of the compound

(295)

Type: other: in vitro DNA damage – eukaryotes (mammalian cells/SCE)
System of testing: human lymphocytes
Concentration: 0.1 – 15 mg/l
Metabolic activation: no data
Result: positive
Method: other: Sister chromatid exchange assay
Year: **GLP:** no data
Test substance: no data
Remark: Increase in the number of SCE with a statistical significance at doses >= 10 mg/l; Polish publication with English abstract.
Reliability: 2 (reliable with restrictions)
Source: BASF AG Ludwigshafen
Test substance: formaldehyde; no data on purity of the compound

(296)

Type: other: in vitro DNA damage – eukaryotes (mammalian cells/SCE)
System of testing: human lymphocytes
Concentration: 0.01 – 100 mg/l
Metabolic activation: without
Result: positive
Method: other: Sister chromatid exchange assay
Year: **GLP:** no data
Test substance: no data
Remark: low SCE induction rate at doses > 5 mg/l; cytotoxicity at all doses; significant SCE induction only at 80% nonviable cells
Reliability: 2 (reliable with restrictions)
Source: BASF AG Ludwigshafen
Test substance: formaldehyde; no data on purity of the compound

(297)

Type: other: in vitro DNA damage – eukaryotes (mammalian cells/SCE)
System of testing: CHO cells
Concentration: 0.003 – 0.024 ul/ml
Metabolic activation: with and without
Result: positive
Method: other: Sister chromatid exchange assay
Year: **GLP:** no data
Test substance: no data
Remark: dose–related increase in the SCE frequency with and without S–9 mix; slight reduction of SCE frequencies with S–9
Reliability: 2 (reliable with restrictions)
Source: BASF AG Ludwigshafen
Test substance: formaldehyde; no data on purity of the compound
(298)

Type: other: in vitro DNA damage – eukaryotes (mammalian cells/SCE)
System of testing: CHO cells
Concentration: 0.0001 – 0.0004 %
Metabolic activation: without
Result: positive
Method: other: Sister chromatid exchange assay
Year: **GLP:** no data
Test substance: no data
Remark: Reliability: 2 (reliable with restrictions)
Slight, but dose–dependent increase in the SCE frequency; increase ca. 2–fold over background
Source: BASF AG Ludwigshafen
Test substance: formaldehyde; no data on purity of the compound
(299)

Type: other: in vitro DNA damage – eukaryotes (mammalian cells/SCE)
System of testing: human lymphocytes
Concentration: 0.0001 – 0.001 %
Metabolic activation: without
Result: positive
Method: other: Sister chromatid exchange assay
Year: **GLP:** no data
Test substance: no data
Remark: Reliability: 2 (reliable with restrictions)
Slight, but dose–dependent increase in the SCE frequency; increase ca. 4–fold over background
Source: BASF AG Ludwigshafen
Test substance: formaldehyde; no data on purity of the compound
(299)

Type: other: in vitro DNA damage – eukaryotes (mammalian cells/SCE)
System of testing: human lymphocytes
Concentration: 0.032 – 1.0 mM (ca. 1.0 – 30 mg/l)
Metabolic activation: with and without
Result: positive
Method: other: Sister chromatid exchange assay
Year: **GLP:** no data
Test substance: no data
Remark: Dose-related increase in SCE frequencies with and without S-9 mix prepared from liver homogenate of Clophen A50 induced Wistar rats at 0.125 – 0.25 (ca. 3.75 – 7.5 mg/l); at 0.5 mM (ca. 15 mg/l) with S-9 mix, SCE frequency was significantly reduced.
Reliability: 2 (reliable with restrictions)
Source: BASF AG Ludwigshafen
Test substance: formaldehyde; no data on purity of the compound

(300)

Type: other: in vitro DNA damage – eukaryotes (mammalian cells/SCE)
System of testing: V79 cells
Concentration: 0.5 – 20 mg/l
Metabolic activation: with and without
Result: positive
Method: other: Sister chromatid exchange assay
Year: **GLP:** no data
Test substance: no data
Remark:
- exposure for 4 h; dose-related increase at 0.5-5 mg/l without S-9 (prepared from liver homogenate of Aroclor pretreated Wistar rats) and at 2.5-15 mg/l with S-9; toxicity was observed at doses >= 7.5 mg/l (-S-9) or at 20 mg/l (+S-9).
- exposure for 2x4 h: dose-related increase at 0.5-5 mg/l (-S-9) and at 0.5-10 mg/l (+S-9); toxicity was observed at >=7.5 mg/l (-S-9) and at >=15 mg/l (+S-9).
- exposure for 3x4 h: dose-related increase at 0.5-2.5 mg/l (-S-9) and at 0.5-7.5 mg/l (+S-9); toxicity was observed at >=5 mg/l (-S-9) and at >=10 mg/l (+S-9).

Reliability: 2 (reliable with restrictions)
Source: BASF AG Ludwigshafen
Test substance: formaldehyde; no data on purity of the compound

(301)

Type: other: in vitro DNA damage – eukaryotes (mammalian cells/SCE)
System of testing: rat nasal epithelial cells
Concentration: 0.5 – 20 mg/l
Metabolic activation: with and without
Result: positive
Method: other: Sister chromatid exchange assay
Year: **GLP:** no data
Test substance: no data
Remark: – treatment for 4 h; dose-related increase in the SCE frequency at 5–15 mg/l without S-9 (prepared from liver homogenate of Aroclor pretreated Wistar rats); no differential stained cells at 20 mg/l; weakly positive reaction at 20 mg/l with S-9; significant reduction of MII cells at >= 10 mg/l (–S-9); toxicity was reduced after adding a metabolizing system.
– treatment for 2x4 h (with an interval of 24 h): dose-related increase at 5–10 mg/l (–S-9) and at 15–20 mg/l (+S-9).
– treatment for 3x4 h (with an interval of 24 h): dose-relatd increase at 1–10 mg/l (–S-9) and at 10–15 mg/l (+S-9).
Toxicity was observed at a dose >10 mg/l (–S-9) after 2 or 3 treatments and at 20 mg/l (+S-9) after 3 treatments.
Reliability: 2 (reliable with restrictions)
Source: BASF AG Ludwigshafen
Test substance: formaldehyde; no data on purity of the compound

(301)

Type: other: in vitro DNA damage – eukaryotes (mammalian cells/UDS)
System of testing: HeLa S3 cells
Concentration: 10E-6 – 10E-8 M (ca. 0.03 – 0.0003 mg/l)
Metabolic activation: without
Result: positive
Method: other: Unscheduled DNA synthesis
Year: **GLP:** no data
Test substance: no data
Remark: induction of UDS; 56 dpm/ug DNA above background
Reliability: 2 (reliable with restrictions)
Source: BASF AG Ludwigshafen
Test substance: formaldehyde; no data on purity of the compound

(302)

Type: other: in vitro DNA damage – eukaryotes (mammalian cells/UDS)
System of testing: CDF rat tracheal epithelial cells
Concentration: 1 – 1000 uM (ca. 0.03 – 30 mg/l)
Metabolic activation: no data
Result: negative
Method: other: Unscheduled DNA synthesis
Year: **GLP:** no data
Test substance: no data
Remark: no induction of UDS; cytotoxicity at doses >100 uM
Reliability: 2 (reliable with restrictions)
Source: BASF AG Ludwigshafen
Test substance: formaldehyde; no data on purity of the compound

(303)

Type: other: in vitro DNA damage – eukaryotes (mammalian cells/UDS)
System of testing: human bronchial epithelial cells
Concentration: 1 – 100 uM (ca. 0.03 – 3 mg/l), 1 – 100 mM (ca. 30 – 3000 mg/l)
Metabolic activation: without
Result: negative
Method: other: Unscheduled DNA synthesis
Year: **GLP:** no data
Test substance: no data
Remark: no induction of UDS; DNA repair was assessed by quantitative autoradiography; cell lethality at 1–100 mM
Reliability: 2 (reliable with restrictions)
Source: BASF AG Ludwigshafen
Test substance: formaldehyde; no data on purity of the compound

(304)

Type: other: in vitro DNA damage – eukaryotes (mammalian cells/UDS)
System of testing: F–344 rat nasal epithelial cells (nasal– and maxillar turbinates)
Concentration: 0.05 – 1.0 mM (ca. 1.5 – 30 mg/l)
Metabolic activation: without
Result: positive
Method: other: Unscheduled DNA synthesis
Year: **GLP:** no data
Test substance: no data
Remark: Reliability: 2 (reliable with restrictions)
UDS (and scheduled DNA synthesis) was stimulated at 0.05–0.1 mM and inhibited at 0.1–1.0 mM; quantitative differences were observed in the response of nasal– and maxillar turbinates
Source: BASF AG Ludwigshafen
Test substance: formaldehyde; no data on purity of the compound

(283)

Type: other: in vitro DNA damage – eukaryotes (mammalian cells/UDS)
System of testing: human bronchial fibroblasts
Concentration: 100 – 1000 uM (ca. 3 – 30 mg/l)
Metabolic activation: without
Result: negative
Method: other: Unscheduled DNA synthesis
Year: **GLP:** no data
Test substance: no data
Remark: no significant increase in UDS; formaldehyde inhibited UDS by UV irradiation
Reliability: 2 (reliable with restrictions)
Source: BASF AG Ludwigshafen
Test substance: formaldehyde; no data on purity of the compound
(270)

Type: other: in vitro DNA damage – eukaryotes (mammalian cells/UDS)
System of testing: human fibroblasts
Concentration: 0.05 – 2 mM (ca. 1.5 – 60 mg/l)
Metabolic activation: without
Result: negative
Method: other: Unscheduled DNA synthesis
Year: **GLP:** no data
Test substance: no data
Remark: no induction of UDS; formaldehyde treatment caused alterations in deoxynuceloside uptake
Reliability: 2 (reliable with restrictions)
Source: BASF AG Ludwigshafen
Test substance: formaldehyde; no data on purity of the compound
(260)

Type: other: in vitro DNA damage – eukaryotes (mammalian cells/UDS)
System of testing: F–344 rat hepatocytes
Concentration: no data
Metabolic activation: no data
Result: positive
Method: other: Unscheduled DNA synthesis
Year: **GLP:** no data
Test substance: no data
Remark: dose–related increase in net grain counts at least at 2 concentrations; according to the authors, the lowest positive concentration used was 400 mM (12000 mg/l).
Reliability: 2 (reliable with restrictions)
Source: BASF AG Ludwigshafen
Test substance: formaldehyde; no data on purity of the compound
(305)

Type: other: in vitro DNA damage – lower eukaryotes (yeast, fungi)
System of testing: Saccharomyces cerevisia D61.M
Concentration: 50 – 137 nl/ml
Metabolic activation: without
Result: positive
Method: other: DNA damage
Year: **GLP:** no data
Test substance: no data
Remark: A dose-related induction of mitotic recombination was observed at doses of 75-100 nl/ml.
Reliability: 2 (reliable with restrictions)
Source: BASF AG Ludwigshafen
Test substance: formaldehyde; no data on purity of the compound

(306)

Type: other: in vitro DNA damage – lower eukaryotes (yeast, fungi)
System of testing: Saccharomyces cerevisia D3, D4
Concentration: 6 – 60 mM (ca. 180 – 1800 mg/l)
Metabolic activation: without
Result: positive
Method: other: DNA damage
Year: **GLP:** no
Test substance: no data
Remark: Induction of intergenic recombinants was observed with tester strain D3 at 60 mM. A dose-related increase in ADE+ and TRP+ intragenic recombinants was observed with tester strain D4 at >=20 mM (ca. 600 mg/l). A decrease in survival was found in both tester strains at concentrations >20 mM.
Reliability: 2 (reliable with restrictions)
Source: BASF AG Ludwigshafen
Test substance: formaldehyde; no data on purity of the compound

(307)

Type: other: in vitro DNA damage – lower eukaryotes (yeast, fungi)
System of testing: Saccharomyces cerevisia N123 (wild type)
Concentration: 8.2 – 66 mM
Metabolic activation: without
Result: positive
Method: other: DNA damage
Year: **GLP:** no data
Test substance: no data
Result: Dose-related increase in single-strand breaks (SSB) in DNA of exponential phase cells of the wild type strain. Strains defective in excision-repair showed a reduced capacity to undergo SSB after FA treatment.
Analysis was done by the alkaline sucrose gradients technique. It is discussed, that the appearance of SSB may be a step in a repair process of FA-induced lesions.
Source: BASF AG Ludwigshafen
Reliability: (2) valid with restrictions

(308)

Type: other: in vitro DNA damage – prokaryotes (bacteria)
System of testing: Escherichia coli K-12 uvrB+/recA+ (343/636), K-12 uvrB-/recA- (343/591)
Concentration: up to 456 mmoles/l (ca. 13680 mg/l)
Metabolic activation: without
Result: positive
Method: other: DNA damage and repair assay
Year: **GLP:** no data
Test substance: no data
Remark: Reliability: 2 (reliable with restrictions)
The viability of the DNA repair deficient strain was significantly reduced at a lower concentration (0.456 mmoles/l; ca. 13.7 mg/l) than that of the DNA repair proficient strain (1.52 mmoles/l; ca. 45.6 mg/l). At doses >= 4.56 mmoles/l (ca. 136.8 mg/l), no surviving colonies were found.
Source: BASF AG Ludwigshafen
Test substance: formaldehyde; no data on purity of the compound

(256)

Type: other: in vitro DNA damage – prokaryotes (bacteria)
System of testing: Escherichia coli WP2 (repair-proficient), WP67 (uvrA- polA-), CM871 (uvrA- recA- lexA-)
Concentration: 0.004 or 0.008 mg
Metabolic activation: with and without
Result: positive
Method: other: DNA damage and repair assay
Year: **GLP:** no data
Test substance: no data
Remark: Liquid micromethod procedure; reproducible induction of DNA damage in the presence and absence of S-9 mix prepared from liver homogenate of Aroclor pretreated rats was observed. According to the authors, the indicated doses were minimal inhibitory concentrations. No further data.
Reliability: 2 (reliable with restrictions)
Source: BASF AG Ludwigshafen
Test substance: formaldehyde; no data on purity of the compound

(309)

Type: other: in vitro DNA damage – prokaryotes (bacteria)
System of testing: Escherichia coli WP2 uvrA (repair-proficient), TM1080 (polA- lexA-)
Concentration: 10 ul
Metabolic activation: without
Result: positive
Method: other: DNA damage and repair assay
Year: **GLP:** no data
Test substance: no data
Remark: A dose-dependent increase in diameters in the repair-deficient tester strain was observed when compared to the repair-proficient tester strain. According to the

authors, the indicated doses were minimal inhibitory concentrations. No further data.
Reliability: 2 (reliable with restrictions)
Source: BASF AG Ludwigshafen
Test substance: formaldehyde; no data on purity of the compound
(309)

Type: other: in vitro DNA damage – prokaryotes (bacteria)
System of testing: Saccharomyces cerevisia N123 (wild type), rad1-3, rad3-e5
Concentration: 8.2 – 66 mM (ca. 246 – 1980 mg/l)
Metabolic activation: without
Result: positive
Method: other: DNA damage and repair assay
Year: **GLP:** no data
Test substance: no data
Remark: A dose-related increase in single strand breaks (SSB) in DNA of exponential phase cells of the wild type strain was observed. Strains defective in excision-repair showed a reduced capacity to undergo SSB after treatment. Analysis was performed by the use of the alkaline sucrose gradients technique. According to the authors, the appearance of SSB might be a step in a repair process of formaldehyde lesions.
Reliability: 2 (reliable with restrictions)
Source: BASF AG Ludwigshafen
Test substance: formaldehyde; no data on purity of the compound
(308)

Type: other: in vitro DNA damage – prokaryotes (bacteria)
System of testing: Escherichia coli GE94, KY943 (lexA), KY945 (recA), KY946 (uvrA)
Concentration: no data
Metabolic activation: without
Result: positive
Method: other: Rec-lac test
Year: **GLP:** no data
Test substance: no data
Remark: Reliability: 2 (reliable with restrictions)
The SOS-inducing activity was detectable in tester strains GE94 and KY946, but not in tester strains KY943 and KY945. Only abstract available; no further data.
Source: BASF AG Ludwigshafen
Test substance: formaldehyde; no data on purity of the compound
(310)

Type: other: in vitro DNA damage – prokaryotes (bacteria)
System of testing: Escherichia coli KY945 (recA), KY946 (uvrA)
Concentration: 1.7 – 16.5 mg/l
Metabolic activation: without
Result: positive
Method: other: Rec-lac test
Year: **GLP:** no data
Test substance: no data
Remark: Reliability: 2 (reliable with restrictions)
Tester strains KY946 and KY945 were positive (SOS inducible) and negative (SOS uninducible) indicator strains, respectively. A dose-dependent increase in beta-galactosidase activity was observed in tester strain KY946, but not in tester strain KY945.
Source: BASF AG Ludwigshafen
Test substance: formaldehyde; no data on purity of the compound

(311)

Type: other: in vitro DNA damage – prokaryotes (bacteria)
System of testing: Escherichia coli PQ37
Concentration: 1 – 30000 mg/l
Metabolic activation: without
Result: positive
Method: other: SOS chromotest
Year: **GLP:** no data
Test substance: no data
Remark: Genotoxicity at 15-50 ug/ml, toxicity at doses >=50 ug/ml
Reliability: 2 (reliable with restrictions)
Source: BASF AG Ludwigshafen
Test substance: formaldehyde; no data on purity of the compound

(312)

Type: other: in vitro DNA damage – prokaryotes (bacteria)
System of testing: Escherichia coli PQ37
Concentration: no data
Metabolic activation: no data
Result: negative
Method: other: SOS chromotest
Year: **GLP:** no data
Test substance: no data
Remark: no increase in beta-galactosidase activity was observed; only abstract available; no further data.
Source: BASF AG Ludwigshafen
Test substance: formaldehyde; no data on purity of the compound
Reliability: (3) invalid

(313)

Type: other: in vitro DNA damage – prokaryotes (bacteria)
System of testing: Salmonella typhimurium TA1535/pSK1002
Concentration: 19 mg/ml
Metabolic activation: without
Result: positive
Method: other: umu
Year: **GLP:** no data
Test substance: no data
Remark: Reliability: 2 (reliable with restrictions)
The induction of umu gene expression was defined on an increase in beta-galactosidase activity 2-fold over background level. According to the authors, the indicated concentration was the lowest one which induced umu gene expression.
Source: BASF AG Ludwigshafen
Test substance: formaldehyde; no data on purity of the compound

(314)

Type: other: in vitro DNA damage – prokaryotes (bacteria)
System of testing: Salmonella typhimurium TA1535/pSK1002
Concentration: no data
Metabolic activation: no data
Result: positive
Method: other: umu test
Year: **GLP:** no data
Test substance: no data
Remark: positive reaction, i.e. induction of beta-galactosidase; only abstract available; no further data.
Source: BASF AG Ludwigshafen
Test substance: formaldehyde; no data on purity of the compound
Reliability: (3) invalid

(315)

Type: other: in vitro DNA damage – prokaryotes (bacteria)
System of testing: Salmonella typhimurium TA1535/pSK1002
Concentration: 3 – 30 mg/l
Metabolic activation: without
Result: positive
Method: other: umu test
Year: **GLP:** no data
Test substance: no data
Remark: dose-dependent increase in beta-galactosidase activity (ca. 3-fold over background at 30 mg/l)
Reliability: 2 (reliable with restrictions)
Source: BASF AG Ludwigshafen
Test substance: formaldehyde; no data on purity of the compound

(316)

Type: other: in vitro chromosomal aberrations – eukaryotes (mammalian cells)
System of testing: CHO cells
Concentration: (a) 1.6–16 mg/l –S–9; (b) 1.6–50 mg/l +S–9; (c) 1.1–11 mg/l –S–9; (d) 1.1–11 mg/l + S–9; (e) 15–25 mg/ml + S–9
Metabolic activation: with and without
Result: positive
Method: other: Cytogenetic assay
Year: **GLP:** no data
Test substance: no data
Remark: positive response at protocols (a), (b), and (e); protocol (a) at only 1 dose level; negative response at protocols (c)and (d).
With S–9 mix (prepared from liver homogenate of Aroclor pretreated Sprague–Dawley rats), high level of damage at toxic doses with marked mitotic suppression was observed.
The tests were performed by 2 laboratories (lab. 1: protocols (a) and (b), lab. 2: protocols (c) – (e)).
Reliability: 2 (reliable with restrictions)
Source: BASF AG Ludwigshafen
Test substance: formaldehyde; no data on purity of the compound

(294)

Type: other: in vitro chromosomal aberrations – eukaryotes (mammalian cells)
System of testing: human fibroblasts
Concentration: 2 – 8 mM (ca. 60 – 240 mg/l)
Metabolic activation: without
Result: positive
Method: other: Cytogenetic assay
Year: **GLP:** no data
Test substance: no data
Remark: dose–related increase in the number of aberrations (chromatid– and chromosome–type) including and excluding gaps
Reliability: 2 (reliable with restrictions)
Source: BASF AG Ludwigshafen
Test substance: formaldehyde; no data on purity of the compound

(317)

Type: other: in vitro chromosomal aberrations – eukaryotes (mammalian cells)
System of testing: CHO cells
Concentration: no data
Metabolic activation: with and without
Result: negative
Method: other: Cytogenetic assay
Year: **GLP:** no data
Test substance: no data
Remark: only abstract available; no further data
Source: BASF AG Ludwigshafen

Test substance: formaldehyde; no data on purity of the compound
Reliability: (3) invalid

(293)

Type: other: in vitro chromosomal aberrations – eukaryotes (mammalian cells)
System of testing: CHO cells
Concentration: 0.003 – 0.024 ul/ml
Metabolic activation: with and without
Result: positive
Method: other: Cytogenetic assay
Year: **GLP:** no data
Test substance: no data
Remark: dose–related increase of all types of aberrations (gaps, breaks, exchanges); at all doses with and without S–9 mix; S–9 mix reduced the frequency of aberrations; all the aberrations were chromatid–type, indicating an S–phase–dependent agent; no data on toxicity. Reliability: 2 (reliable with restrictions)
Source: BASF AG Ludwigshafen
Test substance: formaldehyde; no data on purity of the compound

(298)

Type: other: in vitro chromosomal aberrations – eukaryotes (mammalian cells)
System of testing: human lymphocytes
Concentration: 0.125 – 0.5 mM (ca. 3.75 – 15 mg/l)
Metabolic activation: without
Result: negative
Method: other: Cytogenetic assay
Year: **GLP:** no data
Test substance: no data
Remark: Reliability: 2 (reliable with restrictions) Unstimulated human lymphocytes were used in the test. No increase in chromosomal changes was found in a conventional chromosome analysis in the first post–treatment metaphases. However, a dose–dependent clastogenic effect (ca. 4–5 fold) was observed using the premature chromosome condensation (PCC) technique, i.e. a high yield of fragments. No toxicity was observed.
Source: BASF AG Ludwigshafen
Test substance: formaldehyde; no data on purity of the compound

(318)

Type: other: in vitro chromosomal aberrations – eukaryotes (mammalian cells)
System of testing: human lymphocytes
Concentration: 0.032 – 1.0 mM (ca. 0.96 – 30 mg/l)
Metabolic activation: with and without
Result: positive
Method: other: Cytogenetic assay
Year: **GLP:** no data
Test substance: no data
Remark: dose–related increase in the number of chromatid–type aberrations (gaps, breaks, exchanges); at 0.25 and 0.5 mM (7.5 and 15 mg/l, respectively) with and without S–9 mix prepared from liver homogenate of Clophen A50 pretreated Wistar rats; addition of S–9 mix reduced the yields; cell proliferation was clearly reduced in the presence and absence of S–9 with increasing formaldehyde concentrations. Reliability: 2 (reliable with restrictions)
Source: BASF AG Ludwigshafen
Test substance: formaldehyde; no data on purity of the compound

(300)

Type: other: in vitro chromosomal aberrations – eukaryotes (mammalian cells)
System of testing: CHL cells
Concentration: no data
Metabolic activation: with and without
Result: positive
Method: other: Cytogenetic assay
Year: **GLP:** no data
Test substance: no data
Remark: Reliability: 2 (reliable with restrictions)
The test was performed in the presence and absence of S–9 mix prepared from liver homogenate of PCB (KC400) pretreated Wistar rats. Clastogenic effects were observed without S–9. D20 (concentration at which aberrations were detected in 20%of the metaphases) = 0.018 mg/l.
Source: BASF AG Ludwigshafen
Test substance: formaldehyde; no data on purity of the compound

(319)

Type: other: in vitro chromosomal aberrations – eukaryotes (mammalian cells)
System of testing: CHO cells, AS52 cells
Concentration: no data
Metabolic activation: no data
Result: positive
Method: other: Cytogenetic assay
Year: **GLP:** no data
Test substance: no data
Remark: Induction of chromosome aberrations was quite similar in the different cell lines and exhibits a similar threshold

and kinetics. Only abstract available; no further data.
Reliability: 2 (reliable with restrictions)

Source: BASF AG Ludwigshafen
Test substance: formaldehyde; no data on purity of the compound

(320)

Type: other: in vitro chromosomal aberrations – eukaryotes (mammalian cells)
System of testing: V79 cells
Concentration: 0.5 – 20 mg/l
Metabolic activation: with and without
Result: positive
Method: other: Cytogenetic assay
Year: **GLP:** no data
Test substance: no data
Remark: – Exposure for 4 h: dose-related increase in chromosomal aberrations at 7.5–20 mg/l without S–9 and at 10–20 mg/l with S–9; weaker clastogenic response with S–9 (prepared from liver homogenate of Aroclor pretreated Wistar rats); reduced mitotic index at doses >= 10 mg/l (–S–9) or at 20 mg/l (+S–9).
– Exposure for 2x4 h (with an interval of 24 h): dose-related increase on chromosomal aberrations at 7.5–20 mg/l with and without S–9.
– Exposure for 3x4 h (with an interval of 24 h): dose-related increase in chromosomal aberrations at 1.0–20 mg/l without S–9 and at 5–20 mg/l with S–9.
A dose-realted reduction in the number of mitoses was observed after multiple treatment. Weaker clastogenic and cytotoxic effects were found after the addition of S–9.
Reliability: 2 (reliable with restrictions)

Source: BASF AG Ludwigshafen
Test substance: formaldehyde; no data on purity of the compound

(301)

Type: other: in vitro chromosomal aberrations – eukaryotes (mammalian cells)
System of testing: rat nasal epithelial cells
Concentration: 0.5–20 mg/l
Metabolic activation: with and without
Result: positive
Method: other: Cytogenetic assay
Year: **GLP:** no data
Test substance: no data
Remark: – treatment for 4 h: chromosomal aberrations only at 20 mg/l without S–9; increase in the mitotic index up to 7.5 mg/l (–S–9) or at 10 mg/l (+S–9 prepared from liver homogenate of Aroclor pretreated Wistar rats), then decrease.
– treatment for 2x4 h (with an interval of 24 h):

dose-related
increase in chromosomal aberrations only at doses >= 10 mg/l
without S-9; increase in the mitotic index up to 5 mg/l (-S-9)
or up to 10 mg/l (+S-9), then decrease.
- treatment for 3x4 h (with an interval of 24 h):
dose-related increase in chromosomal aberrations only at doses >= 1.0 mg/l without S-9; increase in the mitotic index up to 7.5 mg/l (+-S-9), then decrease.
Reliability: 2 (reliable with restrictions)

Source: BASF AG Ludwigshafen
Test substance: formaldehyde; no data on purity of the compound

(301)

Type: other: in vitro chromosomal aberrations - eukaryotes (mammalian cells)
System of testing: human lymphocytes
Concentration: 10 - 5000 mg/l
Metabolic activation: no data
Result: positive
Method: other: Cytogenetic assay
Year: **GLP:** no data
Test substance: no data
Remark: induction of polyploidy and chromosome aberrations; Russian publication with English abstract
Source: BASF AG Ludwigshafen
Test substance: formaldehyde; no data on purity of the compound
Reliability: (2) valid with restrictions

(321)

Type: other: in vitro chromosomal aberrations - eukaryotes (mammalian cells)
System of testing: human lymphocytes
Concentration: 0.125 - 0.5 mM (ca. 3.75 - 15 mg/l)
Metabolic activation: no data
Result: positive
Method: other: Cytogenetic assay
Year: **GLP:** no data
Test substance: no data
Remark: dose-dependent increase in premature chromosome condensation (PCC) fragments in G0 lypmphocytes; only abstract available; no further data
Source: BASF AG Ludwigshafen
Test substance: formaldehyde; no data on purity of the compound
Reliability: (2) valid with restrictions

(318)

Type: other: in vitro chromosomal aberrations – eukaryotes (mammalian cells)
System of testing: CHO cells
Concentration: up to 4 mg/l (–S–9); up to 3 mg/l (+S–9)
Metabolic activation: with and without
Result: negative
Method: other: Cytogenetic assay
Year: **GLP:** no data
Test substance: no data
Remark: No chromosome aberrations both with and without S–9 mix prepared from liver homogenate of Aroclor pretreated Wistar rats. Higher doses were completely cytotoxic.
Reliability: 2 (reliable with restrictions)
Source: BASF AG Ludwigshafen
Test substance: formaldehyde; no data on purity of the compound
(292)

Type: other: in vitro chromosomal aberrations – eukaryotes (mammalian cells)
System of testing: CHL cells
Concentration: 15 mg/l
Metabolic activation: no data
Result: positive
Method: other: Cytogenetic assay
Year: **GLP:** no data
Test substance: no data
Remark: Increase in chromosome aberrations after 48–h treatment; no further data.
Reliability: 2 (reliable with restrictions)
Source: BASF AG Ludwigshafen
Test substance: formaldehyde; no data on purity of the compound
(322)

Type: other: in vitro chromosomal aberrations – eukaryotes (mammalian cells)
System of testing: CHL cells
Concentration: 7.5 – 30 mg/l
Metabolic activation: without
Result: positive
Method: other: Cytogenetic assay
Year: **GLP:** no data
Test substance: no data
Remark: Increase in chromosome aberrations after treatment for 24 and 48 h; no further data.
Reliability: 2 (reliable with restrictions)
Source: BASF AG Ludwigshafen
Test substance: formaldehyde; no data on purity of the compound
(323)

Type: other: in vitro chromosomal aberrations – eukaryotes (mammalian cells)
System of testing: V79 cells
Concentration: (a) 5–15 mg/l, 6 h; (b) 0.1–2.5 mg/l, 3x2 h within 1 day
Metabolic activation: without
Result: positive
Method: other: Micronucleus test
Year: **GLP:** no data
Test substance: no data
Remark: After treatment of the cells for 6 h, a clear increase in micronucleated cells was found at 7–10 mg/l; a slight decrease in cell numbers was observed at doses >= 10 mg/l (protocol (a)).
After treatment for 3x2 h, a clear increase in micronucleated cells was observed at 0.1–1.0 mg/l; a slight decrease in cell numbers was found at >= 1.0 mg/l (protocol (b)).
Reliability: 2 (reliable with restrictions)
Source: BASF AG Ludwigshafen
Test substance: formaldehyde; no data on purity of the compound

(301)

Type: other: in vitro chromosomal aberrations – eukaryotes (mammalian cells)
System of testing: rat nasal epithelial cells
Concentration: (a) 0.5–15 mg/l for 6 h; (b) 0.1–2.5 mg/l, 3x2 h within 1 day
Metabolic activation: without
Result: positive
Method: other: Micronucleus test
Year: **GLP:** no data
Test substance: no data
Remark: A clear increase in micronuclei was observed at doses >10 and >=1.0 mg/l (protocol (a) and (b), respectively).
Reliability: 2 (reliable with restrictions)
Source: BASF AG Ludwigshafen
Test substance: formaldehyde; no data on purity of the compound

(301)

Type: other: in vitro chromosomal aberrations – eukaryotes (mammalian cells)
System of testing: rat nasal epithelial cells
Concentration: no data
Metabolic activation: no data
Result: positive
Method: other: Micronucleus test
Year: **GLP:** no data
Test substance: no data
Remark: significant increase in micronuclei formation; Japanese publication with English abstract
Source: BASF AG Ludwigshafen
Test substance: formaldehyde; no data on purity of the compound

Reliability: (3) invalid

(324)

Type: other: in vitro chromosomal aberrations – eukaryotes (non–mammalian cells)
System of testing: Chortophaga viridifasciata (Grasshopper) neuroblast cells
Concentration: 10E–8 M (0.0003 ppm) – 10E–3 M (30 ppm)
Metabolic activation: without
Result: positive
Method: other: Cytogenetic assay
Year: **GLP:** no data
Test substance: no data
Remark: Embryos were exposed in vitro. Scoring was carried out at the late anaphase and very early telophase of the neuroblast cells. An increase in fragment and chromosome stickiness was observed. Low frequency of distinct acentric chromosome fragments was found at 7.5x10E–4 or 10E–3 M, but not at lower concentrations. No obvious dose–response was observed. The increase in the number of cells with sticky chromosomes was linear for cells with slight and moderate stickiness but not for those with severe stickiness. Reliability: 2 (reliable with restrictions)
Source: BASF AG Ludwigshafen
Test substance: formaldehyde; no data on purity of the compound

(325) (326)

Type: other: in vitro chromosomal aberrations – eukaryotes (plants)
System of testing: Allium cepa root tips
Concentration: 33 – 1000 uM (ca. 1 – 30 mg/l)
Metabolic activation: without
Result: negative
Method: other: Anaphase–telophase test aberrations – eukaryotes (plants)
Year: **GLP:** no data
Test substance: as prescribed by 1.1 – 1.4
Remark: No increase in the frequency of chromosome aberrations was obtained with formaldehyd of analytical grade. However, application of a technical batch gave positive response. Reliability: 2 (reliable with restrictions)
Source: BASF AG Ludwigshafen
Test substance: formaldehyde; analytical grade

(327)

Type: other: in vitro chromosomal aberrations – eukaryotes (plants)
System of testing: Crepis capillaris
Concentration: 0.05, 0.1% (ca. 0.5, 1.0 mg/ml)
Metabolic activation: without
Result: positive
Method: other: Metaphase test, Anaphase-telophase test
Year: **GLP:** no data
Test substance: as prescribed by 1.1 – 1.4
Remark: Increase in chromosomal lesions, greater sensitivity of metaphase scoring on seedlings of Crepis capillaris seeds. Reliability: 2 (reliable with restrictions)
Source: BASF AG Ludwigshafen
Test substance: formaldehyde; no data on purity of the compound

(328)

Type: other: in vitro chromosomal aberrations – eukaryotes (plants)
System of testing: Allium cepa root tips
Concentration: no data
Metabolic activation: without
Result: positive
Method: other: Micronucleus test
Year: **GLP:** no data
Test substance: as prescribed by 1.1 – 1.4
Remark: F1 generation of the treated cells were examined. Only abstract available; no further data.
Source: BASF AG Ludwigshafen
Test substance: formaldehyde; no data on purity of the compound
Reliability: (3) invalid

(329)

Type: other: in vitro chromosomal aberrations – eukaryotes (plants)
System of testing: Tradescantia
Concentration: 38 ppm/min (ca. 0.05 mg/l/min)
Metabolic activation: without
Result: positive
Method: other: Micronucleus test
Year: **GLP:** no data
Test substance: as prescribed by 1.1 – 1.4
Remark: Treatment of meiotic pollen mother cells with formaldehyde vapour; dose-related increase of micronucleus frequencies ranging from 8.2 (3-h treatment) to 39.2 MCN/100tetrads (36-h treatment). Only abstract available; no further data.
Source: BASF AG Ludwigshafen
Test substance: formaldehyde; no data on purity of the compound
Reliability: (3) invalid

(330)

Type: other: in vitro chromosomal aberrations – eukaryotes (plants)
System of testing: Tradescantia
Concentration: 3.3 – 330 mM (ca. 100 – 10000 mg/l)
Metabolic activation: without
Result: negative
Method: other: Micronucleus test
Year: **GLP:** no data
Test substance: as prescribed by 1.1 – 1.4
Remark: Treatment of early stages of meiotic chromosomes of pollen mother cells with formaldehyde in its liquid form for 6 h; micronuclei were analyzed 24 h after treatment in the early tetrads; treatment did not result in elevated micronucleus frequencies. Only abstract available; no further data.
Source: BASF AG Ludwigshafen
Test substance: formaldehyde; no data on purity of the compound
Reliability: (3) invalid

(331)

Type: other: in vitro chromosomal aberrations – eukaryotes (plants)
System of testing: Tradescantia
Concentration: (a) 62 ppm (ca. 0.077 mg/l), 3–6 h; (b) 1200 ppm (ca. 1.5 mg/l), 2–6 h; (c) 3100 ppm (ca. 3.9 mg/l), 20–60 min
Metabolic activation: without
Result: positive
Method: other: Micronucleus test
Year: **GLP:** no data
Test substance: as prescribed by 1.1 – 1.4
Remark: Treatment of early stages of meiotic chromosomes of pollen mother cells with formaldehyde in its gaseous form; micronuclei were analyzed 24 h after treatment in the early tetrads; in each protocol, treatment resulted in a marked increase in micronucleus frequency. Only abstract available; no further data.
Source: BASF AG Ludwigshafen
Test substance: formaldehyde; no data on purity of the compound
Reliability: (3) invalid

(331)

Type: other: in vitro chromosomal aberrations – eukaryotes (plants)
System of testing: Tradescantia
Concentration: (a) 0.5 ppm/min (ca. 0.0006 mg/l/min), 1 h; (b) 1.56 ppm/min (ca. 0.0019 mg/l/min), 6 h; (c) 62 ppm/min (ca.0.077 mg/l/min), 3 h
Metabolic activation: without
Result: positive
Method: other: Micronucleus test
Year: **GLP:** no data
Test substance: as prescribed by 1.1 – 1.4
Remark: Reliability: 2 (reliable with restrictions)
Treatment of early prophase-I meiotic chromosomes of pollen mother cells with formaldehyde; micronuclei were analyzed 24

h after treatment in the early tetrads. An increase in micronucleus frequency was observed at 0.5 and 1.56 ppm; toxicity was observed at 62 ppm.
Source: BASF AG Ludwigshafen
Test substance: formaldehyde; no data on purity of the compound

(332)

Type: other: in vitro chromosomal aberrations – eukaryotes (plants)
System of testing: Tradescantia
Concentration: no data
Metabolic activation: without
Result: positive
Method: other: Micronucleus test
Year: **GLP:** no data
Test substance: as prescribed by 1.1 – 1.4
Remark: Treatment of early prophase-I meiotic chromosomes of pollen mother cells resulted in a positive response; only abstract available; no further data.
Source: BASF AG Ludwigshafen
Test substance: formaldehyde; no data on purity of the compound
Reliability: (3) invalid

(333)

Type: other: in vitro chromosomal aberrations – lower eukaryotes (yeast, fungi)
System of testing: Saccharomyces cerevisiae D61.M
Concentration: 50 – 137 nl/ml
Metabolic activation: without
Result: ambiguous
Method: other: Yeast Cytogenetic assay
Year: **GLP:** no data
Test substance: no data
Remark: Reliability: 2 (reliable with restrictions)
The test substance did not clearly induce mitotic chromosome loss when applied in pure form. According to the authors, pure formaldehyde gave some tantalizing results which indicated that it might induce chromosome loss. The enhancement assay showed definitely that formaldehyde combined with propionitrile induced chromosome malsegregation (synergistic effect).
Source: BASF AG Ludwigshafen
Test substance: formaldehyde; no data on purity of the compound

(306)

Type: other: in vitro gene mutation – lower eukaryotes (yeast, fungi)
System of testing: Saccharomyces cerevisiae TF1, EH3951
Concentration: 10 – 40 mM (ca. 300 – 1200 mg/l)
Metabolic activation: without
Result: positive
Method: other: Yeast gene mutation assay
Year: **GLP:** no data
Test substance: no data
Remark: A dose-dependent weak increase of reverse mutation of yeast strains lacking the SFA gene, i.e. disruption mutants was observed. According to the authors, very little genetic activity was observed in the diploid wild type (2 SFA genes) and in multi-copy SFA-containing transformants. Reliability: 2 (reliable with restrictions)
Source: BASF AG Ludwigshafen
Test substance: formaldehyde; no data on purity of the compound

(334)

Type: other: in vitro gene mutation – lower eukaryotes (yeast, fungi)
System of testing: Saccharomyces cerevisiae N123, UVSz, DH2252-6a, XV185-14C, XV423-2A, YO14-2C
Concentration: 0.05-60 mM (ca. 1.5-1800 mg/l)
Metabolic activation: without
Result: positive
Method: other: Yeast gene mutation assay
Year: **GLP:** no data
Test substance: no data
Remark: Reliability: 2 (reliable with restrictions)
Several concentrations were tested:
- No indication of a nuclear mutagenic effect was observed after various periods of treatment (5-20 min.) with 60 mM (ca. 1800 mg/l), however, the same test concentration resulted in induction of cytoplasmatic "petite" or p-mutation in tester strains N123 and UVSz (no data on test duration).
- Concentrations of 0.1-0.7 mM (ca. 3-21 mg/l) resulted in dose-related mutagenicity. Optimum response in the fluctuation test was found in tester strain N123 at 0.2 and 0.4 mM (ca. 6 and 12 mg/l, respectively). The optimum depended on the test method.
- After tretment with concentrations of 0.05-0.2 mM (ca. 1.5-6 mg/l) or 0.4 mM (ca. 12 mg/l), a dose-related mutagenicity was observed with the tester strains N123, XV185-14C and XV423-2A (his1 gene) and with the tester strain DH2252-6a (ade5 gene). In all cases, the mutagenic action of the test substance was weak.

Source: BASF AG Ludwigshafen
Test substance: formaldehyde; no data on purity of the compound

(335)

Type: other: in vitro gene mutation – lower eukaryotes (yeast, fungi)
System of testing: Aspergillus niger A15
Concentration: 1.0% (10 mg/ml)
Metabolic activation: no data
Result: positive
Method: other: gene mutation
Year: **GLP:** no
Test substance: no data
Remark: Reliability: 2 (reliable with restrictions)
The spores were treated for 5, 10, 15, and 20 min.; survival and mutation rates were determined after 5 days of incubation. The increase in the mutation frequency was treatment time–dependent.
Source: BASF AG Ludwigshafen
Test substance: formaldehyde; no data on purity of the compound

(336)

Type: other: in vitro gene mutation – lower eukaryotes (yeast, fungi)
System of testing: Neurospora crassa H–12, H–59
Concentration: no data
Metabolic activation: no data
Result: positive
Method: other: gene mutation
Year: **GLP:** no data
Test substance: no data
Remark: Treatment of conidial suspension resulted in an induction of ad–3 forward mutations.
Source: BASF AG Ludwigshafen
Test substance: formaldehyde; no data on purity of the compound
Reliability: (3) invalid

(337)

Type: other: in vitro gene mutation – lower eukaryotes (yeast, fungi)
System of testing: Neurospora crassa H–12, H–59, H–71
Concentration: 0.005 – 0.075%
Metabolic activation: no data
Result: positive
Method: other: gene mutation
Year: **GLP:** no data
Test substance: no data
Remark: Reliability: 2 (reliable with restrictions)
Tester strains H–12 and H–71 were treated with 0.01–0.075%; tester strain H–59 was treated with 0.005–0.04%. Induction of ad–3 forward mutants was about 8–11 fold over background in tester strains H–12 and H–71 and about 320 fold over background in tester strain H–59. According to the authors, formaldehyde treatment resulted in about the same killing effect in H–12 and H–71 but in a 9 fold increase in H–59.

Source: BASF AG Ludwigshafen
Test substance: formaldehyde; no data on purity of the compound (338)

Type: other: in vitro gene mutation – prokaryotes (bacteria)
System of testing: Salmonella typhimurium TA98, TA100, UTH8413, UTH8414
Concentration: 0.02 – 0.5 mg/plate
Metabolic activation: with and without
Result: positive
Method: other: Ames test
Year: **GLP:** no data
Test substance: no data
Remark: Preincubation Test with and without metabolic activation with S-9 mix prepared from liver homogenate of Aroclor pretreated Sprague-Dawlwey rats.
Reliability: 2 (reliable with restrictions)
Source: BASF AG Ludwigshafen
Test substance: formaldehyde; no data on purity of the compound (339) (340)

Type: other: in vitro gene mutation – prokaryotes (bacteria)
System of testing: Salmonella typhimurium TA98, TA100, TA102
Concentration: 0.0001 – 0.03 mg/plate
Metabolic activation: without
Result: positive
Method: other: Ames test
Year: **GLP:** no data
Test substance: no data
Remark: Fluctuation Test without metabolic activation.
Reliability: 2 (reliable with restrictions)
Source: BASF AG Ludwigshafen
Test substance: formaldehyde; no data on purity of the compound (312)

Type: other: in vitro gene mutation – prokaryotes (bacteria)
System of testing: Salmonella typhimurium, no data on strain
Concentration: no data
Metabolic activation: without
Result: negative
Method: other: Ames test
Year: **GLP:** no data
Test substance: no data
Remark: Only abstract available; no data on doses, preparation of S-9 mix, tester strain, or method.
Reliability: 3 (not reliable)
Source: BASF AG Ludwigshafen
Test substance: formaldehyde; no data on purity of the compound (293)

Type: other: in vitro gene mutation – prokaryotes (bacteria)
System of testing: Salmonella typhimurium TA102, TA2638
Concentration: 0.1 mg/plate
Metabolic activation: no data
Result: positive
Method: other: Ames test
Year: **GLP:** no data
Test substance: no data
Remark: Reliability: 2 (reliable with restrictions)
Standard Plate Test; no data on dose range or S–9 mix; weak response with TA102.
Source: BASF AG Ludwigshafen
Test substance: formaldehyde; no data on purity of the compound

(341)

Type: other: in vitro gene mutation – prokaryotes (bacteria)
System of testing: Salmonella typhimurium TA97, TA98, TA100
Concentration: 0.5 – 2.0 mM (ca. 15 – 60 mg/l); no further data
Metabolic activation: without
Result: positive
Method: other: Ames test
Year: **GLP:** no data
Test substance: no data
Remark: Reliability: 2 (reliable with restrictions)
Standard Plate Test; only abstract available; no data on exact dose or test method
Source: BASF AG Ludwigshafen
Test substance: formaldehyde; no data on purity of the compound

(342)

Type: other: in vitro gene mutation – prokaryotes (bacteria)
System of testing: Salmonella typhimurium TA100, TM677
Concentration: 0.06 – 0.25 mM (ca. 1.8 – 7.5 mg/l); no further data
Metabolic activation: without
Result: positive
Method: other: Ames test
Year: **GLP:** no data
Test substance: no data
Remark: Forward mutation assay, 8–azaguanidine resistance (Preincubation Test); only abstract available; no data on exact dose or test method
Reliability: 2 (reliable with restrictions)
Source: BASF AG Ludwigshafen
Test substance: formaldehyde; no data on purity of the compound

(342)

Type: other: in vitro gene mutation – prokaryotes (bacteria)
System of testing: Salmonella typhimurium TA98, TA100, TA102, TA1535, TA1537, TA1538
Concentration: up to 0.2 mg/plate
Metabolic activation: without
Result: positive
Method: other: Ames test
Year: **GLP:** no data
Test substance: no data
Remark: Reliability: 2 (reliable with restrictions)
Standard Plate Test and Preincubation Test without metabolic activation
Source: BASF AG Ludwigshafen
Test substance: formaldehyde; no data on purity of the compound

(343)

Type: other: in vitro gene mutation – prokaryotes (bacteria)
System of testing: Salmonella typhimurium TM677
Concentration: 0.33 – 20 mM (ca. 10 – 600 mg/l); no further data
Metabolic activation: with and without
Result: positive
Method: other: Ames test
Year: **GLP:** no data
Test substance: no data
Remark: Forward mutation assay, 8–azaguanidine resistance (Preincubation Test) with and without metabolic activation with S–9 mix prepared from liver homogenate of Aroclor pretreated Sprague–Dawley rats; minimum concentrations to induce mutagenicity were 0.167 mM (ca. 5 mg/l) without S–9 or 0.33 mM (ca. 10 mg/l) with S–9; mutagenicity depended on concentration and time of preincubation (between 15 and 120 minutes).
Reliability: 2 (reliable with restrictions)
Source: BASF AG Ludwigshafen
Test substance: formaldehyde; no data on purity of the compound

(344)

Type: other: in vitro gene mutation – prokaryotes (bacteria)
System of testing: Salmonella typhimurium TA100, TA102
Concentration: no data
Metabolic activation: with and without
Result: positive
Method: other: Ames test
Year: **GLP:** no data
Test substance: no data
Remark: Reliability: 3 (not reliable)
Result: mutagenic; only abstract available; no data on method, S–9 mix, or exact results
Source: BASF AG Ludwigshafen
Test substance: formaldehyde; no data on purity of the compound

(345)

Type: other: in vitro gene mutation – prokaryotes (bacteria)
System of testing: Salmonella typhimurium BA13 (wild type), BA9 (deep rough)
Concentration: 167 – 1332 nmoles/ml (ca. 5 – 40 mg/l)
Metabolic activation: without
Result: positive
Method: other: Ames test
Year: **GLP:** no data
Test substance: no data
Remark: Forward mutation assay (Preincubation Test, L–arabinose resistance) without metabolic activation; dose–dependent increase in mutant colonies (ARAR)
Reliability: 2 (reliable with restrictions)
Source: BASF AG Ludwigshafen
Test substance: formaldehyde; no data on purity of the compound
(346)

Type: other: in vitro gene mutation – prokaryotes (bacteria)
System of testing: Salmonella typhimurium TA98, TA100, TA1535, TA1537, TA1538
Concentration: 0.00005 – 1 mg/plate
Metabolic activation: with and without
Result: negative
Method: other: Ames test
Year: **GLP:** no data
Test substance: no data
Remark: Reliability: 2 (reliable with restrictions)
Standard Plate Test with and without metabolic activation with S–9 mix prepared from liver homogenate of Aroclor induced Sprague–Dawley rats. Accoring to the author,no mutagenic response was observed, however, NTP results showed a positive response in the Preincubation assay.
Source: BASF AG Ludwigshafen
Test substance: formaldehyde; no data on purity of the compound
(292)

Type: other: in vitro gene mutation – prokaryotes (bacteria)
System of testing: Salmonella typhimurium TA100
Concentration: up to 30 umoles (ca. 0.9 mg)
Metabolic activation: without
Result: positive
Method: other: Ames test
Year: **GLP:** no data
Test substance: no data
Remark: Preincubation Test without metabolic activation, the test substance was strongly mutagenic at the 5uM level (ca. 0.15 mg); cytotoxicity was observed at doses >5uM.
Reliability: 2 (reliable with restrictions)
Source: BASF AG Ludwigshafen
Test substance: formaldehyde; no data on purity of the compound
(347)

Type: other: in vitro gene mutation – prokaryotes (bacteria)
System of testing: Salmonella typhimurium TA100
Concentration: 0.1 – 1.0 umoles/plate (ca. 0.003 – 0.03 mg/plate)
Metabolic activation: with
Result: positive
Method: other: Ames test
Year: **GLP:** no data
Test substance: no data
Remark: Preincubation Test and Standard Plate Test both with metabolic activation with S-9 prepared from liver homogenateof Aroclor pretreated rats, both with S-9 with and without cofactors. Positive reaction was only observed in the Preincubation Test (60 min); the greatest effect was observed using S-9 without cofactors. No further data on Standard Plate Test.
Reliability: 2 (reliable with restrictions)
Source: BASF AG Ludwigshafen
Test substance: formaldehyde; no data on purity of the compound

(348)

Type: other: in vitro gene mutation – prokaryotes (bacteria)
System of testing: Salmonella typhimurium TA98, TA1535, TA1537, TA1538
Concentration: 0.1 – 0.6 umoles/plate (ca. 0.003 – 0.018 mg/plate)
Metabolic activation: with
Result: positive
Method: other: Ames test
Year: **GLP:** no data
Test substance: no data
Remark: Reliability: 2 (reliable with restrictions)
Standard Plate Test with S-9 without cofactors. Mutagenicity was observed only with tester strain TA98.
Source: BASF AG Ludwigshafen
Test substance: formaldehyde; no data on purity of the compound

(348)

Type: other: in vitro gene mutation – prokaryotes (bacteria)
System of testing: Salmonella typhimurium TA100
Concentration: up to 1.5 mM (ca. 45 mg/l)
Metabolic activation: with and without
Result: positive
Method: other: Ames test
Year: **GLP:** no data
Test substance: no data
Remark: Reliability: 2 (reliable with restrictions)
Standard Plate Test (SPT) concentration up to 1.5 mM (ca. 45 mg/l) and Preincubation Test (PIT); concentration up to 0.3 mM (ca. 9 mg/l) with and without metabolic activation with S-9 mix prepared from liver homogenate of Clophen A50 pretreated Wistar rats. Increase over background by a factor of 1.3 (-S-9) or 1.7 (+S-9) in SPT and by a factor of 1.6 (-S-9) or 2.7 (+S-9) in PIT.

Source: BASF AG Ludwigshafen
Test substance: formaldehyde; no data on purity of the compound
(300)

Type: other: in vitro gene mutation – prokaryotes (bacteria)
System of testing: Salmonella typhimurium TA97, TA98, TA100, TA102, TA104
Concentration: up to 1 mg/plate
Metabolic activation: without
Result: positive
Method: other: Ames test
Year: **GLP:** no data
Test substance: no data
Remark: Preincubation Test without metabolic activation; clearly positive and dose-related mutagenic effect at doses up to 1.25 umoles (37.5 ug) in tester strain TA104 and up to 2.0 umoles (60 ug) in tester strain TA102; only weak response in tester strains TA97, TA98, and TA100
Reliability: 2 (reliable with restrictions)
Source: BASF AG Ludwigshafen
Test substance: formaldehyde; no data on purity of the compound
(349)

Type: other: in vitro gene mutation – prokaryotes (bacteria)
System of testing: Salmonella typhimurium TA98, TA100, TA1537
Concentration: no data
Metabolic activation: without
Result: positive
Method: other: Ames test
Year: **GLP:** no data
Test substance: no data
Remark: Preincubation Test with and without metabolic activation with S-9 prepared from liver homogenate of PCB (KC-400) pretreated Wistar rats; mutagenic effect with TA100 without S-9 mix; 2000 his+ revertants/mg.
Reliability: 2 (reliable with restrictions)
Source: BASF AG Ludwigshafen
Test substance: formaldehyde; no data on purity of the compound
(319)

Type: other: in vitro gene mutation – prokaryotes (bacteria)
System of testing: Salmonella typhimurium TA98, TA100, TA104
Concentration: no data
Metabolic activation: with and without
Result: positive
Method: other: Ames test
Year: **GLP:** no data
Test substance: no data
Remark: Preincubation Test with and without metabolic activation; positive results in all tester strains with and without S-9. Only abstract available; no further data.
Reliability: 3 (not reliable)

Source: BASF AG Ludwigshafen
Test substance: formaldehyde; no data on purity of the compound
(350)

Type: other: in vitro gene mutation – prokaryotes (bacteria)
System of testing: Salmonella typhimurium TA98, TA100
Concentration: 0.2 – 10 mM (ca. 6 – 300 mg/l)
Metabolic activation: without
Result: positive
Method: other: Ames test
Year: **GLP:** no data
Test substance: no data
Remark: Preincubation Test without metabolic activation; only weak response in both tester strains.
Reliability: 2 (reliable with restrictions)
Source: BASF AG Ludwigshafen
Test substance: formaldehyde; no data on purity of the compound
(351)

Type: other: in vitro gene mutation – prokaryotes (bacteria)
System of testing: Salmonella typhimurium TA98, TA100, TA1535, TA1537
Concentration: (a) 0.001–0.1 mg/plate (lab. 1); (b) 0.0033–0.3 mg/plate (lab. 2) ; (c) 0.0033–0.3333 mg/plate (lab. 3)
Metabolic activation: with and without
Result: positive
Method: other: Ames test
Year: **GLP:** no data
Test substance: no data
Remark: Preincubation Test with and without metabolic activation with S-9 mix prepared from liver homogenate of both Aroclor pretreated Sprague-Dawley rats and Syrian hamsters; dose-related increase in the revertants was observed with tester strains TA98 and TA100.
"Round Robin Test" with 3 different laboratories.
Reliability: 2 (reliable with restrictions)
Source: BASF AG Ludwigshafen
Test substance: formaldehyde; no data on purity of the compound
(352)

Type: other: in vitro gene mutation – prokaryotes (bacteria)
System of testing: Salmonella typhimurium TA104
Concentration: 370 – 1500 uM (ca. 11.1 – 45 mg/l)
Metabolic activation: with and without
Result: positive
Method: other: Ames test
Year: **GLP:** no data
Test substance: no data
Remark: Preincubation Test with and without metabolic activation with S-9 mix prepared from liver homogenate of Aroclor pretreated Sprague-Dawley rats; dose-related increase in the revertants was observed with S-9.

Reliability: 2 (reliable with restrictions)
Source: BASF AG Ludwigshafen
Test substance: formaldehyde; no data on purity of the compound
(353)

Type: other: in vitro gene mutation – prokaryotes (bacteria)
System of testing: Salmonella typhimurium; no data on tester strain
Concentration: no data
Metabolic activation: with and without
Result: positive
Method: other: Ames test
Year: **GLP:** no data
Test substance: no data
Remark: Preincubation Test with and without metabolic activation with S-9 mix prepared from liver homogenate of Aroclor pretreated Sprague-Dawley rats; mutagenicity was observed inpresence and absence of S-9; no data on doses and tester strains.
Reliability: 3 (not reliable)
Source: BASF AG Ludwigshafen
Test substance: formaldehyde; no data on purity of the compound
(264)

Type: other: in vitro gene mutation – prokaryotes (bacteria)
System of testing: Salmonella typhimurium TA98, TA100
Concentration: no data
Metabolic activation: without
Result: negative
Method: other: Ames test
Year: **GLP:** no data
Test substance: no data
Remark: Reliability: 3 (not reliable)
Standard Plate Test without metabolic activation; no mutagenic repsonse was observed. No further data.
Source: BASF AG Ludwigshafen
Test substance: formaldehyde; no data on purity of the compound
(354)

Type: other: in vitro gene mutation – prokaryotes (bacteria)
System of testing: Salmonella typhimurium TA100, TA102
Concentration: no data
Metabolic activation: with and without
Result: positive
Method: other: Ames test
Year: **GLP:** no data
Test substance: no data
Remark: Reliability: 3 (not reliable)
Standard Plate Test and Preincubation Test both with and without metabolic activation with S-9 mix prepared from liver homogenate of Aroclor pretreated Syrian hamsters; mutagenic response in presence and absence of S-9. According

to the authors, the results suggested that the preincubation was more sensitive than the standard procedure. Only abstract available; no further data.
Source: BASF AG Ludwigshafen
Test substance: formaldehyde; no data on purity of the compound

(355)

Type: other: in vitro gene mutation - prokaryotes (bacteria)
System of testing: Salmonella typhimurium TA102
Concentration: no data
Metabolic activation: no data
Result: positive
Method: other: Ames test
Year: **GLP:** no data
Test substance: no data
Remark: According to the authors, the test substance was mutagenic. Only abstract available; no data on method, metabolic activation, doses, exact results etc.
Reliability: 3 (not reliable)
Source: BASF AG Ludwigshafen
Test substance: formaldehyde; no data on purity of the compound

(356)

Type: other: in vitro gene mutation - prokaryotes (bacteria)
System of testing: Salmonella typhimurium TA98, TA100
Concentration: no data
Metabolic activation: with and without
Result: positive
Method: other: Ames test
Year: **GLP:** no data
Test substance: no data
Remark: Preincubation Test with and without metabolic activation with liver homogenate from KC-500 pretreated rats; weak response with tester strain TA100 in absence of S-9; no mutagenic response in presence of S-9. Only abstract available; no furhter data.
Reliability: 3 (not reliable)
Source: BASF AG Ludwigshafen
Test substance: formaldehyde; no data on purity of the compound

(357)

Type: other: in vitro gene mutation – prokaryotes (bacteria)
System of testing: Salmonella typhimurium TA100, TM 677
Concentration: 0.002 – 0.01 mg/plate
Metabolic activation: without
Result: positive
Method: other: Ames test
Year: **GLP:** no data
Test substance: no data
Remark: Reliability: 2 (reliable with restrictions)
Standard Plate Test (SPT) and Preincubation Test (PIT) without metabolic activation; positive response with TA 100 (3 fold) and TM 677 (7 fold) only in the PIT; only abstract available no further data.
Source: BASF AG Ludwigshafen
Test substance: formaldehyde; no data on purity of the compound

(358)

Type: other: in vitro gene mutation – prokaryotes (bacteria)
System of testing: Salmonella typhimurium TA98, TA100, TA1535, TA1537, TA1538
Concentration: up to 2 umoles/plate (ca. 0.06 mg/plate)
Metabolic activation: with and without
Result: negative
Method: other: Ames test
Year: **GLP:** no data
Test substance: no data
Remark: Reliability: 2 (reliable with restrictions)
Standard Plate Test with and without metabolic activation with S–9 prepared from liver homogenate of Aroclor pretreated Sprague–Dawley rats; no mutagenic activity was observed.
Source: BASF AG Ludwigshafen
Test substance: formaldehyde; no data on purity of the compound

(359)

Type: other: in vitro gene mutation – prokaryotes (bacteria)
System of testing: Salmonella typhimurium TA97, TA102
Concentration: 0.025 – 0.2 mg/plate
Metabolic activation: with and without
Result: positive
Method: other: Ames test
Year: **GLP:** no data
Test substance: no data
Remark: Reliability: 2 (reliable with restrictions)
Standard Plate Test with and without metabolic activation with S–9 prepared from liver homogenate of Aroclor pretreated Sprague–Dawley rats; no differences in mutagenic activity was observed in the presence or absence of S–9; weakly positive response with tester strain TA102; maximum response +/–S–9 at 100 ug/plate (2–3–fold).
Source: BASF AG Ludwigshafen
Test substance: formaldehyde; no data on purity of the compound

(309) (360)

Type: other: in vitro gene mutation – prokaryotes (bacteria)
System of testing: Salmonella typhimurium TA102
Concentration: up to 5.0 mg/plate
Metabolic activation: with and without
Result: ambiguous
Method: other: Ames test
Year: **GLP:** no data
Test substance: no data
Remark: Reliability: 2 (reliable with restrictions)
Standard Plate Test with and without metabolic activation with S-9 prepared from liver homogenate of Aroclor pretreated Sprague-Dawley rats; the test was performed as a Round Robin Test in 3 different laboratories. The results were conflicting: no mutagenicity was observed in 2 laboratories, weakly positive reaction was observed in 1 laboratory.
Source: BASF AG Ludwigshafen
Test substance: formaldehyde; no data on purity of the compound

(361) (362)

Type: other: in vitro gene mutation – prokaryotes (bacteria)
System of testing: Salmonella typhimurium TA98, TA100, TA1535, TA1537, TA1538
Concentration: no data
Metabolic activation: with and without
Result: negative
Method: other: Ames test
Year: **GLP:** no data
Test substance: no data
Remark: Reliability: 3 (not reliable)
Standard Plate Test with and without metabolic activation with S-9 prepared from liver homogenate of Aroclor pretreated Sprague-Dawley rats; no increase in the number of mutant colonies was observed in the presence and absence of S-9.
Source: BASF AG Ludwigshafen
Test substance: formaldehyde; no data on purity of the compound

(309) (360)

Type: other: in vitro gene mutation – prokaryotes (bacteria)
System of testing: Salmonella typhimurium TA100
Concentration: 1 – 30 umoles (ca. 0.030 – 0.9 mg)
Metabolic activation: without
Result: positive
Method: other: Ames test
Year: **GLP:** no data
Test substance: no data
Remark: Reliability: 2 (reliable with restrictions)
Standard Plate Test without metabolic activation, the test substance was strongly mutagenic at the 5 uMole level (ca.

0.15 mg); cytotoxicity was observed at doses >5 uMole.
Source: BASF AG Ludwigshafen
Test substance: formaldehyde; no data on purity of the compound

(363)

Type: other: in vitro gene mutation – prokaryotes (bacteria)
System of testing: Salmonella typhimurium TA98, TA100
Concentration: up to 20 ul
Metabolic activation: with and without
Result: positive
Method: other: Ames test
Year: **GLP:** no data
Test substance: no data
Remark: Mutagenicity was observed in the presence and absence of S-9 mix (prepared from liver homogenate of Aroclor pretreated Wistar rats) with both tester strains with the most marked activity towards tester strain TA100. Mutagenic acitivity was reduced in the presence of S-9 mix.
Reliability: 2 (reliable with restrictions)
Source: BASF AG Ludwigshafen
Test substance: formaldehyde; no data on purity of the compound

(364)

Type: other: in vitro gene mutation – prokaryotes (bacteria)
System of testing: Escherichia coli AB1157 (wild type), AB1886 (uvrA), AB2480 (recA/uvrA)
Concentration: 0.625 – 5 mM (ca. 18.8 – 150 mg/l)
Metabolic activation: without
Result: positive
Method: other: Bacterial forward mutation assay
Year: **GLP:** no data
Test substance: no data
Remark: Preincubation Test (rifampicin resistance) without metabolic activation. A dose-related mutagenicity was observed in the wild type tester strain AB1157, only; according to the authors, this was a characteristic shared with cross-linking agents.
Reliability: 2 (reliable with restrictions)
Source: BASF AG Ludwigshafen
Test substance: formaldehyde; no data on purity of the compound

(274)

Type: other: in vitro gene mutation – prokaryotes (bacteria)
System of testing: Escherichia coli B/r WP2 Hcr+ (Trp–), B/r WP2 Hcr– (Trp–)
Concentration: 40, 80, 320, 640 mM (1200, 2400, 9600, 19200 mg/l)
Metabolic activation: without
Result: positive
Method: other: Bacterial forward mutation assay
Year: **GLP:** no data
Test substance: no data
Remark: Reliability: 2 (reliable with restrictions)
Standard Plate Test (streptomycin resistance) without metabolic activation; Hcr+ strain tested with 40 and 80 mM (1200 and 2400 mg/l), Hcr– strain tested with 320 and 640 mM (9600 and 19200 mg/l). Induction of both types of mutations (SMr and Trp+) was found only on Hcr– cells; according to the authors, these resuslts indicated that the test substance produced mutagenic lesions which were subject to cellular Hcr repair.
Source: BASF AG Ludwigshafen
Test substance: formaldehyde; no data on purity of the compound

(365)

Type: other: in vitro gene mutation – prokaryotes (bacteria)
System of testing: Escherichia coli DB2
Concentration: 1 – 40 mg/l
Metabolic activation: without
Result: positive
Method: other: Bacterial forward mutation assay
tes (bacteria)
Year: **GLP:** no data
Test substance: no data
Remark: ampicillin resistance test; non–linear dose–response; minimum detectable dose was ca. 6 and 9 ug/ml in the first and second experimental run, respectively
Reliability: 2 (reliable with restrictions)
Source: BASF AG Ludwigshafen
Test substance: formaldehyde; no data on purity of the compound

(366)

Type: other: in vitro gene mutation – prokaryotes (bacteria)
System of testing: Escherichia coli (gpt locus)
Concentration: 40 mM (ca. 1200 mg/l)
Metabolic activation: with and without
Result: positive
Method: other: Bacterial gene mutation assay
Year: **GLP:** no data
Test substance: no data
Remark: According to the authors, 8/9 mutants analyzed were AT–to–CG transitions and 1/9 was a GC–to–AT transition.
No details concerning method, S–9 mix, doses, exact results etc. were given. Dideoxy DNA sequencing was used to determine the specific base changes.

Reliability: 3 (not reliable)
Source: BASF AG Ludwigshafen
Test substance: formaldehyde; no data on purity of the compound
(367)

Type: other: in vitro gene mutation – prokaryotes (bacteria)
System of testing: Escherichia coli K12GP120, carrying the pSV2gpt plasmid
Concentration: 4 or 40 mM (ca. 120 and 1200 mg/l)
Metabolic activation: no data
Result: positive
Method: other: Bacterial gene mutation assay
Year: **GLP:** no data
Test substance: no data
Remark: 4 mM induced point mutations (41%), large insertions (41%), and large deletions (18%); average mutation frequency was 2.3-fold over background. Most of the point mutations were transversions at CG base pairs.
40 mM induced point mutations (92%), large insertions (3%), and large deletions (5%); average mutation frequency was 3-7-fold over background. Most of the point mutations were transitions at a single TA base pair.
According to the authors, the test substance induced different alterations at different concentrations.
Reliability: 2 (reliable with restrictions)
Source: BASF AG Ludwigshafen
Test substance: formaldehyde; no data on purity of the compound
(368)

Type: other: in vitro gene mutation – prokaryotes (bacteria)
System of testing: other: Escherichia coli K12GP120 and naked pSV2gpt plasmid DNA
Concentration: 3.3 or 10 mM (ca. 100 or 300 mg/l)
Metabolic activation: no data
Result: positive
Method: other: Bacterial gene mutation assay
Year: **GLP:** no data
Test substance: no data
Remark: Naked plasmid DNA was exposed and transformed into Escherichia coli. Formaldehyde induced point mutations (86%) and large deletions (14%). Most of the resulting mutations were frameshifts.
Reliability: 2 (reliable with restrictions)
Source: BASF AG Ludwigshafen
Test substance: formaldehyde; no data on purity of the compound
(368)

Type: other: in vitro gene mutation – prokaryotes (bacteria)
System of testing: Escherichia coli K12/343/113 (uvrB+), K12/343/268 (uvrB–)
Concentration: no data
Metabolic activation: no data
Result: positive
Method: other: Bacterial gene mutation assay
Year: **GLP:** no data
Test substance: no data
Remark: Mutagenicity was increased 8–fold only at higher concentrations while at low concentrations, no influence of liquid holding was observed. The 60–fold increase over control was dependent on the presence of the intact uvrB function. NALres and VALres forward mutations, nad (frame shift and arg reversions (point mutations) were determined. Only abstract available; no further data.
Reliability: 3 (not reliable)
Source: BASF AG Ludwigshafen
Test substance: formaldehyde; no data on purity of the compound

(369)

Type: other: in vitro gene mutation – prokaryotes (bacteria)
System of testing: Escherichia coli K12/343/113, K12/343/268
Concentration: up to 12 mM (ca. 480 mg/l)
Metabolic activation: without
Result: positive
Method: other: Bacterial gene mutation assay
Year: **GLP:** no data
Test substance: no data
Remark: Reliability: 2 (reliable with restrictions)
The test substance was clearly mutagenic in the nalr system of Escherichia coli K12/343/113. Maximum response was observed at 2mM (ca. 60 mg/l; ca. 20–fold increase); further increase after liquid holding (24 hours) up to 12 mM (ca. 480 mg/l; 56–fold) was recorded.
Source: BASF AG Ludwigshafen
Test substance: formaldehyde; no data on purity of the compound

(370)

Type: other: in vitro gene mutation – prokaryotes (bacteria)
System of testing: Escherichia coli WP2 (pKM101), WP2 uvrA (pKM101)
Concentration: up to 0.2 mg/plate
Metabolic activation: without
Result: positive
Method: other: Bacterial reverse mutation assay
Year: **GLP:** no data
Test substance: no data
Remark: Reliability: 2 (reliable with restrictions)
Standard Plate Test (SPT) and Preincubation Test (PIT) without metabolic activation; positive result in SPT with WP2 uvrA (pKM101) strain only.
Source: BASF AG Ludwigshafen

Test substance: formaldehyde; no data on purity of the compound
(343)

Type: other: in vitro gene mutation – prokaryotes (bacteria)
System of testing: Escherichia coli B/r WP2 Hcr+ (Trp–), B/r WP2 Hcr– (Trp–)
Concentration: 40, 80, 320, 640 mM (1200, 2400, 9600, 19200 mg/l)
Metabolic activation: without
Result: positive
Method: other: Bacterial reverse mutation assay
Year: **GLP:** no data
Test substance: no data
Remark: Preincubation Test without metabolic activation; Hcr+ strain tested with 40 and 80 mM (1200 and 2400 mg/l), Hcr– strain tested with 320 and 640 mM (9600 and 19200 mg/l). Induction of both types of mutations (SMr and Trp+) was found only on Hcr– cells; according to the authors, these resuslts indicated that the test substance produced mutagenic lesionswhich were subject to cellular Hcr repair. Reliability: 2 (reliable with restrictions)
Source: BASF AG Ludwigshafen
Test substance: formaldehyde; no data on purity of the compound
(365)

Type: other: in vitro gene mutation – prokaryotes (bacteria)
System of testing: Escherichia coli WP2 uvrA/pKM101
Concentration: no data
Metabolic activation: with and without
Result: positive
Method: other: Bacterial reverse mutation assay
Year: **GLP:** no data
Test substance: no data
Remark: Preincubation Test with and without metabolic activation; positive results with and without S–9. Only abstract available; no further data.
Reliability: 3 (not reliable)
Source: BASF AG Ludwigshafen
Test substance: formaldehyde; no data on purity of the compound
(350)

Type: other: in vitro gene mutation – prokaryotes (bacteria)
System of testing: Escherichia coli – B tester strains H/r30R (wild–type), Hs30R (uvrA), NG30 (recA), O16 (polA)
Concentration: 0.05 – 5 mM (ca. 1.5 – 150 mg/l) or 20 mM (ca. 600 mg/l)
Metabolic activation: without
Result: positive
Method: other: Bacterial reverse mutation assay
Year: **GLP:** no data
Test substance: no data
Remark: Preincubation Test without metabolic activation; dose–related increase in the number of arg+ revertants of tester strains H/r30R and O16; the repair deficient tester

strains were more sensitive to the lethal effect of formaldehyde than the wild type.
Reliability: 2 (reliable with restrictions)
Source: BASF AG Ludwigshafen
Test substance: formaldehyde; no data on purity of the compound
(351)

Type: other: in vitro gene mutation - prokaryotes (bacteria)
System of testing: Escherichia coli - B/r tester strains WP2 (wild-type), WP2 uvrA
Concentration: 0.2 - 20 mM (ca. 6 - 600 mg/l)
Metabolic activation: without
Result: positive
Method: other: Bacterial reverse mutation assay
Year: **GLP:** no data
Test substance: no data
Remark: Preincubation Test without metabolic activation; dose-related increase in the number of trp+ revertants with both tester strains; the repair deficient tester strain was more sensitive to the lethal effect of formaldehyde than the wild type.
Reliability: 2 (reliable with restrictions)
Source: BASF AG Ludwigshafen
Test substance: formaldehyde; no data on purity of the compound
(351)

Type: other: in vitro gene mutation - prokaryotes (bacteria)
System of testing: Escherichia coli WP2 uvrA
Concentration: 0.02 - 10 mM (ca. 0.6 - 300 mg/l)
Metabolic activation: without
Result: negative
Method: other: Bacterial reverse mutation assay
Year: **GLP:** no data
Test substance: no data
Remark: Preincubation Test without metabolic activation for 18 h; no mutagenic response was observed; no further data.
Reliability: 2 (reliable with restrictions)
Source: BASF AG Ludwigshafen
Test substance: formaldehyde; no data on purity of the compound
(371)

Type: other: in vitro gene mutation – prokaryotes (bacteria)
System of testing: Escherichia coli WP2/pKM101, WP2 uvrA/pKM101
Concentration: no data
Metabolic activation: no data
Result: ambiguous
Method: other: Bacterial reverse mutation assay
Year: **GLP:** no data
Test substance: no data
Remark: Reliability: 3 (not reliable)
The mutagenicity of the test substance was questionable. Only abstract available; no data on method, metabolic activation, doses, exact results etc.
Source: BASF AG Ludwigshafen
Test substance: formaldehyde; no data on purity of the compound

(356)

Type: other: in vitro gene mutations – eukaryotes (mammalian cells)
System of testing: human lymphoblasts TK6 (HPRT–)
Concentration: 150 uM (ca. 4.5 mg/l), 8 times
Metabolic activation: without
Result: positive
Method: other: HGPRT assay
Year: **GLP:** no data
Test substance: no data
Remark: About 50% of the induced mutations had visible deletions, indicating large losses of DNA. The remainder probably consisted of point mutations or smaller insertions or deletions (characterized by Southern blot). The test substance was a weak mutagen at the hprt locus in TK6 cells (12.4 fold over background).
Reliability: 2 (reliable with restrictions)
Source: BASF AG Ludwigshafen
Test substance: formaldehyde; no data on purity of the compound

(368)

Type: other: in vitro gene mutations – eukaryotes (mammalian cells)
System of testing: human lymphoblasts TK6 (TK+/–)
Concentration: up to 150 uM (ca. 4.5 mg/l)
Metabolic activation: without
Result: positive
Method: other: HGPRT assay
Year: **GLP:** no data
Test substance: no data
Remark: Induction of a significant number of F3TdR–resistant mutants was observed at 150 uM; minimum detectable concentration which induced mutants was ca. 130 uM (3.9 mg/l).
Reliability: 2 (reliable with restrictions)
Source: BASF AG Ludwigshafen
Test substance: formaldehyde; no data on purity of the compound

(372)

Type: other: in vitro gene mutations – eukaryotes (mammalian cells)
System of testing: human lymphoblasts TK6 (TK+/–)
Concentration: (a) 0.015–0.15 mM (ca. 0.45–4.5 mg/l); (b) 3x0.05 mM (ca. 1.5 mg/l); (c) 5x0.03 mM (ca. 0.9 mg/l); (d) 10x0.015 mM (ca. 0.45 mg/l)
Metabolic activation: without
Result: positive
Method: other: HGPRT assay
Year: **GLP:** no data
Test substance: no data
Remark: According to protocol (a), a nonlinear increase in induced F3TdR–resistant mutants with increasing slope above 125 uM (ca. 3.75 mg/l) was observed (mutant fraction: 4.8x10E–6). Significant response was obtained at doses of 30 uM (ca. 0.9 mg/l) and more. 125 and 150 uM resulted in ca. 30% and 20% survival, respectively. Increases of F3TdR–resistant mutants were 2.1x10E–6, 2.2x10E–6, and 3.0x10E–6 after application according to protocol (b), (c), and (d), respectively. According to the authors, combined effect of multiple treatments was less than single treatment with an equivalent concentration (0.15 mM).
Reliability: 2 (reliable with restrictions)
Source: BASF AG Ludwigshafen
Test substance: formaldehyde; no data on purity of the compound

(373) (285)

Type: other: in vitro gene mutations – eukaryotes (mammalian cells)
System of testing: human lymphoblasts TK6 (Oub)
Concentration: 150 uM (ca. 4.5 mg/l), 4 times
Metabolic activation: without
Result: negative
Method: other: HGPRT assay
Year: **GLP:** no data
Test substance: no data
Remark: No increase in the number of ouabain–resistant (Oubr) cells was observed. According to the authors, this result suggested that formaldehyde did not induce a wide variety of base substitution mutation.
Reliability: 2 (reliable with restrictions)
Source: BASF AG Ludwigshafen
Test substance: formaldehyde; no data on purity of the compound

(373) (285)

Type: other: in vitro gene mutations – eukaryotes (mammalian cells)
System of testing: CHO/HPRT (hprt locus)
Concentration: no data
Metabolic activation: without
Result: negative
Method: other: HGPRT assay
Year: **GLP:** no data
Test substance: no data
Remark: No induction of mutations in the hprt locus; only abstract available; no further data.
Source: BASF AG Ludwigshafen
Test substance: formaldehyde; no data on purity of the compound
Reliability: (3) invalid

(374)

Type: other: in vitro gene mutations – eukaryotes (mammalian cells)
System of testing: AS52/XPRT (gpt locus)
Concentration: no data
Metabolic activation: without
Result: positive
Method: other: HGPRT assay
Year: **GLP:** no data
Test substance: no data
Remark: Mutagenic response at the gpt locus (i.e. mutation to TGr); only abstract available; no further data.
Source: BASF AG Ludwigshafen
Test substance: formaldehyde; no data on purity of the compound
Reliability: (3) invalid

(374)

Type: other: in vitro gene mutations – eukaryotes (mammalian cells)
System of testing: AS52/XPRT
Concentration: 1 – 50 mg/l
Metabolic activation: without
Result: positive
Method: other: HGPRT assay
Year: **GLP:** no data
Test substance: no data
Remark: No mutagenicity at low doses (1–10 mg/l); linear increase in XPRT mutant frequencies at higher concentrations; only abstract available; no further data.
Reliability: 2 (reliable with restrictions)
Source: BASF AG Ludwigshafen
Test substance: formaldehyde; no data on purity of the compound

(320)

Type: other: in vitro gene mutations – eukaryotes (mammalian cells)
System of testing: human bronchial fibroblasts
Concentration: 50 – 175 uM (ca. 1.5 – 5.25 mg/l)
Metabolic activation: without
Result: positive
Method: other: HGPRT assay
Year: **GLP:** no data
Test substance: no data
Remark: A dose-related induction of 6-thioguanine-resistant (6-TGr) mutants was observed. According to the authors, formaldehyde also inhibited the repair of O6-methylguanine and potentiated the mutagenicity of N-methyl-N-nitrosourea (probably by repair inhibition).
Reliability: 2 (reliable with restrictions)
Source: BASF AG Ludwigshafen
Test substance: formaldehyde; no data on purity of the compound

(375)

Type: other: in vitro gene mutations – eukaryotes (mammalian cells)
System of testing: human fibroblasts
Concentration: 50 and 75 uM (ca. 1.5 and 2.25 mg/l)
Metabolic activation: without
Result: negative
Method: other: HGPRT assay
Year: **GLP:** no data
Test substance: no data
Remark: No detectable increase in 6-thioguanine-resistant (6-TGr) mutants was observed. Cell survival was 82% and 40% at 50 and 75 uM, respectively. Only abstract available; no furtherdata.
Reliability: 2 (reliable with restrictions)
Source: BASF AG Ludwigshafen
Test substance: formaldehyde; no data on purity of the compound

(376)

Type: other: in vitro gene mutations – eukaryotes (mammalian cells)
System of testing: human lymphoblasts TK6 (hprt locus)
Concentration: 8 x 150 uM (ca. 4.5 mg/l)
Metabolic activation: without
Result: positive
Method: other: HGPRT assay
Year: **GLP:** no data
Test substance: no data
Remark: Induction of 6-thioguanine-resistant (6-TGr) mutants following treatment with formaldehyde was observed. According to the authors, 6/30 mutants had completely lost the hprt gene, 8/30 had partial deletions, and 16/30 had been described as point mutations (characterized by Southern and Northern blot analysis).
Reliability: 2 (reliable with restrictions)
Source: BASF AG Ludwigshafen

Test substance: formaldehyde; no data on purity of the compound

(377)

Type: other: in vitro gene mutations – eukaryotes (mammalian cells)
System of testing: Chinese hamster V79 cells
Concentration: 0.1 – 1.0 mM (ca. 3 – 30 mg/l)
Metabolic activation: without
Result: positive
Method: other: HGPRT assay
Year: **GLP:** no data
Test substance: no data
Remark: A dose-related increase in the frequency of 6-thioguanine resistance in the HPRT gene locus was observed at doses of 0.3 to 1.0 mM. Accordding to the authors, 0.1 and 1.0 mM decreased the colony-forming ability.
Reliability: 2 (reliable with restrictions)
Source: BASF AG Ludwigshafen
Test substance: formaldehyde; no data on purity of the compound

(378)

Type: other: in vitro gene mutations – eukaryotes (mammalian cells)
System of testing: V79 cells
Concentration: (a) 1.0-15 mg/l, 6 h; (b) 1.0-7.5 mg/l, 4 h; (c) 1.0-7.5 mg/l, 2x2 h; (d) 1.0-7.7 mg/l, 3x2 h
Metabolic activation: without
Result: positive
Method: other: HGPRT assay
Year: **GLP:** no data
Test substance: no data
Remark: – Treatment for 6 h: a slight increase in the mutation rates was observed at 15 mg/l (protocol (a)).
– Treatment for 4 h: a slight increase in the mutation frequency was observed at >= 5 mg/l (protocol (b)).
– 2 treatments for 2 h (with an interval of 24 h): a clearly positive and dose-dependent reaction was observed already at the lowest dose (protocol (c)).
– 3 treatments for 2 h (with a day): a clearly positive and dose-dependent reaction was observed already at the lowest dose; the degree of the reaction increased dose-dependently (protocol (d)).
According to the authors, significantly higher mutation rates were observed after 2 treatments on 2 consecutive days compared to 3 treatments within 1 day.
Reliability: 2 (reliable with restrictions)
Source: BASF AG Ludwigshafen
Test substance: formaldehyde; no data on purity of the compound

(301)

Type: other: in vitro gene mutations – eukaryotes (mammalian cells)
System of testing: human lymphoblasts (hprt locus)
Concentration: 150 uM (ca. 4.5 mg/l)
Metabolic activation: without
Result: positive
Method: other: HGPRT assay
Year: **GLP:** no data
Test substance: no data
Remark: Visible deletions were found in 14/30 DNAs; only abstract available; no further data.
Source: BASF AG Ludwigshafen
Test substance: formaldehyde; no data on purity of the compound
Reliability: (2) valid with restrictions

(367)

Type: other: in vitro gene mutations – eukaryotes (mammalian cells)
System of testing: human lymphoblasts
Concentration: 15 – 150 uM (ca. 0.45 – 4.5 mg/l)
Metabolic activation: without
Result: positive
Method: other: HGPRT assay
Year: **GLP:** no data
Test substance: no data
Remark: Induction of mutants at a concentration of > 15 uM with a maximum of 4.8x10E-6 at 150 uM; cytotoxicity was detected > 50 uM; only abstract available; no further data.
Reliability: 2 (reliable with restrictions)
Source: BASF AG Ludwigshafen
Test substance: formaldehyde; no data on purity of the compound

(379)

Type: other: in vitro gene mutations – eukaryotes (mammalian cells)
System of testing: CHO/HPRT cells (hprt locus) and AS52/XRPT (gpt locus)
Concentration: 37% (w/v)
Metabolic activation: with and without
Result: positive
Method: other: HGPRT assay
Year: **GLP:** no data
Test substance: no data
Remark: Equivocal results were obtained for induction of HPRT mutants without S-9; weak response with S-9 (prepared from liver homogenate of Aroclor induced rats). Significant induction of the mutant frequencies at the gpt locus was observed with and without S-9. According to the authors, mutation induction varied considerably between the 2 cell lines.
Reliability: 2 (reliable with restrictions)
Source: BASF AG Ludwigshafen
Test substance: formaldehyde; no data on purity of the compound

(380)

Type: other: in vitro gene mutations – eukaryotes (mammalian cells)
System of testing: AS52/XPRT cells (gpt locus)
Concentration: 50 mg/l
Metabolic activation: with
Result: positive
Method: other: HGPRT assay
Year: **GLP:** no data
Test substance: no data
Remark: An increase in the mutant frequencies at the gpt locus was observed in the presence of S–9 prepared from liver homogenate of Aroclor induced rats.
Reliability: 2 (reliable with restrictions)
Source: BASF AG Ludwigshafen
Test substance: formaldehyde; no data on purity of the compound
(381)

Type: other: in vitro gene mutations – eukaryotes (mammalian cells)
System of testing: CHO cells (hprt locus)
Concentration: up to 0.05 mg/l
Metabolic activation: without
Result: negative
Method: other: HGPRT assay
Year: **GLP:** no data
Test substance: no data
Remark: No mutagenicity was observed after exposure to vapours of the test substance for 1 h without S–9.
Reliability: 2 (reliable with restrictions)
Source: BASF AG Ludwigshafen
Test substance: formaldehyde; no data on purity of the compound
(382)

Type: other: in vitro gene mutations – eukaryotes (mammalian cells)
System of testing: human fibroblasts
Concentration: 100 mM (ca. 3000 mg/l)
Metabolic activation: without
Result: positive
Method: other: HGPRT assay
Year: **GLP:** no data
Test substance: no data
Remark: Induction of 6–thioguanine–resistant mutants was observed.
Reliability: 2 (reliable with restrictions)
Source: BASF AG Ludwigshafen
Test substance: formaldehyde; no data on purity of the compound
(272)

Type: other: in vitro gene mutations – eukaryotes (mammalian cells)
System of testing: human fibroblasts
Concentration: 50, 75 uM (ca. 1.5, 2.25 mg/l)
Metabolic activation: without
Result: negative
Method: other: HGPRT assay
Year: **GLP:** no data
Test substance: no data
Remark: No induction of 6–thioguanine–resistant mutants was observed.
Reliability: 2 (reliable with restrictions)
Source: BASF AG Ludwigshafen
Test substance: formaldehyde; no data on purity of the compound

(271)

Type: other: in vitro gene mutations – eukaryotes (mammalian cells)
System of testing: mouse lymphoma cells L5178Y (TK+/–)
Concentration: (a) 0.008–0.020 ul/ml (–S–9, –FDA); (b) 0.008–0.024 ul/ml (–S–9, +FDA); (c) 0.04–0.065 ul/ml (+S–9, +–FDA)
Metabolic activation: with and without
Result: positive
Method: other: Mouse lymphoma assay
Year: **GLP:** no data
Test substance: no data
Remark:
– About 30–fold increase in mutation frequency in the absence of both S–9 and formaldehyde dehydrogenase (FDA) and its co–factor NAD+. Parallel to the increasing mutant frequency, total cell growth declined to zero (protocol (a)).
– Negative resonse in mutation frequency in the absence of S–9 and presence of FDA / NAD+. No change in cell growth was observed (protocol (b)).
– About 10 fold increase in mutation frequency in the presence of S–9 (prepared from liver homogenate of Aroclor pretreated rats) and absence of FDA / NAD+; parallel to the increasing mutant frequency, total cell growth declined 10%. Negative response in the presence of both S–9 and FDA / NAD+; no change in cell growth was observed (protocol (c)).
Reliability: 2 (reliable with restrictions)
Source: BASF AG Ludwigshafen
Test substance: formaldehyde; no data on purity of the compound

(383)

Type: other: in vitro gene mutations – eukaryotes (mammalian cells)
System of testing: mouse lypmoma cells L5178Y (TK+/–)
Concentration: 140 – 260 umoles/l (ca. 4.2 – 7.8 mg/l)
Metabolic activation: without
Result: positive
Method: other: Mouse lymphoma assay
Year: **GLP:** no data
Test substance: no data
Remark: Clear increase in the forward mutation frequency without dose-response
Reliability: 2 (reliable with restrictions)
Source: BASF AG Ludwigshafen
Test substance: formaldehyde; no data on purity of the compound

(384)

Type: other: in vitro gene mutations – eukaryotes (mammalian cells)
System of testing: mouse lypmoma cells L5178Y (TK+/–)
Concentration: no data
Metabolic activation: with and without
Result: positive
Method: other: Mouse lymphoma assay
Year: **GLP:** no data
Test substance: no data
Remark: A dose-related increase in TK forward mutation was observed in the absence and presence of S-9; only abstract available; no further data.
Source: BASF AG Ludwigshafen
Test substance: formaldehyde; no data on purity of the compound
Reliability: (3) invalid

(293)

Type: other: in vitro gene mutations – eukaryotes (mammalian cells)
System of testing: mouse lypmoma cells L5178Y (TK+/–)
Concentration: 0.06 – 15 mg/l (–S-9), 0.06 – 3.8 mg/l (+S-9)
Metabolic activation: with and without
Result: positive
Method: other: Mouse lymphoma assay
Year: **GLP:** no data
Test substance: no data
Remark: Positive response from ca. 7.5 ug/ml and 1.9 ug/ml in the absence and presence of S-9 (prepared from liver homogenate of Aroclor pretreated rats), respectively. According to the author, the presence of S-9 lowered the minimum effecitve mutagenic concentration.
Reliability: 2 (reliable with restrictions)
Source: BASF AG Ludwigshafen
Test substance: formaldehyde; no data on purity of the compound

(292)

Type: other: in vitro gene mutations – eukaryotes (mammalian cells)
System of testing: mouse lypmoma cells L5178Y (TK+/–)
Concentration: 0.4–0.9 mM (ca. 1.2–27 mg/l) (+S–9), 0.07–0.2 mM (ca. 2.1–6 mg/l) (–S–9)
Metabolic activation: with and without
Result: positive
Method: other: Mouse lymphoma assay
Year: **GLP:** no data
Test substance: no data
Remark: Dose–dependent increase in mutant frequency (2–18 fold). Coadministration of formaldehyde dehydrogenase and NAD+ completely eliminated both toxicity and mutagenicity; only abstract available; no further data.
Reliability: 2 (reliable with restrictions)
Source: BASF AG Ludwigshafen
Test substance: formaldehyde; no data on purity of the compound

(385)

Type: other: in vitro gene mutations – eukaryotes (mammalian cells)
System of testing: mouse lypmoma cells L5178Y (TK+/–)
Concentration: no data
Metabolic activation: without
Result: positive
Method: other: Mouse lymphoma assay
Year: **GLP:** no data
Test substance: no data
Remark: only abstract available; no further data.
Source: BASF AG Ludwigshafen
Test substance: formaldehyde; no data on purity of the compound
Reliability: (3) invalid

(386)

Type:
System of testing:
Concentration:
Metabolic activation:
Result:
Method:
Year: **GLP:**
Test substance:
Remark: Pas de données disponibles
Source: PROTEX S.A LEVALLOIS PERRET

Type:
System of testing:
Concentration:
Metabolic activation:
Result:
Method:
Year: **GLP:**
Test substance:
Source: STRATHCLYDE CHEMICAL COMPANY LIMITED JOHNSTONE

5.6 Genetic Toxicity 'in Vivo'

Type: Cytogenetic assay
Species: rat **Sex:** no data
Strain: Wistar
Route of admin.: inhalation
Exposure period: 5 d, 6 h/d
Doses: 0.1 – 20 ppm (ca. 0.0001 – 0.025 mg/l)
Result:
Method: other: ex vivo (in vitro/in vivo) chromosomal aberrations – eukaryotes (mammalian cells)
Year: **GLP:** no data
Test substance: no data
Remark: Reliability: 2 (reliable with restrictions)
Result: positive

Chromosome analysis of nasal epithelial cells nasal–, maxillar– and ethmoturbinates) was performed. Application of the test substance via inhalation route resulted in an increase in the number of aberrant metaphases only at a dose level of 20 ppm; additionally, a 30% reduction of the mitotic index was observed at this dose level. Positive reaction was observed in nasal– and maxillar–, but not in ethmoturbinates.
Source: BASF AG Ludwigshafen
Test substance: formaldehyde; no data on purity of the compound

(301)

Type: Cytogenetic assay
Species: mouse **Sex:** female
Strain: ICR
Route of admin.: i.v.
Exposure period: no data
Doses: 1.5, 3.0 mg
Result:
Method: other: ex vivo (in vitro/in vivo) chromosomal aberrations – eukaryotes (mammalian cells)
Year: **GLP:** no data
Test substance: no data
Remark: Reliability: 3 (not reliable)
Result: positive

Injection of the test substance into the tail vein of pregnant mice resulted in induction of chromosomal

aberrations (gaps, breaks, and exchanges) in fetal liver cells. No further data; interpretation of the results is not possible.
Source: BASF AG Ludwigshafen
Test substance: formaldehyde; no data on purity of the compound

(387)

Type: Cytogenetic assay
Species: Drosophila melanogaster **Sex:** no data
Strain: no data
Route of admin.: unspecified
Exposure period: no data
Doses: no data
Result:
Method: other: in vivo chromosomal aberrations – eukaryotes (non-mammalian/Drosophila)
Year: **GLP:** no data
Test substance: no data
Remark: Reliability: 2 (reliable with restrictions)
Result: positive

ADH system; deletions were recognized by the absence of salivary chromosome bands; 14 out of 18 induced lesions were found to be deletions, 4 mutants exhibited no detectable loss of genetic material.
Source: BASF AG Ludwigshafen
Test substance: formaldehyde; no data on purity of the compound

(388)

Type: Cytogenetic assay
Species: rat **Sex:** female
Strain: other: no data
Route of admin.: inhalation
Exposure period: no data
Doses: 0.0005, 0.0015 mg/l
Result:
Method: other: in vivo chromosomal aberrations – mammals (germ cells)
Year: **GLP:** no data
Test substance: no data
Remark: Reliability: 3 (not reliable)
Result: positive

Germ cell chromosome analysis; harmful effect was noted only at the high dose. Russian publication with English abstract.
Source: BASF AG Ludwigshafen
Test substance: formaldehyde; no data on purity of the compound

(389)

Type: Cytogenetic assay
Species: mouse **Sex:** male
Strain: other: Q–strain
Route of admin.: i.p.
Exposure period: single dose
Doses: 50 mg/kg
Result:
Method: other: in vivo chromosomal aberrations – mammals (germ cells)
Year: **GLP:** no data
Test substance: no data
Remark: Reliability: 2 (reliable with restrictions)
Result: negative

After a single i.p. injection of the test substance, 2 males/day were analyszed (scoring of a total of 400 spermatocytes for spermatocyte I chromosome analysis): no increase in chromosomal lesions were observed on days 8–15 after treatment, i.e. during diakinese–metaphase 1.
Source: BASF AG Ludwigshafen
Test substance: formaldehyde; no data on purity of the compound

(390)

Type: Cytogenetic assay
Species: rat **Sex:** male/female
Strain: Fischer 344
Route of admin.: inhalation
Exposure period: 5 days, 6 h/d
Doses: 15 ppm (ca. 0.019 mg/l)
Result:
Method: other: in vivo chromosomal aberrations – mammals (somatic cells)
Year: **GLP:** no data
Test substance: no data
Remark: Reliability: 2 (reliable with restrictions)
Result: negative

Lymphocytes chromosome analysis was carried out with 3 animals/sex/dose group. Fifty first–division metaphases were scored. No significant effects on mitotic activity and no increase in chromosomal aberrations were observed.
Source: BASF AG Ludwigshafen
Test substance: formaldehyde; no data on purity of the compound

(391)

Type: Cytogenetic assay
Species: rat **Sex:** no data
Strain: Sprague–Dawley
Route of admin.: inhalation
Exposure period: 1 week, 2, 4, 6 months; 5 d/w, 6 h/d
Doses: 0.5 – 15 ppm (ca. 0.0006 – 0.019 mg/l)
Result:
Method: other: in vivo chromosomal aberrations – mammals (somatic cells)
Year: **GLP:** no data
Test substance: no data
Result: negative in bone marrow;
positive in pulmonary alveolar macrophage

Four to 5 animals per group were sacrificed after 1 week, 2, 4, and 6 months of treatment; 50 cells/animal were scored for bone marrow and pulmonary alveoar macrophage chromosome analysis. After 1 week and after 2 months, no increase in chromosomal aberrations was observed in bone marrow but a 2–fold increase in chromosomal aberrations (mostly chromatid–type) over background was found in pulmonary alveolar macrophages. After 4 and 6 months of treatment, there were not enough cell available for scoring. Only abstract available; no further data.
Source: BASF AG Ludwigshafen
Test substance: formaldehyde; no data on purity of the compound
Reliability: (3) invalid

(392)

Type: Cytogenetic assay
Species: mouse **Sex:** male/female
Strain: CBA
Route of admin.: i.p.
Exposure period: 2 injections
Doses: 6.25 – 25 mg/kg
Result:
Method: other: in vivo chromosomal aberrations – mammals (somatic cells)
Year: **GLP:** no data
Test substance: no data
Remark: Reliability: 2 (reliable with restrictions)
Result: negative

The test substance was administered to 3–5 mice/sex/group by 2 intraperitoneal injections with an interval of 24 h. Cells of bone marrow and spleen were sampled for chromosome analysis 16 an 40 h after the 2nd injection. No induction of chromosomal aberration was observed.
Source: BASF AG Ludwigshafen
Test substance: formaldehyde; no data on purity of the compound

(298)

Type: Cytogenetic assay
Species: rat **Sex:** no data
Strain: Sprague–Dawley
Route of admin.: inhalation
Exposure period: 1 or 8 weeks; 5 d/w, 6 h/d
Doses: 0.5 – 15 ppm (ca. 0.0006 – 0.019 mg/l)
Result:
Method: other: in vivo chromosomal aberrations – mammals (somatic cells)
Year: **GLP:** no data
Test substance: no data
Remark: Reliability: 2 (reliable with restrictions)
Result: negative in bone marrow;
positive in pulmonary macrophages

The test substance was administered to 4–5 animals, 50 cells/animal of bone marrow and pulmonary macrophages were scored for chromosome analysis. No increase in the number of chromosomal aberration was observed in bone marrow. In pulmonary macrophages, a slight but dose–related increase in cells with chromosomal abnormalities was observed after 1 and 8 weeks; this increase was significant at a dose of 15 ppm (ca. 0.019 mg/l).
Source: BASF AG Ludwigshafen
Test substance: formaldehyde; no data on purity of the compound

(393)

Type: Cytogenetic assay
Species: rat **Sex:** no data
Strain: other: no data
Route of admin.: inhalation
Exposure period: 4 months
Doses: 0.0005, 0.0015 mg/l
Result:
Method: other: in vivo chromosomal aberrations – mammals (somatic cells)
Year: **GLP:** no data
Test substance: no data
Remark: Reliability: 3 (not reliable)
Result: positive

Bone marrow chromosome analysis; an increase in the number of chromosomal aberrations and aneuploid cells was observed. Russian publication with English abstract.
Source: BASF AG Ludwigshafen
Test substance: formaldehyde; no data on purity of the compound

(394)

Type: Cytogenetic assay
Species: rat **Sex:** female
Strain: other: no data
Route of admin.: inhalation
Exposure period: chronic; no data specified
Doses: 0.0005, 0.0015 mg/l
Result:
Method: other: in vivo chromosomal aberrations – mammals (somatic cells)
Year: **GLP:** no data
Test substance: no data
Remark: Reliability: 3 (not reliable)
Result: positive

Bone marrow chromosome analysis; clastogenic effects were observed at both doses after chronic inhalation. Russian publication with English abstract.
Source: BASF AG Ludwigshafen
Test substance: formaldehyde; no data on purity of the compound

(389)

Type: Cytogenetic assay
Species: mouse **Sex:** no data
Strain: CD–1
Route of admin.: inhalation
Exposure period: 4 or 5 days, 6 h/d
Doses: 6 and 12 ppm (ca. 0.007 and 0.015 mg/l) for 5 days or 25 ppm (ca. 0.03 mg/l) for 4 days
Result:
Method: other: in vivo chromosomal aberrations – mammals (somatic cells)
Year: **GLP:** no data
Test substance: no data
Remark: Reliability: 2 (reliable with restrictions)
Result: negative

Preliminary results of bone marrow chromosome analysis; no increase in the number of chromosomal aberrations.
Source: BASF AG Ludwigshafen
Test substance: formaldehyde; no data on purity of the compound

(292)

Type: Cytogenetic assay
Species: mouse **Sex:** no data
Strain: other: no data
Route of admin.: i.p.
Exposure period: 3 daily doses
Doses: 15 – 60 mg/kg
Result:
Method: other: in vivo chromosomal aberrations – mammals (somatic cells)
Year: **GLP:** no data
Test substance: no data
Remark: Reliability: 3 (not reliable)
Result: positive

Bone marrow chromosome analysis; dose–related response of structural aberrations, especially of centric fusions; 3 daily doses. Only abstract available; no further data.
Source: BASF AG Ludwigshafen
Test substance: formaldehyde; no data on purity of the compound

(395)

Type: Cytogenetic assay
Species: mouse **Sex:** female
Strain: other: no data
Route of admin.: oral unspecified
Exposure period: no data
Doses: 100 mg/kg
Result:
Method: other: in vivo chromosomal aberrations – mammals (somatic cells)
Year: **GLP:** no data
Test substance: no data
Remark: Reliability: 3 (not reliable)
Result: positive

A bone marrow chromosome analysis revealed an increase in the incidence of chromosomal aberrations, particularly aneuploidy and exchanges. Only abstract available; no further data.
Source: BASF AG Ludwigshafen
Test substance: formaldehyde; no data on purity of the compound

(396)

Type: Cytogenetic assay
Species: mouse **Sex:** female
Strain:
Route of admin.:
Exposure period:
Doses: 30 MG/L
Result:
Method:
Year: **GLP:**
Test substance:
Source: STRATHCLYDE CHEMICAL COMPANY LIMITED JOHNSTONE

(207)

Type: Dominant lethal assay
Species: mouse **Sex:** male
Strain: other: ICR/Ha Swiss
Route of admin.: i.p.
Exposure period: single dose
Doses: (a) 32–40 mg/kg, 3 weeks of mating; (b) 16–20 mg/kg, 3 weeks of mating; (c) 16–20 mg/kg, 8 weeks of mating
Result:
Method: other: in vivo chromosomal aberrations – mammals (germ cells)
Year: **GLP:** no
Test substance: no data
Remark: Reliability: 2 (reliable with restrictions)
Result: negative

Five to 9 treated males were used. Each male was caged with 3 untreated females which were replaced weekly for 3 or 8 consecutive weeks. Mortality was observed in all dose groups. No induction of dominant lethal effects was found.
Source: BASF AG Ludwigshafen
Test substance: formaldehyde; no data on purity of the compound

(158)

Type: Dominant lethal assay
Species: mouse **Sex:** male
Strain: CD–1
Route of admin.: i.p.
Exposure period: no data
Doses: 20 mg/kg
Result:
Method: other: in vivo chromosomal aberrations – mammals (germ cells)
Year: **GLP:** no
Test substance: no data
Remark: Reliability: 2 (reliable with restrictions)
Result: negative

Each treated male was caged with 3 untreated females which were replaced weekly for 8 consecutive weeks. No induction of dominant lethal effects was observed.
Source: BASF AG Ludwigshafen
Test substance: formaldehyde; no data on purity of the compound

(397)

Type: Dominant lethal assay
Species: mouse **Sex:** no data
Strain: other: no data
Route of admin.: oral unspecified
Exposure period: no data
Doses: 70 mg/kg
Result:
Method: other: in vivo chromosomal aberrations – mammals (germ cells)
Year: **GLP:** no data
Test substance: no data
Remark: Reliability: 3 (not reliable)
Result: negative

No induction of dominant lethal efffect was observed after oral administration of the test substance. Japanese publication with English abstract.
Source: BASF AG Ludwigshafen
Test substance: formaldehyde; no data on purity of the compound

(398)

Type: Dominant lethal assay
Species: mouse **Sex:** male
Strain: other: Q–strain
Route of admin.: i.p.
Exposure period: single dose
Doses: 50 mg/kg
Result:
Method: other: in vivo chromosomal aberrations – mammals (germ cells)
Year: **GLP:** no data
Test substance: no data
Remark: Reliability: 3 (not reliable)
Result: positive

After a single i.p. injection of the test substance, 10 males were caged with 2 untreated females each which were replaced weekly for 7 weeks. According to the author, substance–related effects were observed in the 1st and 3rd weeks.
Source: BASF AG Ludwigshafen
Test substance: formaldehyde; no data on purity of the compound

(390)

Type: Drosophila SLRL test
Species: Drosophila melanogaster **Sex:** male
Strain: other: no data
Route of admin.: oral feed
Exposure period: no data
Doses: 1100, 2600 ppm
Result:
Method: other: in vivo gene mutations – eukaryotes (non-mammalian/Drosophila)
Year: **GLP:** no data
Test substance: no data
Remark: Reliability: 2 (reliable with restrictions)
Result: positive

Treated males (larvae) were mated only twice and left with 3 BASC-females for 1 dayonly. During the treatment period, spermatogonia were the only germ cells present. Mutagenicity was observed (total number of lethals per number tested was 37/5833 and 69/2445 in the 1100 and 2600 ppm group, respectively).
Source: BASF AG Ludwigshafen
Test substance: formaldehyde; no data on purity of the compound

(399)

Type: Drosophila SLRL test
Species: Drosophila melanogaster **Sex:** male
Strain: other: no data
Route of admin.: oral feed
Exposure period: during first instar larval stage
Doses: 0.25 % (ca. 2.5 mg/g)
Result:
Method: other: in vivo gene mutations – eukaryotes (non-mammalian/Drosophila)
Year: **GLP:** no data
Test substance: no data
Remark: Reliability: 2 (reliable with restrictions)
Result: positive

Raising of first-instar larvae on formaldehyde-containing medium resulted in an induction of lethal mutations.
Source: BASF AG Ludwigshafen
Test substance: formaldehyde; no data on purity of the compound

(400)

Type: Drosophila SLRL test
Species: Drosophila melanogaster **Sex:** male
Strain: other: no data
Route of admin.: oral feed
Exposure period: 3 days
Doses: 12000 ppm (ca. 12 mg/g)
Result:
Method: other: in vivo gene mutations – eukaryotes (non–mammalian/Drosophila)
Year: **GLP:** no data
Test substance: no data
Remark: Reliability: 2 (reliable with restrictions)
Result: negative

Feeding of the test substance for 3 days did not induce sex–linked recessive lethal mutations.
Source: BASF AG Ludwigshafen
Test substance: formaldehyde; no data on purity of the compound

(401)

Type: Drosophila SLRL test
Species: Drosophila melanogaster **Sex:** male
Strain: other: no data
Route of admin.: other: injection
Exposure period: no data
Doses: 2000 ppm
Result:
Method: other: in vivo gene mutations – eukaryotes (non–mammalian/Drosophila)
Year: **GLP:** no data
Test substance: no data
Remark: Reliability: 2 (reliable with restrictions)
Result: positive

Injection of the test substance resulted in an induction of sex–linked recessive lethal mutations but not in an induction of reciprocal translocations.
Source: BASF AG Ludwigshafen
Test substance: formaldehyde; no data on purity of the compound

(401)

Type: Drosophila SLRL test
Species: Drosophila melanogaster **Sex:** male
Strain: other: no data
Route of admin.: oral feed
Exposure period: no data
Doses: 1000 ppm
Result:
Method: other: in vivo gene mutations – eukaryotes (non–mammalian/Drosophila)
Year: **GLP:** no data
Test substance: no data
Remark: Reliability: 2 (reliable with restrictions)
Result: positive

Larval feeding of the test substance resulted in a 6–fold increase of the mutation frequency.

Source: BASF AG Ludwigshafen
Test substance: formaldehyde; no data on purity of the compound

(381)

Type: Drosophila SLRL test
Species: Drosophila melanogaster **Sex:** male
Strain: other: no data
Route of admin.: oral feed
Exposure period: no data
Doses: according to the authors, a concentration which allowed 50% of the larvae to develop to the adult stage
Result:
Method: other: in vivo gene mutations – eukaryotes (non–mammalian/Drosophila)
Year: **GLP:** no data
Test substance: no data
Remark: Reliability: 2 (reliable with restrictions)
Result: positive

Larval feeding of the test substance resulted in an induction of lethal mutations; no induction of lethal mutations was observed after feeding of adults. The mutagenic effect of the treatment on the male germ–line cells was tested by the M–5 technique.
Source: BASF AG Ludwigshafen
Test substance: formaldehyde; no data on purity of the compound

(402)

Type: Drosophila SLRL test
Species: Drosophila melanogaster **Sex:** male
Strain: other: no data
Route of admin.: oral feed
Exposure period: no data
Doses: 20 mM (ca. 600 mg/l)
Result:
Method: other: in vivo gene mutations – eukaryotes (non–mammalian/Drosophila)
Year: **GLP:** no data
Test substance: no data
Remark: Reliability: 2 (reliable with restrictions)
Result: positive

Significant effects on the induction of sex–linked recessive lethals was observed.
Source: BASF AG Ludwigshafen
Test substance: formaldehyde; no data on purity of the compound

(403)

Type: Drosophila SLRL test
Species: Drosophila melanogaster **Sex:** male
Strain: other: no data
Route of admin.: other: injection
Exposure period: no data
Doses: 25, 50 mM (ca. 750, 1500 mg/l)
Result:
Method: other: in vivo gene mutations – eukaryotes (non–mammalian/Drosophila)
Year: **GLP:** no data
Test substance: no data
Remark: Reliability: 2 (reliable with restrictions)
Result: positive

A dose–related increase in mutagenicity was observed: raising the concentration from 25 to 50 mM resulted in an 8–fold increase of sex–linked recessive lethals.
Source: BASF AG Ludwigshafen
Test substance: formaldehyde; no data on purity of the compound

(404)

Type: Micronucleus assay
Species: rat **Sex:** no data
Strain: Wistar
Route of admin.: inhalation
Exposure period: 5 days or 4 weeks (5 d/wk); 6 h/d
Doses: (a) 20 ppm (ca. 0.025 mg/l) for 4 weeks; (b) 0.1–20 ppm (ca. 0.0001–0.025 mg/l) for 5 days; (c) 0.5–1.0 ppm (ca. 0.0006–0.0012 mg/l) for 4 weeks
Result:
Method: other: ex vivo (in vitro/in vivo) chromosomal aberrations – eukaryotes (mammalian cells)
Year: **GLP:** no data
Test substance: no data
Remark: Reliability: 2 (reliable with restrictions)
Result: positive

Chromosome analysis of nasal epithelial cells (nasal– and maxillarturbinates in all experiments; ethmoturbinates only in experiment (a)) was performed. Application of the test substance via inhalation route resulted in an increase in the number of micronucleated cells; positive reaction was observed in nasal– and maxillar–, but not in ethmoturbinates. The effects were more pronounced in nasal– than in maxillar turbinates (experiment (a)). In experinment(b) and (c), an increase in micronucleated cells was observed only at the highest dose levels.
Source: BASF AG Ludwigshafen
Test substance: formaldehyde; no data on purity of the compound

(301)

Type: Micronucleus assay
Species: other: Pleurodeles waltl (newt) **Sex:** no data
Strain: no data
Route of admin.: unspecified
Exposure period: 8 days
Doses: 5 ppm
Result:
Method: other: in vivo chromosomal aberrations – eukaryotes (non-mammalian)
Year: **GLP:** no data
Test substance: no data
Remark: Reliability: 2 (reliable with restrictions)
Result: negative

The micronuclei were analyzed in blood smears after larval treatment (scoring of >1000 cells). According to the authors, the dose corresponded to half the concentration which did not induce toxicity. No clastogenic effects were observed.
Source: BASF AG Ludwigshafen
Test substance: formaldehyde; no data on purity of the compound

(405)

Type: Micronucleus assay
Species: other: Pleurodeles waltl (newt) **Sex:** no data
Strain: no data
Route of admin.: unspecified
Exposure period: 12 days
Doses: 5 ug/ml
Result:
Method: other: in vivo chromosomal aberrations – eukaryotes (non-mammalian)
Year: **GLP:** no data
Test substance: no data
Remark: Reliability: 2 (reliable with restrictions)
Result: negative

The micronuclei were analyzed in peripheral blood erythrocytes after larval treatment (scoring of 1000 cells).No clastogenic effects were observed.
Source: BASF AG Ludwigshafen
Test substance: formaldehyde; no data on purity of the compound

(312)

Type: Micronucleus assay
Species: other: Pleurodeles waltl (newt) **Sex:** no data
Strain: no data
Route of admin.: unspecified
Exposure period: 1 week
Doses: 5 ppm
Result:
Method: other: in vivo chromosomal aberrations – eukaryotes (non–mammalian)
Year: **GLP:** no data
Test substance: no data
Result: negative

After larval treatment, red blood cells were scored. No clastogenic effects were observed. Only abstract available; no further data.
Source: BASF AG Ludwigshafen
Test substance: formaldehyde; no data on purity of the compound
Reliability: (3) invalid

(406)

Type: Micronucleus assay
Species: other: Pleurodeles waltl (newt) **Sex:** no data
Strain: no data
Route of admin.: unspecified
Exposure period: 1 week
Doses: 5 ppm
Result:
Method: other: in vivo chromosomal aberrations – eukaryotes (non–mammalian)
Year: **GLP:** no data
Test substance: no data
Remark: Reliability: 2 (reliable with restrictions)
Result: negative

After larval treatment, red blood cells were scored. No clastogenic effects were observed. Doses >5 ppm were toxic.
Source: BASF AG Ludwigshafen
Test substance: formaldehyde; no data on purity of the compound

(407)

Type: Micronucleus assay
Species: mouse **Sex:** male/female
Strain: NMRI
Route of admin.: i.p.
Exposure period: 2 injections
Doses: 10 – 30 mg/kg
Result:
Method: other: in vivo chromosomal aberrations – mammals (somatic cells)
Year: **GLP:** no data
Test substance: no data
Remark: Reliability: 2 (reliable with restrictions)
Result: negative

The test substance was applied 6 and 30 h prior to sacrifice of 2 animals/sex/dose group. Bone marrow was prepared, 1000

polychromatic erythrocytes per animal were analyzed. No increase in the number of micronuclei in polychromatic erythrocytes were observed.
Source: BASF AG Ludwigshafen
Test substance: formaldehyde; no data on purity of the compound

(359)

Type: Micronucleus assay
Species: rat **Sex:** male
Strain: Sprague–Dawley
Route of admin.: gavage
Exposure period: single dose
Doses: 200 mg/kg
Result:
Method: other: in vivo chromosomal aberrations – mammals (somatic cells)
Year: **GLP:** no data
Test substance: no data
Remark: Reliability: 2 (reliable with restrictions)
Result: positive

Micronucleus test was performed by histology in cells of the gastro–intestinal epithelium (stomach, duodenum, ileum, and colon). The test substance was administered to groups of 5 animals 16, 24, and 30 h prior to sacrifice, 3000 cells for each tissue per animal were scored. An increase in the number of micronucleated cells was observed in the stomach at each time point, in the duodenum after 24 h and in the cells of both ileum and colon after 30 h. According to the authors, the observed effects were clearly correlated with severe local irritation. Nuclear anomalies were increased in all tissues.
Source: BASF AG Ludwigshafen
Test substance: formaldehyde; no data on purity of the compound

(408)

Type: Micronucleus assay
Species: mouse **Sex:** male/female
Strain: CBA
Route of admin.: i.p.
Exposure period: 2 injections
Doses: 6.25 – 25 mg/kg
Result:
Method: other: in vivo chromosomal aberrations – mammals (somatic cells)
Year: **GLP:** no data
Test substance: no data
Remark: Reliability: 2 (reliable with restrictions)
Result: negative

The test substance was administered to 3–5 mice/sex/group by 2 intraperitoneal injections with an interval of 24 h. Bone marrow was prepared 16 an 40 h after the 2nd injection.No increase in the number of micronucleated polychromatic erythrocytes obtained from the bone marrow was observed.
Source: BASF AG Ludwigshafen
Test substance: formaldehyde; no data on purity of the compound

(298)

Type: Micronucleus assay
Species: mouse **Sex:** male/female
Strain: CD-1
Route of admin.: i.p.
Exposure period: 15 or 30 days
Doses: 5, 10 mg/kg
Result:
Method: other: in vivo chromosomal aberrations - mammals (somatic cells)
Year: **GLP:** no data
Test substance: no data
Result: ambiguous

Intraperitoneal injection of the test substance to 5 mice/sex/group resulted in increase of the micronucleus frequency in peripheral erythrocytes only in males treated with 5 mg/kg for 15 days (2-fold of control value). Only abstract available; no further data.
Source: BASF AG Ludwigshafen
Test substance: formaldehyde; no data on purity of the compound
Reliability: (3) invalid

(409)

Type: Micronucleus assay
Species: mouse **Sex:** no data
Strain: other: CD-7, C57/BL, HSD-ICR
Route of admin.: unspecified
Exposure period: chronic; no data specified
Doses: no data
Result:
Method: other: in vivo chromosomal aberrations - mammals (somatic cells)
Year: **GLP:** no data
Test substance: no data
Remark: Reliability: 3 (not reliable)
Result: positive

A peripheral erythrocyte micronucleus test resulted in positive response (2-3-fold of control) after a relatively long duration of exposure with a non linear dose-effect correlation. Only abstract available; no further data.
Source: BASF AG Ludwigshafen
Test substance: formaldehyde; no data on purity of the compound

(410)

Type: Micronucleus assay
Species: mouse **Sex:** male/female
Strain: other: CD–7
Route of admin.: i.p.
Exposure period: biweekly for 3 months
Doses: 5 – 15 mg/kg
Result:
Method: other: in vivo chromosomal aberrations – mammals (somatic cells)
Year: **GLP:** no data
Test substance: no data
Result: positive

The test substance was administered to 5 mice/sex/group; 10000 peripheral erythrocytes per animal were scored. In alldose groups, significantly higher frequencies of micronuclei(ca. 0.4%) compared to controls (ca. 0.2%) were observed; however, this increase was found only in blood samples of the first month of treatment. Only abstract available; no further data.
Source: BASF AG Ludwigshafen
Test substance: formaldehyde; no data on purity of the compound
Reliability: (3) invalid

(411)

Type: Micronucleus assay
Species: mouse **Sex:** male/female
Strain: other: no data
Route of admin.: inhalation
Exposure period: 2 hours
Doses: 281 – 299 ppm (ca. 0.35 – 0.37 mg/l; males), 253 – 273 ppm (ca. 0.31 – 0.34 mg/l; females)
Result:
Method: other: in vivo chromosomal aberrations – mammals (somatic cells)
Year: **GLP:** no data
Test substance: no data
Remark: Reliability: 3 (not reliable)
Result: negative

No formation of micronuclei was observed (bone marrow micronucleus test). Korean publication with English abstract.
Source: BASF AG Ludwigshafen
Test substance: formaldehyde; no data on purity of the compound

(412)

Type: Micronucleus assay
Species: mouse **Sex:** no data
Strain: other: LACA
Route of admin.: inhalation
Exposure period: 14 or 30 days
Doses: up to 133 ppm (ca. 0.17 mg/l)
Result:
Method: other: in vivo chromosomal aberrations – mammals (somatic cells)
Year: **GLP:** no data
Test substance: no data
Remark: Reliability: 3 (not reliable)
Result: negative

No increase in of micronucleated cells was observed (bone marrow micronucleus test). Chinese publication with English abstract.
Source: BASF AG Ludwigshafen
Test substance: formaldehyde; no data on purity of the compound

(413)

Type: Micronucleus assay
Species: mouse **Sex:** no data
Strain: other: no data
Route of admin.: oral unspecified
Exposure period: no data
Doses: 100 mg/kg
Result:
Method: other: in vivo chromosomal aberrations – mammals (somatic cells)
Year: **GLP:** no data
Test substance: no data
Remark: Reliability: 3 (not reliable)
Result: positive

A bone marrow micronucleus test revealed an increase in the incidence of micronuclei in polychromatic erythrocytes. Only abstract available; no further data.
Source: BASF AG Ludwigshafen
Test substance: formaldehyde; no data on purity of the compound

(396)

Type: Mouse spot test
Species: mouse **Sex:** female
Strain: other: see result
Route of admin.: inhalation
Exposure period: on days 8, 9, and 10 of pregnancy, 6 h/d
Doses: 0.006–0.0061 or 0.0175–0.0181 mg/l
Result:
Method: other: in vivo gene mutations – mammals (somatic cells)
Year: **GLP:** no data
Test substance: no data
Result: negative

Female C57BL/6J Han and male T–stock mice were used (exposure of mated females to formaldehyde gas). No increase in recessive spots in the offspring of the exposed mice was observed. Only abstract available; no further data.
Source: BASF AG Ludwigshafen
Test substance: formaldehyde; no data on purity of the compound
Reliability: (3) invalid

(414)

Type: Mouse spot test
Species: mouse **Sex:** female
Strain: other: no data
Route of admin.: inhalation
Exposure period: days 9–11 of pregnancy, 6 h/d
Doses: no data
Result:
Method: other: in vivo gene mutations – mammals (somatic cells)
Year: **GLP:** no data
Test substance: no data
Result: negative

No incidence of coat color spots was observed after inhalation exposure of the mice for the test substance.
Source: BASF AG Ludwigshafen
Test substance: formaldehyde; no data on purity of the compound
Reliability: (3) invalid

(292)

Type: Sister chromatid exchange assay
Species: rat **Sex:** no data
Strain: Wistar
Route of admin.: inhalation
Exposure period: 5 days or 4 weeks (5 d/wk); 6 h/d
Doses: 0.1 – 20 ppm (ca. 0.0001 – 0.025 mg/l)
Result:
Method: other: ex vivo (in vitro/in vivo) DNA damage – eukaryotes (mammalian cells/SCE)
Year: **GLP:** no data
Test substance: no data
Remark: Reliability: 2 (reliable with restrictions)
Result: positive

Nasal epithelial cells were examined for sister chromatid exchange (SCE). After exposure for 5 days, an increase in the SCE frequency was observed at 20 ppm (ca. 0.025 mg/l)

in 2/2 experiments and a slight increase was found at 1 ppm (ca. 0.0012 mg/l) in 1/2 experiments. After exposure for 4 weeks, a clear and concentration–related increase in SCE frequencies was observed at doses >= 1.0 ppm (ca. 0.0012 mg/l).

Source: BASF AG Ludwigshafen
Test substance: formaldehyde; no data on purity of the compound

(301)

Type: Sister chromatid exchange assay
Species: rat **Sex:** male/female
Strain: Fischer 344
Route of admin.: inhalation
Exposure period: 5 days, 6 h/d
Doses: 0.5 – 15 ppm (ca. 0.006 – 0.019 mg/l)
Result:
Method: other: in vivo DNA damage – mammals (somatic cells)
Year: **GLP:** no data
Test substance: no data
Remark: Reliability: 2 (reliable with restrictions)
Result: negative

Three rats/sex/dose group were used. No increase in sister chromatid exchange (SCE) frequency in lymphocytes was found; 20 second–divison metaphases/animal were scored; no significant dose–related effect on mitotic activity was observed.

Source: BASF AG Ludwigshafen
Test substance: formaldehyde; no data on purity of the compound

(391)

Type: Sister chromatid exchange assay
Species: rat **Sex:** no data
Strain: Fischer 344
Route of admin.: inhalation
Exposure period: 5 days, 6 h/d
Doses: 0.5, 6.0 ppm (ca. 0.0006, 0.0075 mg/l)
Result:
Method: other: in vivo DNA damage – mammals (somatic cells)
Year: **GLP:** no data
Test substance: no data
Result: negative

no increase in sister chromatid exchange in lymphocytes only abstract available; no further data

Source: BASF AG Ludwigshafen
Test substance: formaldehyde; no data on purity of the compound
Reliability: (3) invalid

(415)

Type: Sister chromatid exchange assay
Species: mouse **Sex:** male/female
Strain: CD–1
Route of admin.: inhalation
Exposure period: 4 or 5 days, 6 h/d
Doses: 6, 12 ppm (ca. 0.007, 0.015 mg/l) for 5 days or 25 ppm (ca. 0.03 mg/l) for 4 days
Result:
Method: other: in vivo DNA damage – mammals (somatic cells)
Year: **GLP:** no data
Test substance: no data
Result: positive

elevated levels of sister chromatid exchange in bone marrow cells at 12 and 25 ppm (ca. 0.015 and 0.03 mg/l) in females, only; preliminary results, no further data
Source: BASF AG Ludwigshafen
Test substance: formaldehyde; no data on purity of the compound
Reliability: (3) invalid

(292)

Type: Unscheduled DNA synthesis
Species: rat **Sex:** no data
Strain: other: CDF
Route of admin.: inhalation
Exposure period: 1, 3, 5 days, 6 h/d
Doses: 0.5 – 15 ppm (ca. 0.0006 – 0.019 mg/l)
Result:
Method: other: ex vivo (in vitro/in vivo) DNA damage – eukaryotes (mammalian cells/UDS)
Year: **GLP:** no data
Test substance: no data
Remark: Reliability: 2 (reliable with restrictions)
Result: negative

Tracheal epithelium, no DNA repair; no increase of cells in S–phase
Source: BASF AG Ludwigshafen
Test substance: formaldehyde; no data on purity of the compound

(303)

Type: other: DNA damage
Species: rat **Sex:** no data
Strain: Fischer 344
Route of admin.: inhalation
Exposure period: 6 hours
Doses: ca. 0.0004 – 0.0124 mg/l (0.3 – 10 ppm 14C HCHO) and 6 ppm (3H HCHO)
Result:
Method: other: in vivo DNA damage – mammals (somatic cells/DNA–protein crosslinks)
Year: **GLP:** no data
Test substance: no data
Remark: Reliability: 2 (reliable with restrictions)
Result: positive

Formation of DNA–protein crosslinks (DPC) in nasal mucosa

cells at all concentrations; the slope of the fitted concentration-response curve at 10 ppm was 7.3-fold greater than at 0.3 ppm.
Source: BASF AG Ludwigshafen
Test substance: formaldehyde; no data on purity of the compound

(416)

Type: other: DNA damage
Species: monkey **Sex:** no data
Strain: other: Rhesus
Route of admin.: inhalation
Exposure period: 6 hours
Doses: ca. 0.0009 – 0.0075 mg/l (0.7 – 6.0 ppm)
Result:
Method: other: in vivo DNA damage – mammals (somatic cells/DNA-protein crosslinks)
Year: **GLP:** no data
Test substance: no data
Remark: Reliability: 2 (reliable with restrictions)
Result: positive

Examination of formation of DNA-protein crosslinks (DPC) in middle turbinates, anterior lateral walls/septum, nasopharynx, maxillary sinuses, larynx/trachea/carina, major intrapulmonary airways, and lungs. Highest DPC concentrations in the mucosa of the middle turbinate at >=0.7 ppm (ca. 0.0009 mg/l); lower DPC concentrations in the larynx/trachea/carina and in the proximal portions of the major bronchi at >=2.0 ppm (ca. 0.0025 mg/l); no DPC in the maxillary sinuses or lung parenchyma.
Source: BASF AG Ludwigshafen
Test substance: formaldehyde; no data on purity of the compound

(417)

Type: other: DNA damage
Species: rat **Sex:** no data
Strain: Fischer 344
Route of admin.: inhalation
Exposure period: 11 weeks + 4 days
Doses: ca. 0.0009 – 0.0187 mg/l (0.7 – 15 ppm)
Result:
Method: other: in vivo DNA damage – mammals (somatic cells/DNA-protein crosslinks)
Year: **GLP:** no data
Test substance: no data
Remark: Reliability: 2 (reliable with restrictions)
Result: positive

Examinations of nasal mucosal tissue, from low and high tumor sites for DNA-protein crosslinks (DPC) after subchronic (whole body) preexposure to 0 ppm (N rats) or 0.7-15 ppm formaldehyde (PE) rats for 11 weeks + 4 days (5 d/w, 6 h/d) followed by acute (nose-only) exposure of N and PE rats to 0.7-15 ppm of H14CHO or unlabeled substance for 3 h on the 5th day of the 12th week were carried out. Acute DPC yields measured with labeled formaldehyde at the high tumor site were ca. 6-fold higher than at the low

tumor site. At 0.7 and 2.0 ppm (ca. 0.0009 and 0.0025 mg/l, respectively), no differences between PE and N rats were detected in either tissue. At 6 and 15 ppm (ca. 0.0075 and 0.0187 mg/l, respectively), acute DPC yields in the high tumor site of PE rats were approximately half those of N rats, but no differenes were detected in the low tumor site. With non-labelled formaldehyde (Interfacial DNA (IF) method) a concentration-dependent increase in DPC was observed in both groups, with yields smaller in PE than in N rats. According to the authors, these result suggested that no accumulation of DPC occurred in PE rats.

Cell proliferation was induced in PE rats at 6 ppm (high tumor site) and at 15 ppm (all sites).

Source: BASF AG Ludwigshafen
Test substance: formaldehyde; no data on purity of the compound

(214)

Type: other: DNA-Damage
Species: rat **Sex:** no data
Strain: other: Fischer 344 tracheal implant model
Route of admin.: other: instillation
Exposure period: no data
Doses: 0.0005 – 0.2% (single dose) 0.2% (3 time twice weekly)
Result:
Method: other: in vivo DNA damage – mammals (somatic cells/DNA-protein crosslinks, Alkaline filter elution assay)
Year: **GLP:** no data
Test substance: no data
Remark: Reliability: 2 (reliable with restrictions)
Result: positive

DNA-protein crosslinks (DPC) were examined in tracheal implants (OETI = Open-Ended Tracheal Implant). Formaldehyde-Phosphate Buffered Saline solutions were introduced into the OETI. A dose-dependent increase in DPC from 0.005% onward with a maximum response at 0.2% was observed. Nearly complete removal of DPC induced by either single of multiple exposure after 72 hours was recorded.

Source: BASF AG Ludwigshafen
Test substance: formaldehyde; no data on purity of the compound

(279)

Type: other: ex vivo (in vitro/in vivo) gene mutations – eukaryotes (mammalian cells)
Species: rat **Sex:** no data
Strain: Wistar
Route of admin.: inhalation
Exposure period: 5 days or 4 weeks (5 d/wk); 6 h/d
Doses: (a) 20 ppm (ca. 0.025 mg/l) for 5 days; (b) 0.1–1.0 ppm (ca. 0.0001–0.0012 mg/l) for 5 days; (c) 1.0 ppm (ca. 0.0012 mg/l) for 4 weeks
Result:
Method: other: gene mutation (HPRT)
Year: **GLP:** no data
Test substance: no data
Remark: Reliability: 2 (reliable with restrictions)
Result: positive

Nasal epithelial cells (nasal– and maxillar turbinates) were investigated. Induction of mutation at the hprt locus was observed only after exposure to 20 ppm (ca. 0.025 mg/l) for 5 days (experiment (a)).
Source: BASF AG Ludwigshafen
Test substance: formaldehyde; no data on purity of the compound

(301)

Type: other: ex vivo (in vitro/in vivo) gene mutations – eukaryotes (non–mammalian)
Species: other: Caenorhabditis elegans (nematode) **Sex:** no data
Strain: other: N2S (various strains)
Route of admin.: unspecified
Exposure period: no data
Doses: 0.01 – 1.0% (ca. 0.1 – 10.0 mg/ml)
Result:
Method:
Year: **GLP:** no data
Test substance: no data
Remark: Reliability: 2 (reliable with restrictions)
Result: positive

Mutations were observed in the unc–22 region of linkage group IV at dose levels of 0.07 and 0.1%. At 0.07%, 22 pointmutations and 11 deficiencies (forward mutation frequency was 2x10E–4) were observed; at 0.1%, 4 point mutations and 3deficiencies (forward mutations frequency was 3x10E–5) were observed. A dose level of 1.0% was lethal to the worms.
Source: BASF AG Ludwigshafen
Test substance: formaldehyde; no data on purity of the compound

(418)

Type: other: ex vivo (in vitro/in vivo) gene mutations – eukaryotes (non-mammalian)
Species: other: Caenorhabditis elegans (nematode) **Sex:** no data
Strain: no data
Route of admin.: unspecified
Exposure period: no data
Doses: 0.07 – 0.175% (ca. 0.7 – 1.75 mg/ml)
Result:
Method:
Year: **GLP:** no data
Test substance: no data
Remark: Reliability: 2 (reliable with restrictions)
Result: positive

Exposure to the test substance resulted in induction of small deficiencies. Lethality rates were 0.3% and 1.6% at dose levels of 0.07% and 0.105–0.175% formaldehyde, respectively.
Source: BASF AG Ludwigshafen
Test substance: formaldehyde; no data on purity of the compound

(419)

Type: other: ex vivo (in vitro/in vivo) gene mutations – eukaryotes (non-mammalian)
Species: other: Caenorhabditis elegans (nematode) **Sex:** no data
Strain: other: BC2200
Route of admin.: unspecified
Exposure period: no data
Doses: 0.07 – 0.18% (ca. 0.7 – 1.8 mg/ml)
Result:
Method:
Year: **GLP:** no data
Test substance: no data
Remark: Reliability: 2 (reliable with restrictions)
Result: positive

The induction of recessive lethal mutations by formaldehyde was studied. The test substance induced putative point mutations, deficiencies, and more complex lesions. Accordingto the authors, the best mutation induction was found after 4-h treatment with 0.1% formaldehyde.
Source: BASF AG Ludwigshafen
Test substance: formaldehyde; no data on purity of the compound

(420)

Type: other: ex vivo (in vitro/in vivo) gene mutations – eukaryotes (non-mammalian/Drosphila)
Species: Drosophila melanogaster **Sex:** male
Strain: other: no data
Route of admin.: unspecified
Exposure period: no data specified
Doses: 0.1% (ca. 1 mg/ml)
Result:
Method:
Year: **GLP:** no data
Test substance: no data
Remark: Reliability: 2 (reliable with restrictions)
Result: positive

Eggs and first instar larvae were exposed to the test substance. Adult males that emerged after treatment were crossed. The Adh gene from 4 formaldehyde-generated ADH-negative mutants had been cloned and sequenced. According to the authors, formaldehyde engendered both large and small deletions at the Adh locus.
Source: BASF AG Ludwigshafen
Test substance: formaldehyde; no data on purity of the compound

(421)

Type: other: gene mutation (P53)
Species: rat **Sex:** male
Strain: Fischer 344
Route of admin.: inhalation
Exposure period: 6 h/d, 5 d/w
Doses: ca. 0.019 mg/l
Result:
Method: other: no data
Year: **GLP:** no data
Test substance: other TS
Remark: No detailed data were given on method, number of animals, duration of exposure. According to the authors, the exposure was carried out as decribed by Chang et al., 1983.
Result: The aim of the study was to investigate the role of mutations of the tumor supressor gene p53 in rat nasal tumors induced by repeated inhalation exposure to formaldehyde (study of Monticello et al.). Male Fischer 344 rats were whole-body exposed to 15 ppm (ca. 0.019 mg/l) formaldehyde gas (6 h/d, 5 d/w). According to the authors, the rats were exposed until macroscopic or behavioural changes suggesting a nasal mass were observed; thereafter the rats were sacrificed. The nasal passages were dissected; sections containing tumors or other substance-related lesions were collected. Cell lines derived from rat nasal tumors induced by the test substance were investigated immunohistochemically to localize the p53 tumor suppressor gene (p53), proliferating cell nuclear antigen (PCNA), and transforming growth factor-alpha proteins (TGF-alpha proteins).
According to the authors, 5 tumors that had p53 mutations were mutant for p53 protein by immunohistochemistry and 3/6 tumors with no detected p53 mutations were immunoreactive for p53 protein, too. The presence, pattern, and

distribution of p53 staining in tissue sections were found to be dependent on the morphology of the lesion. PCNA immunoreaction was strikingly similar in pattern and distribution to p53 immunoreactivity. The pattern and distribution of immunoreactivity for TGF-alpha did not correlate with the other markers.
According to the authors, this study demonstrated that immunohistochemistry might be a useful tool to identify the sites within a tumor that might have p53 mutations. The results suggest that mutation of the p53 tumor suppressor gene might be an important step of formaldehyde-induced nasal carcinogenesis in the rat. However it is not clear if FA exposure is causally related to p53 mutation induction.

Source: BASF AG Ludwigshafen
Test substance: formaldehyde; no data on purity of the compound
Reliability: (2) valid with restrictions

(422)

Type: other: in vivo DNA damage - eukaryotes (non-mammalian/Drosphila)
Species: Drosophila melanogaster **Sex:** no data
Strain: no data
Route of admin.: oral unspecified
Exposure period: no data specified
Doses: 12.5 mM (ca. 375 mg/l)
Result:
Method: other: SMART = Somatic mutation and recombination test
Year: **GLP:** no data
Test substance: no data
Remark: Reliability: 2 (reliable with restrictions)
Result: positive

Chronic exposure of larvae; positive effect,i.e. twin (TS) and single light (LS) mosaic spots in adult flies of both sexes; formaldehyde caused high yields of small eye spots inthird larval instar. According to the authors, ca. 95% of all TS and LS induced appeared to be a result of recombinogenic activity between the 2 homologous X-chromosomes.

Source: BASF AG Ludwigshafen
Test substance: formaldehyde; no data on purity of the compound

(423)

Type: other: in vivo DNA damage – eukaryotes (non-mammalian/Drosphila)
Species: Drosophila melanogaster **Sex:** no data
Strain: no data
Route of admin.: oral unspecified
Exposure period: no data specified
Doses: 12.5 mM (ca. 375 mg/l)
Result:
Method: other: eye mosaic assay
Year: **GLP:** no data
Test substance: no data
Remark: Reliability: 2 (reliable with restrictions)
Result: positive

Chronic exposure of larvae; induction of mosaic spots with a majority of small spots: According to the authors, the events were predominantly caused by interchromosomal mitotic recombination.
Source: BASF AG Ludwigshafen
Test substance: formaldehyde; no data on purity of the compound

(424)

Type: other: in vivo DNA damage – mammals (somatic cells/DNA-protein crosslinks)
Species: rat **Sex:** no data
Strain: Fischer 344
Route of admin.: inhalation
Exposure period: 3 hours
Doses: ca. 0.0012 – 0.0075 mg/l (1 – 6 ppm)
Result:
Method: other: Alkaline filter elution assay
Year: **GLP:** no data
Test substance: no data
Result: positive

DNA-protein crosslinks (DPC) were examined in nasoturbinates and maxilloturbinates after 3-hours nose-only exposure. A dose-dependent increase of DPC from 2 ppm (ca. 0.0025 mg/l) onward was observed in both locations; DPC were readily reversible. Only abstract available; no further data.
Source: BASF AG Ludwigshafen
Test substance: formaldehyde; no data on purity of the compound
Reliability: (3) invalid

(379)

Type: other: in vivo gene mutations – eukaryotes (non–mammalian Drosophila)
Species: Drosophila melanogaster **Sex:** male
Strain: other: no data
Route of admin.: other: abdominal injection
Exposure period: no data
Doses: 25 mM (ca. 750 mg/l)
Result:
Method: other: SLRL test and Ring–X loss test
Year: **GLP:** no data
Test substance: no data
Remark: Reliability: 2 (reliable with restrictions)
Result: positive

Injection of the test substance resulted in induction of both sex–linked recessive lethals and ring–X loss in male adults. According to the authors, the low ratio sex–linked recessive lethals : ring–X loss indicated the involvement of cross–links in genotoxic action.
Source: BASF AG Ludwigshafen
Test substance: formaldehyde; no data on purity of the compound

(425)

Type: other: in vivo gene mutations – eukaryotes (non–mammalian/Drosophila)
Species: Drosophila melanogaster **Sex:** no data
Strain: other: no data
Route of admin.: oral feed
Exposure period: no data
Doses: 20 mM (ca. 600 mg/l)
Result:
Method: other: Visible mutation test
Year: **GLP:** no data
Test substance: no data
Remark: Reliability: 2 (reliable with restrictions)
Result: negative

No induction of visible mutations at several selected loci were observed.
Source: BASF AG Ludwigshafen
Test substance: formaldehyde; no data on purity of the compound

(403)

Type: other: in vivo gene mutations – eukaryotes (non-mammalian/Drosophila)
Species: Drosophila melanogaster **Sex:** no data
Strain: other: no data
Route of admin.: oral feed
Exposure period: 48 or 72 h
Doses: 10, 50 mM (ca. 300, 1500 mg/l)
Result:
Method: other: Wing SMART = Wing Somatic Mutation and Recombination Test
Year: **GLP:** no data
Test substance: no data
Remark: Reliability: 2 (reliable with restrictions)
Result: positive

Negative or inconclusive results in the repair proficient genotype but positive ones in the excision repair defective genotype, i.e. high frequency of total spots (single and twin spots) in excision repair defective wings were obtained after chronic larval feeding. Single spots were produced by pount mutation, chromosome breakage, and mitotic recombination. Twin spots were produced by mitotic recombination, exclusively. According to the authors, 72h treatment with 10 mM was less efficient than the 48h treatment with 50 mM.
Source: BASF AG Ludwigshafen
Test substance: formaldehyde; no data on purity of the compound

(426)

Type: other: in vivo gene mutations – eukaryotes (non-mammalian/Drosophila)
Species: Drosophila melanogaster **Sex:** male/female
Strain: other: no data
Route of admin.: other
Exposure period: during larval stage
Doses: according to the authors, a concentration which allowed 50% of the larvae to develop to the adult stage
Result:
Method: other: mosaic test
Year: **GLP:** no data
Test substance: no data
Remark: Reliability: 2 (reliable with restrictions)
Result: positive

Larval feeding (second instar larvae) with formaldehyde-containing food for 3-4 days until pupation resulted in an increase in the frequency of mosaic spots (eye mosaicism). Fewer clones were induced in males than in females (ca. 59% were twin spot females). Highly significant elevations in wing-clone frequency (wing mosaicism) was observed. Accoring to the authors, there was no indication of female germ-line mosaicism.
Source: BASF AG Ludwigshafen
Test substance: formaldehyde; no data on purity of the compound

(402)

Type: other: in vivo gene mutations – eukaryotes (non–mammalian/Drosophila)
Species: Drosophila melanogaster **Sex:** male
Strain: other: no data
Route of admin.: oral feed
Exposure period: during the entire larval and pupal development stages
Doses: 30 – 70 mM (ca. 900 – 2100 mg/l)
Result:
Method: other: unstable zeste–white test
Year: **GLP:** no data
Test substance: no data
Remark: Reliability: 2 (reliable with restrictions)
Result: positive

Exposure to the test substance resulted in a dose–related increase of somatic mutations (aberrantly pigmented spots in the eyes) in adult males.
Source: BASF AG Ludwigshafen
Test substance: formaldehyde; no data on purity of the compound

(427)

Type: other: in vivo gene mutations – eukaryotes (non–mammalian/Drosophila)
Species: Drosophila melanogaster **Sex:** male
Strain: other: no data
Route of admin.: oral feed
Exposure period: during larval stage
Doses: 50 mM (ca. 1500 mg/l)
Result:
Method: other: unstable zeste–white test
Year: **GLP:** no data
Test substance: no data
Remark: Reliability: 2 (reliable with restrictions)
Result: negative

Exposure of males (P fathers) to the test substance did not induce any germ cell mutations i.e. no mutations in F1 males were observed after treatment of P fathers.
Source: BASF AG Ludwigshafen
Test substance: formaldehyde; no data on purity of the compound

(427)

Type: other: in vivo gene mutations – eukaryotes (non-mammalian/Drosophila)
Species: Drosophila melanogaster **Sex:** male
Strain: other: no data
Route of admin.: oral feed
Exposure period: no data specified
Doses: 50, 160 mM (ca. 1500, 4800 mg/l)
Result:
Method: other: unstable zeste-white test
Year: **GLP:** no data
Test substance: no data
Remark: Reliability: 2 (reliable with restrictions)
Result: positive in somatic mutation;
negative in germinal mutation

An increase in delayed somatic mutations but no increase in the frequency of germinal mutations was observed in the male offspring after adult feeding. According to the authors, formaldehyde was not totally hampered from reaching the male gonads even after adult feeding, since it was capable of causing premutational DNA lesions in sperm, as revealed by the occurrance of delayed somatic spots.
Source: BASF AG Ludwigshafen
Test substance: formaldehyde; no data on purity of the compound

(427)

Type:
Species: **Sex:**
Strain:
Route of admin.:
Exposure period:
Doses:
Result:
Method:
Year: **GLP:**
Test substance:
Remark: Pas de données disponibles
Source: PROTEX S.A LEVALLOIS PERRET

5.7 Carcinogenicity

Species: mouse **Sex:** male/female
Strain: other: hairless (hr/hr, Oslo)
Route of admin.: dermal
Exposure period: 60 weeks
Frequency of treatment: twice a week
Post. obs. period: none
Doses: ca. 2, 20 mg/animal (200 ul of a 1 and 10% aqueous solution, respectively)
Result:
Control Group: no data specified
Method: other: carcinogenicity study
Year: **GLP:** no data
Test substance: no data
Remark: Reliability: 2 (reliable with restrictions)
Result: The tumorigenic effect of dermally applied formaldehyde was studied in 16 mice/sex/group. Two hundred microlitres ofa 1% and 10% aqueous solution was applied. Examinations on general health, autopsy, and histopathology of brain, nasal mucosa, lungs, skin tumors and other tumors were performed. According to the authors, no skin tumors were observed. In a few animals of the high dose group, slight hyperplasia of the epidermis and skin ulcers were found. These results were part of an initiation-promotion study.
Source: BASF AG Ludwigshafen
Test substance: formaldehyde; no data on purity of the compound

(251)

Species: mouse **Sex:** male/female
Strain: other: hairless (hr/hr, Oslo)
Route of admin.: dermal
Exposure period: up to 60 weeks
Frequency of treatment: twice a week
Post. obs. period: none
Doses: ca. 20 mg/animal (200 ul of a 10% aqueous solution)
Result:
Control Group: no data specified
Method: other: initiation-promotion study
Year: **GLP:** no data
Test substance: no data
Remark: Reliability: 2 (reliable with restrictions)
Result: The tumorigenic effect of dermally applied formaldehyde was studied. All groups were treated once with 51.2 ug dimethyl benz(a)anthracene (DMBA in acetone; initiation). Thereafter the animals were treated with 200 ul 10% aqueous solution of formaldehyde (FA) or 17 nmoles of 12-O-tetradecanoylphorbol-13acetate (TPA) twice a week for 60 or 46 weeks; these groups consisted of 16 mice/sex. Hundred and seventy-six animals remained untreated for 80 weeks after the initiation. Examinations on general health, autopsy, and histopathology of brain, nasal mucosa, lungs, and skin and other tumors were performed.

In the group treated with DMBA + FA, skin tumors were observed in 11/32 (34%) mice, 3 squamous cell carcinomas and 22 papillomas were recorded (first tumors at week 10). In the group treated with DMBA + TPA, increased mortality was observed. Incidence of skin tumors was 100% at week 20; all animals had papillomas. In the group treated with DMBA alone, skin tumors were present in 85/176 (48%) mice, 6 squamous cell carcinomas and 219 papillomas were found. The first tumors were observed after ca. 22 weeks.

In FA treated mice, the incidence of lung adenomas was low and not statistically significantly different from historical control. Thus, according to the authors, the presence of a weak promoting activity of 10% FA due to the shortening of the latency time for tumor formation was concluded.

Source: BASF AG Ludwigshafen
Test substance: formaldehyde; no data on purity of the compound

(251)

Species: mouse **Sex:** female
Strain: Sencar
Route of admin.: dermal
Exposure period: 48 weeks
Frequency of treatment: once or twice a week
Post. obs. period: none
Doses: 3.7 – 4% solution; no further data
Result:
Control Group: yes
Method: other: initiation-promotion study
Year: **GLP:** no data
Test substance: no data
Remark: Reliability: 2 (reliable with restrictions)
Result: The aim of the study was to evaluate the role of formaldehyde in carcinogenesis (as a complete carcinogen, initiator, or promotor). Groups of 30 mice were treated with formaldehyde solutions (FA; 3.7–4% in acetone), dimethylbenz(a)anthracene (DMBA; 20 ug/dose in acetone), 12-O-tetradecanoylphorbol-13-acetate (TPA; 1.25 ug/dose in acetone), acetone, or with combinations of two compounds. Aninitiator was applied once; thereafter, a promotor was applied once or twice a week for 48 weeks. The incidence of skin papilloma was recorded.

No papilloma formation was observed in mice treated with FA as both initiator and promotor; with DMBA as initiator and acetone as promotor; with FA as initiator and acetone as promotor, and in mice treated with acetone only. Few papillomas were observed in the groups applied DMBA as initiator and FA as promotor; and acetone as initiator and FA as promotor. Some papillomas were found in mice treated with FA as initiator and TPA as promotor; and with acetone as initiator and TPA as promotor. The combination of DMBA asinitiator and TPA as promotor resulted in the formation ofmany papillomas.

According to the authors, these results suggest that formaldehyde was probably not a complete carcinogen or an initiator; the data obtained on promotion effects were inconclusive. According to the authors, it was concluded that the test stubstance problably might be a very weak promotor.

Source: BASF AG Ludwigshafen
Test substance: formaldehyde; no data on purity of the compound

(428)

Species: mouse **Sex:** female
Strain: CD-1
Route of admin.: dermal
Exposure period: 26 weeks
Frequency of treatment: 3 times a week
Post. obs. period: 26 weeks
Doses: up to 10%
Result:
Control Group: yes
Method: other: initiation-promotion study
Year: **GLP:** no data
Test substance: no data
Remark: Reliability: 2 (reliable with restrictions)
Slightly higher numbers of animals at risk reported in the abstract.
Result: The aim of the study was to evaluate the role of formaldehyde in carcinogenesis (as an initiator or as a promotor). Groups of 30 mice were treated with combinations of formaldehyde solutions (FA; in acetone/water 1:1) at different concentrations, benzo(a)pyrene (BaP; 159 ug/dose in acetone), 12-O-tetradecanoylphorbol-13-acetate (TPA; 2.5 ug/dose in acetone), or acetone. The initiator was applied once (50 ul); thereafter, 100 ul of the promotor was applied 3 times a week for 26 weeks. Data on general health and the incidence of skin nodules were recorded.

No tumors (0/28) were observed in both the groups exposed to FA (initiator) plus acetone (promotor), or 10% FA (initiator) plus 1% FA (promotor). Tumor incidences in groups initiated with BaP and treated with FA as promotor were 1/25 (4%), 2/28 (7%), and 7/27 (26%) at FA concentrations of 1%, 0.5%, and 0.1%, respectively. Initiation with BaP followed by promotion with acetone as well as initiation with acetone and promotion with TPA resulted in tumor incidences of 3/27 (11%) in both cases. Five of 28 mice (18%) treated with FA (initiator) and TPA (promotor) had skin nodules. The highest tumor incidence (28/29; 97%) was observed in the group initiated with BaP and treated with TPA as promotor. The average time to the first nodule was ca. 110 days for mice treated with BaP plus TPA and ca. 350 days in all other groups.

Most of the nodules were benign tumors (keratocanthomas or papillomas; malignant tumors were histopathologically diagnosed in the BaP+TPA group, only (ca. 30% squamous cell

carcinomas). No statistically significant differences were observed between the treated groups and appropriate controlsin groups exposed to formaldehyde.

According to the authors, these results suggest that formaldehyde did not initiate or promote skin tumorigenesis in minimally irritating concentrations (in a preliminary test, a concentration of 10% FA was determined as moderately irritating, 1% caused mild irritation, 0.5% was slightly irritating; see chapter 5.4).

Source: BASF AG Ludwigshafen
Test substance: formaldehyde; no data on purity of the compound

(429) (250)

Species: rat **Sex:** male/female
Strain: Wistar
Route of admin.: drinking water
Exposure period: 104 weeks
Frequency of treatment: continuously in the drinking water
Post. obs. period: none
Doses: ca. 10, 50, 300 mg/kg/d (200, 1000, 5000 ppm in the drinking water)
Result:
Control Group: yes, concurrent no treatment
Method: other: carcinogenicity study
Year: **GLP:** no data
Test substance: no data
Result: The tumorigenic effect of orally administered formaldehyde was studied in 4 groups of 20 rats/sex (3 treated groups, 1 control group). Interim sacrifices were carried out with 6 animals/sex/group after 12 and 18 months. Examinations on general health, clinical pathology, autopsy, and histopathology of several organs were performed. The daily doses were calculated from body weight and liquid consumption: 10, 50, 300 mg/kg (200, 1000, 5000 ppm, respectively).

According to the authors, no evidence of substance induced tumors was observed. The stomach was presumed to be the target organ, since there were observed severe non–neoplastic lesions in the high dose group (squamous and basal cell hyperplasia, erosions/ulcers, and submucosal cell infiltration; see chapter 5.4).

Source: BASF AG Ludwigshafen
Test substance: formaldehyde; no data on purity of the compound
Reliability: (3) invalid

(242)

Species: rat **Sex:** male/female
Strain: Wistar
Route of admin.: drinking water
Exposure period: 104 weeks
Frequency of treatment: continuously in the drinking water
Post. obs. period: none
Doses: ca. 1.2, 15, 82 mg/kg/d (males); 1.8, 21, 109 mg/kg/d (females)
Result:
Control Group: yes, concurrent no treatment
Method: other: carcinogenicity study
Year: **GLP:** no data
Test substance: no data
Remark: Reliability: 2 (reliable with restrictions)
Result: The tumorigenic effect of orally administered formaldehyde was studied in 70 rats/sex/group (3 treated groups and 1 control group of each sex). Interim sacrifices were carried out with 10 animals/sex/group after 12 and 18 months. Examinations on general health, clinical pathology, autopsy,and histopathology of ca. 50 organs and tissues were performed. The concentrations of the test substance in the drinking water were adjusted for body weight and liquid consumption up to week 52; the average concentrations were 20, 260, and 1900 mg/l in the low, mid, and high dose groups, respectively.

According to the authors, no evidence of substance induced tumors was observed. The stomach and the kidneys were presumed to be the target organs, since there were observed severe non–neoplastic lesions in the high dose groups (papillary epithelial hyperplasia in the forestomach, chronic atrophic gastritis in the glandular stomach, renal papillary necrosis; see chapter 5.4).
Source: BASF AG Ludwigshafen
Test substance: formaldehyde; no data on purity of the compound

(239)

Species: rat **Sex:** male/female
Strain: Sprague–Dawley
Route of admin.: drinking water
Exposure period: 104 weeks
Frequency of treatment: continuously in the drinking water
Post. obs. period: up to natural death
Doses: ca. 10, 50, 100, 500, 1000, 1500 mg/l in the drinking water
Result:
Control Group: yes
Method: other: carcinogenicity study
Year: **GLP:** no data
Test substance: no data
Remark: The study (Soffritti et al., 1989) was challenged by Feron et al. (1990) because of the following reasons:
– leukemia incidence was not statistically significantly different from methanol controls and was within the range

of historical control data
- there was a lack of dose response relation for gastro-intrestinal tumors
- heterogeneity of tumor types in both leukemias and gastro-intestinal tumors
- non-neoplastic lesions were not reported
- the results were not found in other oral long term studies.

Result: The tumorigenic effect of orally administered formaldehyde was studied. Groups of 50 rats/sex were treated with the test substance at several doses, another 50 rats/sex were given 15 mg/l of methanol, and 100 rats/sex remained untreated. Examinations on general health, autopsy, and histopathology of ca. 50 tissues were performed. At the beginning of the studies, the rats were 7 weeks old.

No substance related effects on survival and body weight gain were observed. According to the authors, increased incidences in leukemia and gastro-intestinal tumors were observed. They concluded that formaldehyde was a multipotential carcinogen.

Source: BASF AG Ludwigshafen
Test substance: formaldehyde; no data on purity of the compound
Reliability: (3) invalid

(430) (431)

Species: rat **Sex:** male/female
Strain: Sprague-Dawley
Route of admin.: drinking water
Exposure period: 104 weeks
Frequency of treatment: continuously in the drinking water
Post. obs. period: up to natural death
Doses: ca. 2500 mg/l in the drinking water
Result:
Control Group: yes, concurrent no treatment
Method: other: carcinogenicity study
Year: **GLP:** no data
Test substance: no data
Remark: The study (Soffritti et al., 1989) was challenged by Feron et al. (1990) because of the following reasons:
- leukemia incidence was not statistically significantly different from methanol controls and was within the range of historical control data
- there was a lack of dose response relation for gastro-intrestinal tumors
- heterogeneity of tumor types in both leukemias and gastro-intestinal tumors
- non-neoplastic lesions were not reported
- the results were not found in other oral long term studies

Result: The tumorigenic effect of orally administered formaldehyde was studied in 25 weeks old breeding rats. A group of 18 males and 18 mated females was exposed to the test substancefrom days 12 of gestation for 104 weeks and observed up to natural death. Another group of 20 males and

20 mated females remained untreated (control). Examinations on general health, autopsy, and histopathology of ca. 50 tissues were performed.

Totally, 59 male and 49 female offsprings were recorded in the control group; 36 male and 37 female offsprings were recorded in the exposed group. No substance related effects on survival and body weight gain was observed in the breeders, however, depression of body weight gain was observed in the offsprings. According to the authors, increased incidences in leukemia and gastro-intestinal tumors were observed. According to the authors, these findings allowed to conclude that formaldehyde was a multipotential carcinogen.

Source: BASF AG Ludwigshafen
Test substance: formaldehyde; no data on purity of the compound
Reliability: (3) invalid

(430) (431)

Species: rat **Sex:** male
Strain: Wistar
Route of admin.: drinking water
Exposure period: 32 weeks
Frequency of treatment: continuously in the drinking water
Post. obs. period: none
Doses: ca. 450 mg/kg/d (calculated from 5000 ppm in the drinking water)
Result:
Control Group: no data specified
Method: other: initiation-promotion study
Year: **GLP:** no data
Test substance: no data
Remark: Reliability: 2 (reliable with restrictions)
Result: The tumor promoting effect of formaldehyde (FA) was studied. Initiation was carried out with 100 mg/l N-methyl-N'-nitroso-N-nitroguanidine (MNNG) in the drinking water plus 10% sodium chloride (NaCl) in the diet for 8 weeks; promotion was carried out with 5000 ppm FA in the drinking water for 32 weeks. Ten rats remained untreated (control), 10 rats were given FA only (promotor only), 30 rats were given MNNG only (initiator only), and 17 rats weregiven MNNG + FA (initiator + promotor). Examinations on general health, autopsy, and histopathology of stomach and duodenum were performed.
Papillomas were observed in 80% of the animals treated with FA alone. In animals treated with MNNG + FA, papillomas of the forestomach (88%) and increased incidence of adenomatous hyperplasia of the fundus (88%), preneoplastic hyperplasia of pylorus (41%), and adenocarcinomas of the pylorus (23.5%) were observed; as compared to the values of initiation alone(0, 23.3 and 3.3%). No increased incidence of duodenal tumors was recorded. Non-neoplastic lesions were diffuse proliferative changes in the superficial epithelium of the glandular stomach, and erosions and ulcers along the limiting ridge of fundic mucosa (see chapter 5.4).

According to the authors, gastric irritation and damage to the mucosa and corresponding proliferation stimuli was discussed as mechanism for promotion.

Source: BASF AG Ludwigshafen
Test substance: formaldehyde; no data on purity of the compound

(241)

Species: rat **Sex:** male
Strain: Fischer 344
Route of admin.: gavage
Exposure period: single dose
Frequency of treatment: single dose
Post. obs. period: none
Doses: 11 – 110 mg/kg (1 ml of 0.185 – 1.85% solution)
Result:
Control Group: yes, concurrent vehicle
Method: other: S-phase-response
Year: **GLP:** no data
Test substance: no data
Remark: Reliability: 2 (reliable with restrictions)
Result: The effect of a single dose of formaldehyde on ornithine decarboxylase and DNA synthesis (in vitro) induction in pyloric mucosa was studied. A concentration (dose) dependentinduction of both decarboxylase and DNA synthesis was observed. Maxima were reached at 16 h post application of ca. 100 or 49 fold of control, respectively; the effects reversed after 48-72 h.
According to the authors, these results allowed to conclude that the test substance had tumor promoting activity.
Source: BASF AG Ludwigshafen
Test substance: formaldehyde; no data on purity of the compound

(432)

Species: rat **Sex:** no data
Strain: no data
Route of admin.: inhalation
Exposure period:
Frequency of treatment:
Post. obs. period:
Doses: 15 ppm
Result:
Control Group:
Method: other: aucune donnée
Year: **GLP:** no data
Test substance: no data
Remark: A review with 15 refs. concluding that although HCHO [50-00-0] was carcinogenic at 15 ppm in inhalation tests with rats, mice were much less affected, and the results have not been confirmed in humans working under extreme exposure conditions. The presence of 10 ppm HCHO in foods is not a hazard.
Source: PROTEX S.A LEVALLOIS PERRET

(433)

Species: rat **Sex:** male/female
Strain:
Route of admin.: inhalation
Exposure period: 16 MESI
Frequency of treatment: 6 ORE/GIORNO
Post. obs. period:
Doses: 15, 6, 2 ppm
Result:
Control Group: yes
Method: other
Year: 1980 **GLP:**
Test substance:
Source: ALDER S.p.A. TRIESTE

Species: rat **Sex:** male
Strain: Wistar
Route of admin.: inhalation
Exposure period: 4, 8, and 13 weeks
Frequency of treatment: 5 d/w, 6 h/d
Post. obs. period: none or up to study week 131
Doses: ca. 0.0124, 0.0245 mg/l (10, 20 ppm)
Result:
Control Group: yes, concurrent no treatment
Method: other: carcinogenicity study
Year: **GLP:** no data
Test substance: no data
Remark: Reliability: 2 (reliable with restrictions)
Result: The incidence of tumors due to exposure to the test substance was investigated in groups of 50-55 rats. The rats were treated with formaldehyde for 4, 8, or 13 weeks with sacrifices immediately after cessation of exposure (5-10 animals per group) or with observation up to study week 131. Data on general health were recorded, autopsy and histopathological examination of the nose was performed.

Nasal tumors were observed in 2/134, 2/132, and 10/132 rats of the control, low dose, and high dose group, respectively. Tumors originating from tissue prone to formaldehyde toxicity and - according to the authors - therefore considered to be associated with exposure to the test substance were only found in 6/132 animals of the high dose group. Particularly, 3 squamous cell carcinomas and 1 carcinoma in situ were observed in animals exposed to 20 ppm for 13 weeks; 2 polyploid adenomas were observed in animals exposed to the high dose level for 4 or 8 weeks. According to the authors, a concentration and exposure time dependent occurrence of non-neoplastic lesions were found (see chapter 5.4)
Source: BASF AG Ludwigshafen
Test substance: formaldehyde; no data on purity of the compound

(221)

Species: rat **Sex:** male
Strain: Fischer 344
Route of admin.: inhalation
Exposure period: 28 months
Frequency of treatment: 5 d/w, 6 h/d
Post. obs. period: none
Doses: ca. 0.0004, 0.0027, 0.0185 mg/l (0.3, 2.2, 14.9 ppm)
Result:
Control Group: yes, concurrent no treatment
Method: other: carcinogenicity study
Year: **GLP:** no data
Test substance: no data
Remark: Reliability: 2 (reliable with restrictions)
Result: The incidence of tumors due to exposure to the test substance was investigated in groups of 32 male rats. The rats were treated for up to 28 months with sacrifices after 12, 18, and 24 months and after termination of exposure. Examinations on general health, clinical pathology, autopsy and histopathology of several tissues were performed.
In the high dose group, neoplastic nasal lesions were observed for the first time after ca. 420 days of treatment. The incidence of squamous cell carcinomas of the nasal cavity was 14/32 (44%); the incidence of squamous cellpapillomas was 5/32 (16%). According to the authors, becauseof the interim sacrifice of 5 animals/group after 12 months,the population of risk (exposure for >= 18 months) would be 27 animals/group; thus, the tumor incidence raised to 52 and 19% for carcinomas and papillomas, respectively. Non-neoplasic lesions observed in the high dose group were squamous metaplasia, epithelial cell hyperplasia, epithelial cell hyperkeratosis, and papillary hyperplasia. At 2.2 and 0.3 ppm, only non-neoplastic lesions (squamous metaplasia and epithelial cell hyperplasia) were observed from months 24 onwards. However, according to the authors, the lesions detected at these dose levels could not be attributed clearly to formaldehyde exposure because there did not exist a clear concentration response relation (see chapter 5.4).
Source: BASF AG Ludwigshafen
Test substance: formaldehyde; no data on purity of the compound

(242) (229)

Species: rat **Sex:** male/female
Strain: Fischer 344
Route of admin.: inhalation
Exposure period: up to 24 months
Frequency of treatment: 5 d/w, 6 h/d
Post. obs. period: up to 6 months
Doses: ca. 0.0025, 0.0070, 0.0178 mg/l (2.0, 5.6, 14.3 ppm)
Result:
Control Group: yes, concurrent no treatment
Method: other: no data
Year: **GLP:** no data
Test substance: no data
Remark: Reliability: 2 (reliable with restrictions)
Result: The incidence of tumors due to exposure to the test substance was investigated in groups of 120 rats/sex. The rats were treated for up to 24 months and were sacrificed 6, 12, 18, 24, 27, and 30 months after beginning of exposure. Autopsy and histopathology of ca. 50 tissues was performed.

In the high dose group, neoplastic nasal lesions were observed for the first time after ca. 12 months of treatment. The incidence of squamous cell carcinomas of the nasal cavity was 51/117 (44%) in males and 52/115 (45%) in females; according to Kaplan–Meier life table analysis, the adjusted cumulative incidence rate was 67% in males and 87% in females. In the mid dose group, the incidence of squamouscell carcinomas of the nasal cavity was 1/119 (0.8%) and 1/116 (0.9%) in males and females, respectively. However, these incidences were not statistically significant.

According to the authors, severe damage of nasal epithelium was observed in the high and mid dose group, anterior nasal lesions were present in the low dose group. The incidence of polyploid adenomas was increased in males without showing concentration response; thus, according to the authors, this finding was judged to be incidental.
Source: BASF AG Ludwigshafen
Test substance: formaldehyde; no data on purity of the compound

(230) (231)

Species: rat **Sex:** male
Strain: Fischer 344
Route of admin.: inhalation
Exposure period: up to 24 months
Frequency of treatment: 5 d/w, 6 h/d
Post. obs. period: none
Doses: ca. 0.0008, 0.0026, 0.0075, 0.0123, 0.0187 mg/l (0.69, 2.1, 6.0, 9.9, 14.9 ppm)
Result:
Control Group: yes, concurrent no treatment
Method: other: no data
Year: **GLP:** no data
Test substance: no data
Result: Examinations:
General health, histopathology of the nasal cavity, mapping of nasal tumours, cell proliferation measurements. No explanation concerning total number of animals at risk (90 animals per group seem to comprise animals for early interim sacrifices (personal communication with CIIT scienctists).
Incidence of squamous cell carcinomas (animal at risk):
0 ppm: 0%
0.69 ppm: 0%
2.1 ppm: 0%
6.0 ppm: 2%
9.9 ppm: 38%
14.9 ppm: 67%
Incidence of polypiod adenomas (animals at risk):
0 ppm: 0/90 = 0%
0.69 ppm: 0/90 = 0%
2.1 ppm: 0/90 = 0%
6.0 ppm: 2%
9.9 ppm: 9%
14.9 ppm: 14%
Increased early mortality at 15 ppm; concentration dependent time to tumours: first tumour observed at about 12 month with 15 ppm, at 18 month with 9.9 ppm and at 20 month with 6 ppm; tumours mostly localised at sites of "high doses": lateral meatus, mid septum; correlation of tumour incidence with population weighted cell proliferation (chapter 5.4).
Source: BASF AG Ludwigshafen
Test substance: formaldehyde; no data on purity of the compound
Reliability: (2) valid with restrictions
(225) (232) (212)

Species: rat **Sex:** male
Strain: Wistar
Route of admin.: inhalation
Exposure period: 28 months
Frequency of treatment: 5 d/w, 6 h/d
Post. obs. period: none
Doses: ca. 0.0001, 0.0012, 0.0115 mg/l (0.1, 1.0, 9.2 ppm)
Result:
Control Group: yes, concurrent no treatment
Method: other: carcinogenicity study
Year: **GLP:** no data
Test substance: no data
Remark: Reliability: 2 (reliable with restrictions)
Result: The formation of nasal tumors after severe nasal injury to the mucosa (due to electrocoagulation) and prolonged exposure to the test substance was investigated. Sixty rats with damaged nose and 30 rats with undamaged nose were used per treated group; controls consisted of 60 rats with undamaged nasal tissue and 120 rats with damaged nasal tissue. After termination of exposure, histopathological examinations of the nose were performed.

After 28 months, the pooled incidence of nasal tumors in controls were 0/52 and 1/111 (0.9%) in rats without and with damaged nasal tissue, respectively. In rats with undamaged nasal tissue, 1/26–1/28 (4%) squamous cell carcinoma was observed in each concentration group. Seventeen out of 58 (29%) rats with damaged nasal tissue exposed to 9.2 ppm had nasal tumors, 15 of which (26%) were squamous cell carcinomas. At 1.0 and 0.1 ppm, tumor incidence was 0 and 1/56–58, respectively.

Non–neoplastic lesions comprised degenerative and inflammatory changes of nasal mucosa were observed at 9.2 ppm in animals with undamaged nasal tissue and at each concentration level in animals with damaged nasal tissue. According to the authors, these changes were independent of exposure regimen (see chapter 5.4).
Source: BASF AG Ludwigshafen
Test substance: formaldehyde; no data on purity of the compound

(434)

Species: rat **Sex:** male
Strain: Wistar
Route of admin.: inhalation
Exposure period: 3 months
Frequency of treatment: 5 d/w, 6 h/d
Post. obs. period: 25 months
Doses: ca. 0.0001, 0.0012, 0.0122 mg/l (0.1, 1.0, 9.8 ppm)
Result:
Control Group: yes, concurrent no treatment
Method: other: carcinogenicity study
Year: **GLP:** no data
Test substance: no data
Remark: Reliability: 2 (reliable with restrictions)
Result: The formation of nasal tumors after severe nasal injury to the mucosa (due to electrocoagulation) and prolonged exposure to the test substance was investigated. Sixty rats with damaged nose and 30 rats with undamaged nose were used per treated group; controls consisted of 60 rats with undamaged nasal tissue and 120 rats with damaged nasal tissue. After termination of exposure, histopathological examinations of the nose were performed.

After 3 months of exposure and 25 months of observation, the pooled incidence of nasal tumors in controls were 0/52 and 1/111 (0.9%) in rats without and with damaged nasal tussue, respectively. In rats with undamaged nasal tissue and treated with 9.8 ppm, 2/26 (8%) nasal tumors were observed, 1 of which (4%) was squamous cell carcinoma. Among the rats with damaged nasal tissue, 2/53–57 (4%) nasal tumors were observed in each concentration group; most of these tumors were squamous cell carcinomas.
Non–neoplastic lesions comprised degenerative and inflammatory changes of nasal mucosa were observed at 9.8 ppm in animals with undamaged nasal tissue and at each concentration level in animals with damaged nasal tissue. According to the authors, these changes were independent of exposure regimen (see chapter 5.4).
Source: BASF AG Ludwigshafen
Test substance: formaldehyde; no data on purity of the compound

(434)

Species: rat **Sex:** male
Strain: Sprague–Dawley
Route of admin.: inhalation
Exposure period: lifetime
Frequency of treatment: 5 d/w, 6 h/d
Post. obs. period: none
Doses: premix of ca. 0.018 mg/l of formaldehyde (FA) + ca. 0.016 mg/l of hydrogen cloride (HCl) (14.7 ppm FA + 10.6 ppm HCl)
Result:
Control Group: yes
Method: other: carcinogenicity study
Year: **GLP:** no data
Test substance: no data
Remark: Reliability: 2 (reliable with restrictions)
Result: The incidence of tumors due to exposure to the test substance (FA) in combination with hydrogen chloride (HCl) was investigated. Two control groups of 50 male rats each were sham exposed or remained untreated; 99 rats were exposed to a premix of 14.7 ppm of FA and 10.6 ppm of HCl. After sacrifice, examinations on general health,autopsy, and histopathology of nose, larynx, trachea, lung, liver, bladder, kidneys, and spleen were performed.

The incidence of squamous cell carcinomas and squamous papillomas were 25/99 (25%) and 3/99 (3%), respectively, in rats exposed to the premix (the first tumor was detected after 223 days); no tumors (0/50) were observed in colony controls; the tumor incidence in sham treated controls was not reported. No increase in extranasal tumorincidence was recorded. In the exposed group, increased mortality and reduced body weight gain was observed. Non–neoplastic lesions of the upper respiratory tract (epithelial hyperplasia and squamous metaplasia) were observed (see chapter 5.4).
Source: BASF AG Ludwigshafen
Test substance: formaldehyde; no data on purity of the compound

(227)

Species: rat **Sex:** male
Strain: Sprague-Dawley
Route of admin.: inhalation
Exposure period: lifetime
Frequency of treatment: 5 d/w, 6 h/d
Post. obs. period: none
Doses: ca. 0.018 mg/l (14.8 – 15.2 ppm) alone or in combination with ca. 0.015 mg/l (9.7 – 10.0 ppm) of hydrogen cloride (HCl)
Result:
Control Group: yes
Method: other: carcinogenicity study
Year: **GLP:** no data
Test substance: no data
Remark: Reliability: 2 (reliable with restrictions)
Result: The incidence of tumors due to exposure to the test substance (FA) in combination with hydrogen chloride (HCl) was investigated in groups of 100 male rats. Groups were exposed to a premix of 15.2 ppm FA + 9.9 ppm HCl, a non-premix of 14.9 ppm FA + 9.7 ppm HCL, 14.8 ppm FA alone, 10.0 ppm HCL alone, air, or remained unexposed. After sacrifice, examinations on general health, autopsy, and histopathology of nose, larynx, trachea, lung, liver, bladder, kidneys, and testes were performed.

The incidence of squamous cell carcinomas and polyps or papillomas were 38/100 and 10/100 in the groups exposed to FA alone, 45/100 and 13/100 in the groups exposed to the premix, 27/100 and 11/100 in the groups exposed to the non-premix, and 0/99 in the HCl group, air control, and unexposed group, respectively. The average latency periods ranged from 603 to 645 days. According to the authors, tumors were originating from naso-maxillary turbinates and nasal septum. No increase in extranasal tumor incidence was recorded. In groups exposed to FA, increased mortality and reduced body weight gain was observed. Non-neoplastic lesions of the upper respiratory tract (epithelial hyperplasia and squamous metaplasia) were observed (see chapter 5.4).
Source: BASF AG Ludwigshafen
Test substance: formaldehyde; no data on purity of the compound

(227) (435) (436)

Species: rat **Sex:** female
Strain: Sprague–Dawley
Route of admin.: inhalation
Exposure period: no data specified
Frequency of treatment: no data specified
Post. obs. period: no data
Doses: ca. 0.016 mg/l (12.4 – 12.7 ppm) alone or in combination with ca. 25 mg/m3 of wood dust
Result:
Control Group: yes
Method: other: carcinogenicity study
Year: **GLP:** no data
Test substance: no data
Remark: Reliability: 2 (reliable with restrictions)
Result: The incidence of tumors due to exposure to the test substance in combination with wood dust was investigated. Groups of 15–16 rats were exposed to 12.4 ppm formaldehyde alone, 12.7 ppm formaldehyde combined with 25 mg/m3 of wood dust, 25 mg/m3 wood dust alone, or remained untreated. Examinations on general health and histopathology of nose and lungs were performed.
According to the authors, tumor incidence was 1/16 (6%) in the group exposed to 12.4 ppm of formaldehyde. No nasal tumors were observed in the animals coexposed to formaldehyde and wood dust, although more severe non–neoplastic lesions (e.g. squamous metaplasia and dysplasia) were present (see chapter 5.4).
Source: BASF AG Ludwigshafen
Test substance: formaldehyde; no data on purity of the compound

(226)

Species: mouse **Sex:**
Strain:
Route of admin.: inhalation
Exposure period: 35 +29 =64 WEEKS
Frequency of treatment: 3 ONE HOUR PERIODS PER WEEK. 50 MG/M3,35WEEKS.+150MG/M3 29 WKS
Post. obs. period: NO PULMONERY TUMOURS
Doses: 50MG/M3 35 WKS + 150 MG/M3 29 WKS
Result:
Control Group: no data specified
Method:
Year: 1963 **GLP:**
Test substance:
Source: STRATHCLYDE CHEMICAL COMPANY LIMITED JOHNSTONE

(207)

Species: mouse **Sex:** male/female
Strain: B6C3F1
Route of admin.: inhalation
Exposure period: 24 months
Frequency of treatment: 5 d/w, 6 h/d
Post. obs. period: up to 6 months
Doses: ca. 0.0025, 0.007, 0.018 mg/l (2.0, 5.6, 14.3 ppm)
Result:
Control Group: yes, concurrent no treatment
Method: other: carcinogenicity study
Year: **GLP:** no data
Test substance: no data
Remark: Reliability: 2 (reliable with restrictions)
Result: The incidence of tumors due to exposure to formaldehyde was investigated in groups of 120 mice/sex. Some animals per group were sacrificed after 6, 12, 18, 24, 27, and 30 months. Autopsy and histopathology of ca. 50 different tissues was performed.
According to the authors, squamous cell carcinomas were found only in 2 males of the high doses group, however, this incidence was not statistically significant (no incidence table presented). Non–neoplastic lesions were found in the high dose group (epithelial dysplasia and squamous metaplasia) and in the mid dose group (epithelial dysplysia). An exposure dependent increase in mortality due to infections of the genitourinary tract was observed in males.
Source: BASF AG Ludwigshafen
Test substance: formaldehyde; no data on purity of the compound

(230)

Species: mouse **Sex:** no data
Strain: C3H
Route of admin.: inhalation
Exposure period: up to 68 weeks
Frequency of treatment: 1 h/d, 3 d/w
Post. obs. period:
Doses: 0, 42, 83, 167 ppm (0. 50, 100, 200 mg/m3) or 42 ppm (50 mg/m3) or 125 ppm (150 mg/m3)
Result:
Control Group: no data specified
Method: other: no data
Year: **GLP:** no
Test substance: no data
Result: Route/Dosage:
Inhalation (whole body) 0, 42, 83, 167 ppm (0, 50, 100, 200, mg/m3) 1h/d, 3d/w for up to 35 weeks or 42 ppm (50 mg/m3) 1h/d, 3d/w for 35 weeks and 125 ppm (150 mg/m3) 1h/d, 3d/w from week 36–68.

Examination:
General health, histopathology of trachea and lungs

Findings:
No increase in tracheobronchial or pulmonary tumors

Exposure to 167 ppm terminated during week 4. No changes in tumour incidence produced by coal tar aerosols with or without pretreatment with FA.

Source: BASF AG Ludwigshafen
Test substance: formaldehyde; no data on purity of the compound
Reliability: (2) valid with restrictions

(437)

Species: Syrian hamster **Sex:** male
Strain: other: no data
Route of admin.: inhalation
Exposure period: lifetime
Frequency of treatment: 5 d/w (10 ppm) or 1 d/w (30 ppm), 5 h/d
Post. obs. period: none
Doses: ca. 0.012 or 0.037 mg/l (10 or 30 ppm, respectively)
Result:
Control Group: yes, concurrent no treatment
Method: other: carcinogenicity study
Year: **GLP:** no data
Test substance: no data
Remark: Reliability: 2 (reliable with restrictions)
Result: The tumorigenic effects of formaldehyde on the respiratory tract were studied. 88 animals were exposed to 10 and 50 animals to 30 ppm of the test substance, 132 control animals and 50 animals remained untreated respectively.
Autopsy and histopathology of the respiratory tract was performed; an evaluation of the respiratory tract for tumors using a special subgross (stereomicroscopical) method. A treatment related reduced survival time and a slight increase in incidence of nasal epithelial hyperplasia or 50 control animals and metaplasia was recorded. However, no increased tumor incidence was observed in any group. The analytical concentration of the test substance was not reported.
Source: BASF AG Ludwigshafen
Test substance: formaldehyde; no data on purity of the compound

(253)

Species: Syrian hamster **Sex:** male
Strain: other: no data
Route of admin.: inhalation
Exposure period: lifetime
Frequency of treatment: 1 d/w, 5 h/d
Post. obs. period: none
Doses: ca. 0.037 mg/l (30 ppm)
Result:
Control Group: yes
Method: other: initiation-promotion study
Year: **GLP:** no data
Test substance: no data
Result: The tumorigenic effects of formaldehyde on the respiratory tract were studied. A group of 50 animals was initiated with diethylnitrosamine (DEN; subcutaneous injection of 0.5 mg once a week for 10 weeks) and then exposed to FA for 5 h/d once a week for lifetime. Another group of 50 hamsters was treated in the same manner; additionally, these animals were exposed to FA for 5 h 48 h prior to each DEN injection. Hundred hamsters were given the s.c.injection of DEN only and 50 control animals remained untreated. An evaluation of the respiratory tract for tumorsusing a special subgross (stereomicroscopical) method and histopathology of selected tumors were performed.

A treatment related reduction of survival time was observed;this reduction was more pronounced in the groups exposed to FA. The incidence of adenomas of the respiratory tract was ca. 80% and was independent from treatment. Tumors were found mainly in lower regions of the respiratory tract. Low tumor incidence (ca. 2%) arising from nasal epithelium was observed. According to the authors, a substantial number of hamsters was lost due to an exposure accident at 48 weeks. An increased number of tumors/tumor bearing animal was observed in the trachea but not in the larynx or lungs of animals exposed to FA prior to DEN injection. According to the authors, this finding was interpreted as enhancement of DEN's effect by FA. The analytical concentration of the test substance was not reported.
Source: BASF AG Ludwigshafen
Test substance: formaldehyde; no data on purity of the compound
Reliability: (2) valid with restrictions

(253)

Species: **Sex:**
Strain:
Route of admin.: other: in vitro assay
Exposure period:
Frequency of treatment:
Post. obs. period:
Doses: 0.5 – 2.5 mg/l
Result:
Control Group:
Method: other: cell transformation assay
Year: **GLP:** no data
Test substance: no data
Remark: Reliability: 2 (reliable with restrictions)
Result: Cell transformation assay without metabolic activation in Balb/c3T3 cells. Concentration dependent increase of transformation rate; concentrations refering to paraformaldehyde; no detailed description of the method
Source: BASF AG Ludwigshafen
Test substance: formaldehyde; no data on purity of the compound

(292)

Species: **Sex:**
Strain:
Route of admin.: other: in vitro assay
Exposure period:
Frequency of treatment:
Post. obs. period:
Doses: 0.1 – 2.5 mg/l
Result:
Control Group:
Method: other: cell transformation assay
Year: **GLP:** no data
Test substance: no data
Remark: Cell transformation assay with C3H/10T1/2 cells; no data on metabolic activation. 24 h exposure, 6 weeks maintainance, both in the presence and absence of 12–O– tetradodecanoyl–phorbol–13–acetate (TPA); no transformation without TPA, concentration dependent transforming effect with TPA; LD50 concentration between 0.5 and 1 mg/l
Reliability: 2 (reliable with restrictions)
Source: BASF AG Ludwigshafen
Test substance: formaldehyde; no data on purity of the compound

(438) (439)

Species: **Sex:**
Strain:
Route of admin.: other: in vitro assay
Exposure period:
Frequency of treatment:
Post. obs. period:
Doses: 0.16, 0.8, 4, 20, 100 mg/l (0.0053, 0.0266, 0.1333, 0.6666. 3.3333 mM)
Result:
Control Group:
Method: other: cell transformation assay
Year: **GLP:** no data
Test substance: no data
Remark: Reliability: 2 (reliable with restrictions)
Result: Cell transformation assay with BHK–21/cl.13 baby hamster kidney cells; no data on metabolic activation. 3 h exposure, 3 weeks maintainance; concentration dependent increase of transformation between 0.8 and 2 mg/l; cytotoxicity: 0 and ca. 90% survival at 100 and 20 mg/l, respectively
Source: BASF AG Ludwigshafen
Test substance: formaldehyde; no data on purity of the compound

(440)

Species: rat **Sex:** male
Strain: Fischer 344
Route of admin.: other: instillation into heterotopic bladder
Exposure period: 34 weeks
Frequency of treatment: 15 applications (every 2 weeks)
Post. obs. period: no data
Doses: 0.3%
Result:
Control Group: yes
Method: other: initiation–promotion study
Year: **GLP:** no data
Test substance: no data
Remark: Reliability: 2 (reliable with restrictions)
Result: The tumor promoting effects of formaldehyde (FA) was studied in 35 rats per group with heterotopically transplanted urinary bladders. Initiation was performed by single dose of 0.25 mg MNU (negative control with saline); thereafter, 15 instillations of 0.3% FA, NaCl solutions, and urine were performed in different patterns every 2 weeks (total study duration 34 weeks). Histopathology of heterotopic urinary bladder was performed and cell proliferation was measured in some non–initiated bladders by 3H–thymidine labelling. Induction of epithelial hyperplasia was observed (40–50% in initiated bladders, 8% in non initiated bladders). Induction of fibrosis of the lamina propria (incidence 19–31%) was recorded. Labelling indices were increased. No significant differences in nodulo–papillary hyperplasia and carcinoma formation was observed in initiated bladders treated with saline of FA.

Acute instillation of 0.3% FA resulted in multiple erosions and focal ulcers. The authors discussed several possibilities for the missing promoting action of FA.

Source: BASF AG Ludwigshafen
Test substance: formaldehyde; no data on purity of the compound

(441)

5.8 Toxicity to Reproduction

Type: Fertility
Species: mouse **Sex:** male
Strain: B6C3F1
Route of admin.: gavage
Exposure Period: 5 days
Frequency of treatment: daily
Premating Exposure Period
male: no mating
female: no mating
Duration of test: until 5 weeks after the last dosing
Doses: 100 mg/kg
Control Group: yes, concurrent vehicle
Method: other: no data
Year: **GLP:** no data
Test substance: no data
Remark: Reliability: 2 (reliable with restrictions)
Result: The effects on sperm morphology of formalin (37% formaldehyde, 10% methanol in water) was determined. The test substance was administered to 10 mice for 5 consecutive days; 5 control mice were given distilled water. Five weeks after treatment, the mice were sacrificed; the cauda epididymides were dissected and flushed for recovery of the spermatozoa. For sperm counting, 7 treated and all control mice were used, 500 spermatozoa/mouse were examined. According to the authors, the overall results indicated a small increase in the number of abnormal cells; however, this was not statistically significant.

According to the authors, application by gavage of 250 and 500 mg/kg/d for 5 consecutive days or intraperitoneal injection of 5 daily doses of 100 mg/kg/d to groups of 10 mice were lethal to all animals treated.

Source: BASF AG Ludwigshafen
Test substance: formalin; 37% formaldehyde; no data on purity of the compound

(442) (249)

Type: other
Species: rat **Sex:** male/female
Strain: Sprague–Dawley
Route of admin.: drinking water
Exposure Period: 104 weeks beginning at day 12 of pregnancy
Frequency of treatment: continuously in the drinking water
Premating Exposure Period
male: none
female: none
Duration of test: lifetime
Doses: 2500 mg/l in the drinking water
Control Group: yes, concurrent no treatment
Method: other: no data
Year: **GLP:** no data
Test substance: no data
Remark: Reliability: 2 (reliable with restrictions)
Result: The effects of orally administered formaldehyde was studied in 25 weeks old breeding rats. A group of 18 males and 18 mated females was exposed to the test substancefrom day 12 of gestation for 104 weeks and observed up to natural death. Another group of 20 males and 20 mated females remained untreated (control). Examinations on general health, autopsy, and histopathology of ca. 50 tissues were performed.

Totally, 59 male and 49 female offsprings were recorded in the control group; 36 male and 37 female offsprings were recorded in the exposed group. No substance related effects on survival and body weight gain was observed in the breeders, however, depression of body weight gain was observed in the offsprings. These results were part of a 2–year carcinogenicity study.
Source: BASF AG Ludwigshafen
Test substance: formaldehyde; no data on purity of the compound

(431)

Type:
Species: **Sex:**
Strain:
Route of admin.:
Exposure Period:
Frequency of treatment:
Duration of test:
Doses:
Control Group:
Method:
Year: **GLP:**
Test substance:
Remark: Pas de données disponibles
Source: PROTEX S.A LEVALLOIS PERRET

Type:
Species: **Sex:**
Strain:
Route of admin.:
Exposure Period:
Frequency of treatment:
Duration of test:
Doses:
Control Group:
Method:
Year: **GLP:**
Test substance:
Source: STRATHCLYDE CHEMICAL COMPANY LIMITED JOHNSTONE

5.9 Developmental Toxicity/Teratogenicity

Species: rat **Sex:** female
Strain: Sprague-Dawley
Route of admin.: inhalation
Exposure period: days 6 to 15 of gestation
Frequency of treatment: 6 h/d
Duration of test:
Doses: ca. 0.002, 0.006, 0.012 mg/l (2, 5, 10 ppm)
Control Group: yes
NOAEL Maternalt.: = .006 mg/l
Method: other: no data
Year: **GLP:** no data
Test substance: no data
Remark: Reliability: 2 (reliable with restrictions)
Result: The teratogenic effects of whole-body inhalation exposure to formaldehyde was studied in groups of 25 rats. Three groups were exposed to the test substance at concentrations of 2, 5, 10 ppm; one group was handled in an identical manner to the formaldehyde-treated groups except that it was treated with air (air-control); one group was maintained in the animal room throughout the study (room-control). The measured concentrations of the test substance were 0.01, 1.88,4.88, and 9.45 ppm in the air-control, 2, 5, and 10 ppm group, respectively.
The pregnancy rate in all groups was at least 80%. In the highest dose group, a significant decrease in maternal food consumption and body weight gain was observed. Pregnancy parameters (numbers of corpora lutea, implantation sites, live fetuses, dead fetuses and resorptions, preimplantation and postimplantation losses, fetal weights, sex ratios) were unaffected. No evidence of maternal toxicity was found in the other groups.
The overall incidences of litters and fetuses with major malformations, minor external and visceral anomalies, and minor skeletal anomalies were similar. At the 10 and 5 ppm levels, an apparently significant dose-related decrease in ossification was detected in the bones of the pelvic girdle. However, this alteration was only significant when compared with air-controls, but not when compared with

room-controls. Thus, according to the authors, this finding was associated with larger litter sizes being accompanied by decreased fetal weights. According to the authors, neither this finding nor other parameters assessed demonstrated any adverse effect on the conceptus due to formaldehyde expusure under the conditions used in this study.

Source: BASF AG Ludwigshafen
Test substance: formaldehyde; no data on purity of the compound

(443) (444) (445)

Species: rat **Sex:** female
Strain: other: albino
Route of admin.: inhalation
Exposure period:
Frequency of treatment: continuously
Duration of test: until delivery
Doses: ca. 0.000012, 0.001 mg/l (0.012, 1 mg/m3)
Control Group: yes, concurrent no treatment
Method: other: no data
Year: **GLP:** no
Test substance: no data
Result: Inhalation, whole-body, 24h/d, male 6-10 days and female 10-14 days before mating until end of pregnancy.
Examinations: Clinical symtoms, visible malformations, selected biochemical parameters.
Findings: Prolongation of pregnancy
Pups/liter: control: 11.3
low : 9.8
high : 8.6
No visible malformations. Changes in organ weights of dams and pups. Morphological changes in some organs. Changes in ascorbic acid, DNA and RNA content in maternal and fetal tissues. Partly in Russian limited examinations and documentation internal contradictions described by Bruehl and Einbrodt.
Source: BASF AG Ludwigshafen
Test substance: formaldehyde; no data on purity of the compound
Reliability: (3) invalid

(446) (447) (448) (449) (450) (442) (451) (452)

Species: rat **Sex:** female
Strain: other: no data
Route of admin.: inhalation
Exposure period: days 1 – 19 of gestation
Frequency of treatment: 4 h/d
Duration of test:
Doses: 0.0005, 0.005 mg/l
Control Group: no data specified
Method: other: no data
Year: **GLP:** no
Test substance: no data
Result: Groups of 15 animals were used. Some of the rats were sacrificed on day 20 of pregnancy, fetuses were removed and examined. The remaining rats were allowed to litter naturally. In the groups sacrificed after exposure, increased preimplantation deaths were observed; no gross malformations were recorded. In the groups which were allowed to litter, reduced body lenght and reduced mobility of female offsprings were observed; males were unaffected.
Source: BASF AG Ludwigshafen
Test substance: formaldehyde; no data on purity of the compound
Reliability: (2) valid with restrictions

(446) (442) (453)

Species: rat **Sex:** female
Strain: other: no data
Route of admin.: inhalation
Exposure period: 20 days
Frequency of treatment: 4 h/d
Duration of test:
Doses: ca. 0.0004, 0.006 mg/l
Control Group: no data specified
Method: other: no data
Year: **GLP:** no
Test substance: no data
Result: Some maternal toxicity at 5 ppm, no effect on pregnancy. No details in Russian, contradictory evaluations by WHO 1989 and Bruehl and Einbrodt.
Source: BASF AG Ludwigshafen
Test substance: formaldehyde; no data on purity of the compound
Reliability: (3) invalid

(446) (454)

Species: rat **Sex:** female
Strain: Sprague–Dawley
Route of admin.: inhalation
Exposure period: days 6 – 20 of gestation
Frequency of treatment: 6 h/d
Duration of test: until day 21 of gestation
Doses: 0.006, 0.012, 0.025, 0.05 mg/l (5, 10, 20, 40 ppm)
Control Group: yes, concurrent no treatment
Method: other: no data
Year: **GLP:** no data
Test substance: no data
Remark: Reliability: 2 (reliable with restrictions)
Result: The effects of inhaled formaldehyde on embryonal and fetal development was studied. The rats were sacrificed on days 21 of gestation for evaluation of maternal reproductive and fetal parameters. No substance–related effect on lethality of embryo or fetus could be recorded. No significant external, visceral, or skeletal anomalies were observed in fetuses of any groups. At the 2 high dose levels, a significant, dose–related reduction of fetal body weight was observed (ca. 20% less than control at 0.05 mg/l). Maternal toxicity was indicated by a significantly reduced body weight gain at the highest dose level. According to the authors, these results suggest that the test substance had a slightly fetotoxic effect at concentrations of 20 ppm and more. Neither embryolethal nor teratogenic effects were observed.
Source: BASF AG Ludwigshafen
Test substance: 37% aqueous solution formaldehyde, containing 10% methanol; no data on purity of the compound

(443) (455)

Species: rat **Sex:** female
Strain: other: no data
Route of admin.: inhalation
Exposure period: no data specified
Frequency of treatment: no data
Duration of test: no data
Doses: 0.0005 mg/l
Control Group: no data specified
Method: other: no data
Year: **GLP:** no data
Test substance: no data
Result: The embryotoxic effects of the test substance were studied. Exposure of pregnant rats to concentrations at the maximum permissible level in the working zone (0.5 mg/m3) increased anomalies of internal organs, retarded the skeletal development, affected the fetal acid–base equilibrium, and affected the behaviour responses of juvenile and adult rats. Only abstract available; no further data.
Source: BASF AG Ludwigshafen
Test substance: formaldehyde; no data on purity of the compound
Reliability: (3) invalid

(456)

Species: mouse **Sex:** female
Strain: CD-1
Route of admin.: gavage
Exposure period: days 6 – 15 of gestation
Frequency of treatment: daily
Duration of test: until day 18 of gestation
Doses: 74, 148, 185 mg/kg/d
Control Group: yes, concurrent no treatment
Method: other: no data
Year: **GLP:** no data
Test substance: no data
Remark: Reliability: 2 (reliable with restrictions)
Result: The influence of formaldehyde on embryo and fetal development was studied. The test substance was applied as different amounts of a 1% solution. The control, low, mid and high dose group consisted of 76, 29, 35, and 34 mice, respectively. The surviving mice were sacrificed on day 18 of gestation; their reproductive status was determined. The high dose was clearly toxic; 22/34 females died before the day of sacrifice. According to the authors, methanol could have contributed to this toxicity; the original solution of the test substance contained 12–15% methanol as a preservative. In the mid dose group, mortality was 1/35. No deaths occurred in the low dose and control groups. Pregnancy rates were 69/76, 26/29, 28/35, and 8/34 in the control, low, mid, and high dose group, respectively.No malformations were found in any of the groups. According to the authors, these results suggested that formaldehyde solution containing 12–15% methanol did not produce statistically significantly teratogenic effects in mice at the doses tested although the high dose of the test substance was toxic to the dams.
Source: BASF AG Ludwigshafen
Test substance: aqueous solution formaldehyde, containing 12–15% methanol; no data on purity of the compound

(446) (443) (442) (457)

Species: dog **Sex:** female
Strain: Beagle
Route of admin.: oral feed
Exposure period: days 4 to 56 of gestation
Frequency of treatment: continuously in the diet
Duration of test: until weaning
Doses: 3.1, 9.4 mg/kg/d (125, 375 ppm in the diet)
Control Group: yes, concurrent no treatment
Method: other: no data
Year: **GLP:** no
Test substance: no data
Remark: Reliability: 2 (reliable with restrictions)
Result: The effects of formaldehyde on reproduction was studied in 32 female beagles. The dogs were fed normal diet (control, 11 bitches mated, 9 pregnant bitches) or diet containing formaldehyde (11 bitches mated and 10 pregnant bitches in the low dose group; 10 bitches mated and 9 pregnant bitches in the high dose group) on days 4 to 56 of pregnancy. On day 56, the dogs were transferred into a whelping room and were allowed to litter. The treatment did not affect the pregnancy rate, the weight gain of the pregnant dogs, the length of gestation or the size of the 28 litters (9, 10, and 9 litters in the control,low dose, and high dose group, respectively). Mean length of gestation was 65.8, 63.6, and 64.7 days in the untreated,low dose, and high dose group, respectively. No malformations (either external of skeletal) were observed in the 170 live-born and 8 still-born pups (56, 50, and 64 live-born in the control, low dose, and high dose group, respectively; 4 still-born pups in both control and low dose group).
Source: BASF AG Ludwigshafen
Test substance: formaldehyde; 40% solution; no data on purity of the compound

(446) (458) (442)

Species: Syrian hamster **Sex:** female
Strain: other: Lak:LVG(SYR) Syrian Golden Hamster
Route of admin.: dermal
Exposure period: on day 8, 9, 10, or 11 of gestation
Frequency of treatment: single dose
Duration of test: 2 hours
Doses: 0.5 ml of a 37% solution
Control Group: yes, concurrent vehicle
Method: other: no data
Year: **GLP:** no data
Test substance: no data
Remark: Reliability: 2 (reliable with restrictions)
Result: The possible embryotoxic effects of formaldehyde after percutaneous exposure was studied in 26 Syrian Golden hamsters (4 control animals; 6, 6, 5, and 5 anmials treated on day 8, 9, 10, or 11 of gestation, respectively). The 37% test substance was applied directly onto the clipped dorsal skin of the anesthetized hamsters by syringe; controls were given water. After 2 h, the skin was washed with water to remove any remaining test substance, and the animals were

returned to their cages. Fetuses were recovered by laparatomy under ether anesthesia at the 15th day of gestation and examined for teratogenic effects. The test substance did not significantly affect litter size and weight or length of the fetuses. A subcutaneous hemorrhage was observed in the dorsal cervical region of 1 normally sized fetus from a dam treated on day 10 of pregnancy; however this was not clearly attributable to the test substance. No skeletal or other malformations were found. According to the authors, it was concluded that fetal risk due to maternal topical exposure to formaldehyde was minimal in this model.

Source: BASF AG Ludwigshafen

Test substance: formaldehyde, 37% aqueous solution; no data on purity of the compound

(443) (442) (459)

Species: mouse **Sex:** female
Strain: other: DDP/Idr and Slc:ICR
Route of admin.: i.p.
Exposure period: on day 7 – 14 of gestation
Frequency of treatment: daily
Duration of test: until day 18 of gestation
Doses: 30, 40, 50 mg/kg/d
Control Group: yes
Method: other: no data
Year: **GLP:** no data
Test substance: no data
Remark: Reliability: 2 (reliable with restrictions)
Result: The study was designed to evaluate the teratogenic effects of intraperitoneally admininstered formaldehyde solution on developing mouse embryos using 2 strains. On day 18 of gestation, the mice were sacrificed; implantations and prenatal deaths were recorded. Mean body weights of exposed fetuses was lower than that of controls. The incidence of prenatal death was slightly increased in the treated groups. The incidence of fetal anomalies was significantly increased in treated mice. The major malformations observed were cleft palates and malformations of the limbs.

Source: BASF AG Ludwigshafen

Test substance: formaldehyde solution; no data on purity of the compound

(442) (460)

Species: dog **Sex:**
Strain:
Route of admin.: oral unspecified
Exposure period: 4 DAYS AFTER MATING TO DAY 56
Frequency of treatment: NO DATA
Duration of test: 52 DAYS
Doses: 125 MK/KG
Control Group:
Method:
Year: 1973 **GLP:**
Test substance:
Source: STRATHCLYDE CHEMICAL COMPANY LIMITED JOHNSTONE

(207)

Species: rat **Sex:** male
Strain: other: no data
Route of admin.: other: combination of drinking water (d.w.) and inhalation (inh.)
Exposure period: 6 months
Frequency of treatment: continuously in the drinking water for 5 d/w; inhalation 5 d/w, 4 h/d
Duration of test: ca. 8 months; no data specified
Doses: 0.005 mg/l d.w. + 0.00012 mg/l (0.1 ppm) inh., 0.01 mg/l d.w. + 0.00025 mg/l (0.2 ppm) inh., 0.1 mg/l d.w. + 0.0005 mg/l (0.4 ppm) inh.
Control Group: yes, concurrent no treatment
Method: other: no data
Year: **GLP:** no
Test substance: no data
Remark: Reliability: 2 (reliable with restrictions)
Result: After termination of exposure, each treated male was mated with 2 females. Gonadotropic effects in treated males were evaluated by determination of testicular nucleic acid contents and the reaction of the genital tract of females after s.c. injection of homogenates of hypophyses of test animals. On the 20th day of gestation, some of the dams were sacrificed; the remaining dams were allowed to litter naturally. Fetuses and newborn pups were examined macroscopically; the newborn rats were observed for 1 month with special regard on their developmental stages (opening of the eyes, development of the fur, and other parameters). These examinations were carried out with the offsprings of the low and high dose groups.

According to the author, no differences in fertility of the treated males were observed. All females became pregnant. Number and weight of fetuses or newborn pups were not significantly different from control. No damage or anomalies in development due to treatment of the fathers were observed in the offsprings during the 1-month observation period. However, the evaluation of testicular nucleic acid content revealed a significant decrease in the testes of males exposed to the high and the mid dose group.

Thus, according to the author, the gonadotropic effects of

the test substance after simultaneous uptake via air and water are of a certain importance, although no adverse effect on the gonadotropic reaction or on fertiltity of the males was observed.
Source: BASF AG Ludwigshafen
Test substance: formaldehyde; no data on purity of the compound

(461) (442)

Species: rat **Sex:** female
Strain: Sprague-Dawley
Route of admin.: other: intrauterine
Exposure period: on day 3 or 7 of gestation
Frequency of treatment: single dose
Duration of test: until day 15 of gestation
Doses: 0.005 ml of 0.005, 0.05, 0.5, 2.0, 3.5, 7, 10, or 40% (v/v) solution
Control Group: yes
NOAEL Maternalt.: = 7 %
Method: other: no data
Year: **GLP:** no
Test substance: as prescribed by 1.1 - 1.4
Remark: Reliability: 2 (reliable with restrictions)
Result: The efficacy of locally applied formaldehyde as a contragestional agent was studied in 2 groups of pregnant rats. The dams were treated either on day 3 (preimplantation) or on day 7 (postimplantation) of pregnancy. 0.05 ml of the test substance was injected directly into the lumen of one uterine horn funder laparotomy; 0.9% saline was injected into the other uterine horn (control). On day 15 of gestation, the rats were sacrificed; corpora lutea, viable conceptuses, and resorption sites were counted. According to the authors, formaldeyde was highly effective in terminating pregnancy when administered on day 3; the number of surviving embryos was statistically significantly decreased at concentrations of 0.5% and more. Treatment on day 7 resulted on a decrease of the number of suviving embryos at concentrations of 2% and more; however, this reduction was not significant. Doses of 10 and 40% produced maternal toxicity and death.
Source: BASF AG Ludwigshafen
Test substance: formaldehyde solution, 40% (v/v); reagent quality

(446) (462)

Species: rat **Sex:** female
Strain: other: no data
Route of admin.: s.c.
Exposure period: during gestation
Frequency of treatment: no data
Duration of test: during gestation
Doses: 0.25 ml * 2
Control Group: no data specified
Method: other: no data
Year: **GLP:** no
Test substance: no data
Result: Pregnant rats were subcutaneously treated with 6% formalin (0.25 ml * 2) during the entire period of pregnancy. According to the autors, atrophy of the thymus and enlargement of the adrenal gland was observed in the dams. No malformations were observed in the pups, however, the median body weights of the pups was increased at delivery and the weights of the adrenals were reduced. Only secondary literature; no further data.
Source: BASF AG Ludwigshafen
Test substance: formaldehyde; no data on purity of the compound
Reliability: (3) invalid

(463)

Species: rat **Sex:** no data
Strain: other: no data
Route of admin.: s.c.
Exposure period: on day 18, 19, 20, or 21 of gestation
Frequency of treatment: single dose
Duration of test:
Doses: 6 ml/kg of a 2% solution (ca. 120 mg/kg)
Control Group: no data specified
Method: other: no data
Year: **GLP:** no
Test substance: no data
Result: The effects of formaldehyde on adrenal ascorbic acid content of fetal rats were studied. Pups gained by Cesarean section on days 18, 19, 20, or 21 of gestation were injected subcutaneously with 6 ul/g of a 2% formaldehyde solution. In the pups treated on the 20th day of gestation, a decrease of the adrenal acsorbic acid content was observed; the pups treated at other points of time were unaffected. Cited from secondary literature; no further data.
Source: BASF AG Ludwigshafen
Test substance: formaldehyde; no data on purity of the compound
Reliability: (3) invalid

(464)

Species: **Sex:**
Strain:
Route of admin.:
Exposure period:
Frequency of treatment:
Duration of test:
Doses:
Control Group:
Method:
Year: **GLP:**
Test substance:
Remark: Pas de données disponibles
Source: PROTEX S.A LEVALLOIS PERRET

5.10 Other Relevant Information

Type: Biochemical or cellular interactions
Result: Endogenous formaldehyde
Formaldehyde (HCHO) is an essential intermediate in cellular metabolism, serving as a precursor for the biosynthesis of amino acids, purines, and thymine. Major sources of endogenous formaldehyde are glycine and serine, both of which are metabolized in the presence of tetrahydrofolic acid to N5,N10-methylene-tetrahydrofolate. This adduct is commonly denoted by the term, active formaldehyde, but this term is misleading, because it implies that formaldehyde not bound to tetrahydrofolate is inactive. In fact, formaldehyde not bound to tetrahydrofolate, which includes free (hydrated) formaldehyde, the hemithioacetal adduct of HCHO with glutathione (GSH), and adducts formed with other nucleophilic substituents, is highly reactive and rapidly metabolized. Therefore, it is appropriate to use the term, reactive formaldehyde, to denote formaldehyde existing in these other forms. Thus, although active formaldehyde is of vital importance to the biochemistry of formaldehyde, several of the adducts of reactive formaldehyde, such as DNA-protein cross-links (DPX), are of critical importance to the toxicology of HCHO.
Active formaldehyde is directly utilized for the biosyn-thesis of serine and thymine. By oxidation of active formaldehyde to active formate (N10-formyl-tetrahydrofolate), the carbon atom of HCHO can be incorporated into purines. Reduction of active formaldehyde to 5-methyl-tetrahydrofolate allows the carbon atom to be incorporated into methionine. Dehydration of serine yields pyruvate, which can be transaminated to alanine and eventually be incorporated into numerous other products. Serine is also a precursor of cysteine, tryptophan, and sphingolipids. Thus, the introduction of labeled formaldehyde molecules into the one-carbon pool results in the labeling of most major classes of macromolecules.
Source: BASF AG Ludwigshafen
Reliability: (2) valid with restrictions

(465) (466)

Type: Metabolism
Result: Reactive formaldehyde can be introduced directly into cells and tissues by inhalation or oral routes. It can also be generated by the metabolism of certain xenobiotics or endogenous compounds, including the oxidative cleavage of N-, O- or S- methyl compounds catalyzed by cytochrome P450-dependent monooxygenases (Sipes and Gandolfi, 1986), the metabolism of dihalogenated methanes catalyzed by glutathione-S-transferase (Anders, 1982), the oxidative dehalogenation of monohalogenated methanes (Anders and Pohl, 1985), the oxidation of methanol catalyzed by alcohol dehydrogenase or the catalase-H2O2 system (Bosron and Li, 1980), and the oxidation and hydrolysis of certain secondary amines catalyzed by flavin-containing amine monooxygenase (Ziegler, 1980). Metabolism of reactive formaldehyde occurs by a variety of pathways, which are described later in this chapter.
The interactions among the various components of endogenous formaldehyde in vivo are not understood in detail, but it would be incorrect to regard active and reactive formaldehyde as separate entities. Reactive formaldehyde can also enter into the one-carbon pool via a direct reaction with tetrahydrofolate (Kallen and Jencks, 1966) or by oxidation to formate followed by incorporation of this molecule into the one-carbon pool. Conversely, active formaldehyde may dissociate to yield various forms of reactive formaldehyde. Thus, active and reactive formaldehyde do not in reality represent separate pools. The major difference between these two forms is the source of formaldehyde and the manner with which it is metabolized. Although active formaldehyde is the form that is utilized for one-carbon biosynthetic reactions, this form accounts for only a very small fraction of the total HCHO that is normally present in cells. The total concentration of a pool of folates in the livers of Sprague-Dawley rats including active formaldehyde and unsubstituted tetra- and dihydrofolates was 2.65 µM (Eto and Krumdieck, 1982). In contrast, the total concentration of formaldehyde, both free and reversibly bound, in freshly-collected and frozen livers of F344 rats was about 188 ± 30 µM (Heck et al., 1982). Thus, neglecting possible strain differences in folate or formaldehyde levels, it would appear that less than 2% of the formaldehyde in rat liver is in the form of active formaldehyde. The remaining > 98% of the formaldehyde exists, therefore, in the various forms of reactive formaldehyde noted above.
Source: BASF AG Ludwigshafen
Reliability: (2) valid with restrictions
(467) (468) (469) (470) (471) (472) (473) (474)

Type: Metabolism
Result: A substantial portion of the formaldehyde denoted as reactive is probably bound to GSH. The nonprotein sulfhydryl (mainly GSH) concentration in normal rat liver is approximately 5.5 6.5 mM (Chasseaud, 1976; Casanova and Heck, 1987), and the equilibrium dissociation constant of the formaldehyde adduct, S-hydroxymethylglutathione, is about 1.5 1.6 mM at 25°C (Uotila and Koivusalo, 1974a; Pourmotabbed et al., 1989). Therefore, the equilibrium concentration of S-hydroxymethylglutathione could be as high as 150 µM, or about 80% of the total formaldehyde in rat liver. The remaining HCHO (ca. 40 µM) may be either hydrated or bound to other nucleophiles.
Source: BASF AG Ludwigshafen
Reliability: (2) valid with restrictions
(475) (476) (477) (478)

Type: Metabolism
Result: The total concentration of formaldehyde in freshly isolated nasal mucosal tissue of F344 rats, which is the primary target tissue for inhaled HCHO, is approximately 420 ± 90 µM (Heck et al., 1982), i.e., about twofold higher than in the liver. (The apparently higher concentration of HCHO in nasal tissue may be due in part to the glycogen content of liver, which imparts to hepatocytes a larger cellular weight and volume than are characteristic of nasal epithelial cells.) However, the GSH concentration in the nasal mucosa is about 3.0 mM, i.e., about half the liver value (Casanova and Heck, 1987). Therefore, the equilibrium concentration of S-hydroxymethylglutathione could be as high as 270 µM, or about 64% of the total formaldehyde. If the GSH concentration were depleted, one would expect an increase to occur in the amount of reactive HCHO bound to other molecules. When nasal GSH was depleted with phorone (Casanova and Heck, 1987) or acrolein (Lam et al., 1985), an increase was observed in the amount of inhaled HCHO covalently bound to nasal mucosal DNA.
Source: BASF AG Ludwigshafen
Reliability: (2) valid with restrictions
(475) (471) (479)

Type: Metabolism
Result: Detoxication of inhaled formaldehyde occurs via folate-dependent incorporation into amino acids, purines, and thymidine, and by folate-independent pathways of oxidation to formate. The oxidation of formaldehyde is catalyzed by enzymes located in the cytosol and in mitochondria. In the cytosol, HCHO reacts with GSH forming the hemithioacetal adduct, S-hydroxymethylglutathione, which is a substrate for the enzyme, formaldehyde dehydrogenase [formaldehyde:NAD+ oxidoreductase (glutathione-formylating), EC 1.2.1.1]. This enzyme catalyzes the oxidation of the adduct to a thiol ester of formic acid, S-formylglutathione (Uotila and Koivusalo, 1974a). The thiol ester is rapidly hydrolyzed to free formate by another cytosolic enzyme, S-formylglutathione hydrolase, which regenerates GSH (Uotila and Koivusalo, 1974b).

All animal tissues tested for formaldehyde dehydrogenase have contained the enzyme (Uotila and Koivusalo, 1983). In particular, formaldehyde dehydrogenase was detected in the respiratory and olfactory nasal mucosa of rats (Casanova-Schmitz et al., 1984a; Keller et al., 1990), the former being the primary target tissue for inhaled formaldehyde in this species. Formaldehyde dehydrogenase has recently been shown to be structurally identical to another enzyme, class III alcohol dehydrogenase, which catalyzes the oxidation of long-chain primary alcohols to aldehydes (Holmquist and Vallee, 1991; Kaiser et al., 1991; Danielsson and Jörnvall, 1992). The enzyme known as formaldehyde dehydrogenase appears, therefore, to have multiple functions.

Class III alcohol dehydrogenase differs from the more familiar class I alcohol dehydrogenase [alcohol:NAD+ oxidoreductase, EC 1.1.1.1] in having a low affinity for ethanol and in not being inhibited by 4-methylpyrazole. Class III alcohol dehydrogenase does not require GSH for the oxidation of primary alcohols, but a thiol group is essential for the oxidation of formaldehyde, presumably because the adduct, S-hydroxymethylglutathione, is structurally similar to a primary alcohol. Several thiols other than GSH can participate in the oxidation of formaldehyde at nearly the same rate as glutathione (Holmquist and Vallee, 1991), but aldehydes other than formaldehyde are not oxidized by the enzyme, presumably because the structures of their GSH adducts would resemble a secondary alcohol.

Owing to the identity of formaldehyde dehydrogenase and class III alcohol dehydrogenase, it cannot be concluded that the primary function of formaldehyde dehydrogenase in vivo is to catalyze the oxidation of formaldehyde to formate. It is likely, however, that formaldehyde dehydrogenase is involved in the detoxication of inhaled formaldehyde. Depletion of glutathione in the rat nasal mucosa, either by i.p. injection of phorone (Casanova and Heck, 1987) or by inhalation of acrolein (Lam et al., 1985), increased the quantity of DPX formed in this tissue relative to that in rats that had not been depleted of GSH. These results demonstrate that the amount of reactive HCHO had increased, despite the presence of other enzymes that are capable of metabolizing HCHO. However, in preparations from rat liver, phorone also inhibited a mitochondrial low-Km aldehyde dehydrogenase [aldehyde:NAD+ oxidoreductase, EC 1.2.1.3], which is also capable of oxidizing formaldehyde (Dicker and Cederbaum, 1985, 1986). Therefore, the effects of phorone on DPX formation in the nose may have been caused both by inhibition of the mitochondrial low-Km aldehyde dehydrogenase and by depletion of GSH.

An aldehyde dehydrogenase having a Km with respect to formaldehyde variously estimated as 0.19 mM (Heck and Casanova, 1987) or 0.4 0.6 mM (Casanova-Schmitz et al., 1984a) was detected in crude homogenates of the rat nasal respiratory and olfactory mucosa. This enzyme might be the mitochondrial low-Km aldehyde dehydrogenase, because the Km of the mitochondrial enzyme with respect to HCHO in rat

liver preparations was found in different assays to be 0.19 mM (Dicker and Cederbaum, 1984) or 0.38 mM (Cinti et al., 1976), values which are similar to the nasal mucosal estimates. Other investigators, using perhaps more highly purified preparations, reported a Km with respect to formaldehyde equal to 0.031 mM (Siew et al., 1976).

The Km of the mitochondrial aldehyde dehydrogenase with respect to formaldehyde measured in rat liver preparations (Siew et al., 1976; Cinti et al., 1976; Dicker and Cederbaum, 1984) is of the same order of magnitude as the concentration of formaldehyde measured in these tissues (see above; Heck et al., 1982). Segel (1975) proposed on physiological grounds that the Km of an enzyme establishes an approximate value for the intracellular level of the substrate. Therefore, if the Segel hypothesis is valid, the endogenous concentration of formaldehyde might be largely controlled by the mitochondrial low-Km aldehyde dehydrogenase. However, this hypothesis requires that the in vitro estimate of Km must be similar to the in vivo value, and that HCHO must diffuse rapidly across the mitochondrial membrane, so that the concentrations of HCHO inside and outside the mitochondrion are similar. Whether these requirements are satisfied is not known.

A corollary of the Segel (1975) hypothesis is that the Km values of other enzymes that act on formaldehyde should be similar to that of the mitochondrial enzyme. This hypothesis appears to be inconsistent with the fact that the Km of formaldehyde dehydrogenase with respect to its substrate, S-hydroxymethylglutathione, (1 µM) (Uotila and Koivusalo, 1974a; Casanova-Schmitz et al., 1984a; Pourmotabbed et al., 1989) is about two orders of magnitude smaller than the estimated tissue concentration of the GSH adduct of formaldehyde (150 µM in rat liver (see above)). Therefore, formaldehyde dehydrogenase should be almost fully saturated with S-hydroxymethylglutathione, which appears to contradict the Segel (1975) hypothesis. However, the substrates for formaldehyde dehydrogenase include compounds other than S-hydroxymethylglutathione (Holmquist and Vallee, 1991; Kaiser et al., 1991; Danielsson and Jörnvall, 1992), and competition with other substrates in vivo may increase the effective Km of formaldehyde dehydrogenase with respect to S-hydroxymethylglutathione. In addition, the local concentration of S-hydroxymethylglutathione in the vicinity of the enzyme at a particular site, e.g., the nucleus (Keller et al., 1990), may be lower than the average concentration measured in a tissue homogenate.

In addition to the two (or possibly three (Tank et al., 1981)) isozymes of aldehyde dehydrogenase that are present in mitochondria, as many as five isozymes are thought to exist in rat liver cytosol and at least one isozyme is present in microsomes (Tank et al., 1981). The mitochondrial aldehyde dehydrogenases include both low- and high-Km forms, but only the low-Km form(s) can efficiently oxidize formaldehyde (Koivula and Koivusalo, 1975a; Siew et al., 1976; Lebsack et al., 1977). Formaldehyde is not considered to be a substrate for either cytosolic (Koivula and Koivusalo, 1975a) or microsomal (Koivula and Koivusalo,

1975b) aldehyde dehydrogenases, but at the relatively high concentrations of HCHO that may be present in the nasal mucosa during an inhalation exposure, these isozymes could also contribute to the oxidation of formaldehyde.

Source: BASF AG Ludwigshafen

Reliability: (2) valid with restrictions

(475) (465) (480) (481) (482) (483) (484) (485) (471) (486) (487) (488) (489) (490) (479) (491) (477) (492) (493) (494) (478) (495) (496)

Type: Metabolism

Result: Formaldehyde can also be oxidized to formic acid by the peroxisomal enzyme, catalase. In this reaction, HCHO serves as a hydrogen donor for the decomposition of the catalase-hydrogen peroxide complex. Oxidation by catalase probably represents only a minor pathway for formaldehyde metabolism, due to the rate limiting generation of hydrogen peroxide (Waydhas et al., 1978). Hydrogen peroxide is also decomposed by the glutathione peroxidase system, which results in the depletion of GSH and the production of oxidized glutathione. When glutathione is depleted, hydrogen peroxide production is increased, which may increase the oxidation of formaldehyde by catalase (Jones et al., 1978).

Source: BASF AG Ludwigshafen

Reliability: (2) valid with restrictions

(497) (498)

Type: Toxicokinetics

Result: The biological fate of inhaled formaldehyde was studied in Fischer 344 rats exposed to either 0.63 or 13.1 ppm of H14CHO for 6 hr (Heck et al., 1983). About 40% of the inhaled 14C was exhaled in the expired air as 14CO2 during the 70-hr postexposure period, 17% was excreted in the urine, 5% was eliminated in the feces, and 35-39% remained in the tissues and carcass, presumably as products of metabolic incorporation. Analysis of the residual radioactivity in the blood following inhalation of H14CHO showed that the profiles of total 14C in plasma and erythrocytes were virtually identical to those following i.v. injection of [14C]formate, suggesting that formaldehyde is rapidly oxidized to formate and incorporated into biological macromolecules. The characteristic pharmacokinetic profiles showed that the 14C atom had been incorporated into serum proteins and erythrocytes, which were subsequently released into the circulation (Heck et al., 1983). The tissue distribution of 14C in the rat is widespread throughout the organism and has been investigated using whole-body autoradiography (Chang et al., 1983).

Source: BASF AG Ludwigshafen

Reliability: (2) valid with restrictions

(499) (500)

Type: Toxicokinetics
Result: The HCHO concentrations in the blood of F344 rats, rhesus monkeys, and adult humans were analyzed before, during, or immediately after an exposure to airborne HCHO to determine whether inhaled HCHO can be detected in the blood.

Exposure concentrations and times were 14.4 ppm, 2 hr (rats); 6 ppm, 6 hr/day, 5 days/week, 4 weeks (monkeys); and 1.9 ppm, 40 min (humans). Preexposure blood concentrations of endogenous formaldehyde were similar in the three species: 74.7 ± 0.2, 80.7 ± 0.3, and 87 ± 5 µM, respectively, and the blood concentrations were not increased significantly by exposure (Heck et al., 1985; Casanova et al., 1988).
Source: BASF AG Ludwigshafen
Reliability: (2) valid with restrictions

(501) (502)

Type: Toxicokinetics
Result: Despite the substantial quantities of endogenous HCHO normally present in tissues and fluids, it has been suggested that exposure of humans to low concentrations of HCHO may cause various forms of distant site toxicity, including hepatotoxicity, leukemia, or DNA-protein cross-link formation in peripheral lymphocytes (Beall and Ulsamer, 1984; Soffritti et al., 1989; Shaham et al., 1996).

These hypotheses have been disputed (Gibson, 1984; Feron et al., 1990; Casanova et al., 1996), and they are inconsistent with a number of studies including: (1) distant site toxicity associated with HCHO exposure has not been observed in at least four inhalation bioassays of formaldehyde (Kerns et al., 1983; Sellakumar et al., 1985; Woutersen et al., 1987; Appelman et al., 1988; Monticello, 1990); (2) formaldehyde concentrations in the blood of rats, monkeys, and humans were not increased by inhalation exposure (Heck et al., 1985; Casanova et al., 1988); (3) chromosomal aberrations in peripheral lymphocytes of rats were not induced by exposure to a high airborne concentration of HCHO (15 ppm; 6 hr/day, 5 days) (Kligerman et al., 1984), although chromosomal aberrations can be induced by HCHO in vitro (IARC, 1995, and chapter 4.7 of this report); (4) chronic administration to rats of very high doses of formaldehyde in the drinking water did not induce hepatotoxicity or cancer (Til et al., 1989); and (5) inhalation of formaldehyde did not cause DNA-protein cross-link formation in the rat bone marrow even under conditions of GSH depletion (Casanova-Schmitz et al., 1984b; Casanova and Heck, 1987). The localization of HCHO toxicity in the upper respiratory tract of rats and the absence of distant site toxicity are consistent with the high reactivity and rapid metabolism of inhaled formaldehyde.
Source: BASF AG Ludwigshafen
Reliability: (2) valid with restrictions

(220) (503) (475) (504) (501) (465) (430) (505) (502) (443) (230) (391) (506) (507) (508) (431) (239) (217)

Type: other: Carcinogenicity (HMT)
Result: Rats were given 1% hexamethylenetetramine in the drinking water for 3 consecutive generation, up to the ages of 40 weeks in both the F1 and F2 generation and up to the age of 20 weeks of the F3 generation. The P, F1, F2, and F3 group consisted of 6 males and 12 females, 13 males and 7 females,15 males and 11 females, and 12 males and 12 females, respectively. Aditionally, a group of offsprings of parents treated with 2% of hexamethylenetetramine (16 males and 16 females) were treated with 2% of the test substance for 50 weeks. The control group consisted of 48 rats of each sex and remained untreated. All groups were observed for more than 2 years of age. According to the authors, no evidence of carcinogenicity due to the test substance was observed.
Source: BASF AG Ludwigshafen
Test substance: hexamethylenetetramine (HMT; in vivo release of formaldehyde); no data on purity of the compound
Reliability: (2) valid with restrictions

(509) (510)

Type: other: Combination toxicity
Remark: Simultaneous inhalation exposure of Wistar rats to formaldehyde, acetaldehyde and acrolein for up to 3 days (Cassee et al, 1994, Cassee, 1995; Cassee et al, 1996) at concentrations representing individual NOAECs was not associated with a greater hazard than treatment with individual compounds. When rats were treated with 9 chemicals by inhalation and oral route (2 compounds inhaled: formaldehyde and dichloromethane; 7 compounds oral: cadmium and stannous chloride, loperamide, spermine, aspirin, DEHP and BHA) for 4 weeks, there was some increased incidence of transitional epithelial hyperplasia at the individual NOAEC of formaldehyde (1 ppm). Overall the authors conclude that simultaneous treatment with several different compounds at or below individual NOAELs does not constitute an evidently increased hazard (Groten et al, 1994; 1996; 1997).
Source: BASF AG Ludwigshafen

(511) (512) (513) (235) (236) (237)

Type: other: Developmental Toxicity/Teratogenicity (GF)
Result: The malformations experimentally induced by intramuscular injection of glycerol formal were studied. Ninety-three rats were divided into 12 groups. One group was administered saline ("negative control") and one group was administered 0.5 ml/kg/d (ca. 600 mg/kg/d; see Aliverti et al) on days 6 to 15 of gestation ("positive control"). The remaining 10 groups were injected 0.5 or 1.5 ml/kg/d (ca. 1800 mg/kg/d) on days 7 and 8, 9 and 10, 11 and 12, 13 and 14, or 15 and 16 of gestation, respectively. On day 21 of pregnancy, all rats were sacrificed; the fetuses were excised and examined for malformations. According to the authors, glycerol formal induced skeletal malformations in all groups treated with the test substance; visceral malformations and malformations of the great vessels were observed in the groups treated on days 10-11 and 12-13 of gestation. Strain: Sprague-Dawley; Abstract only in Italian.

Source: BASF AG Ludwigshafen
Test substance: glycerol formal(GF); no data on purity of the compound
Reliability: (2) valid with restrictions

(514)

Type: other: Developmental Toxicity/Teratogenicity (GF)
Result: Doses: 300, 600, 1200 mg/kg/d (0.25, 0.5, 1)
Strain: Sprague-Dawley
The effects of glycerol formal on embryonal development was studied in groups of 10 rats. The test substance was administered from day 6 to 15 of pregnancy by i.m. injection; the rats were sacrificed on day 21 of pregnancy, the fetuses were examined for malformations. In treated rats, the number of absorptions and the number of dead fetuses was significantly increased; fetal weight was significantly reduced. The number of gross visceral, and skeletal malformations was increased in treated rats showing a trend to dose-response. According to the authors, glycerol formal did not induce systemic toxicity in dams, but showed an embryotoxic and teratogenic activity.

Publication in Italian language, short abstract in English.
Source: BASF AG Ludwigshafen
Test substance: glycerol formal (GF); no data on purity of the compound
Reliability: (2) valid with restrictions

(515)

Type: other: Developmental Toxicity/Teratogenicity (GF)
Result: Doses: 600 mg/kg/d (0.5 ml/kg/d)
Strain: Rat Sprague-Dawley
The cardiovascular malformations experimentally induced by subcutaneous injection of glycerol formal were studied. The test substance was administered s.c.to 40 rats from day 6 to 15 of pregnancy; 20 control rats were treated with saline in the same manner. On day 21 of pregnancy, all rats were sacrificed; the fetuses (193 from treated rats, 119 from control rats) were removed and examined for visceral malformations.
About 40% of the fetuses of the treated group showed anomalies of the interventricular septum; this malformation was associated in nearly 50% of the cases with serious anatomic alterations of the main blood vessels departing from the heart. The anomalies of the interventricular septum were of different types and gravity. In most cases, these anomalies were located at the interventricular foramen (between the muscular septum and the endocardial cushions). Totally, 76/193 of the fetuses of treated dams had cardiovascular malformations.
Source: BASF AG Ludwigshafen
Test substance: glycerol formal (GF); no data on purity of the compound
Reliability: (2) valid with restrictions

(516)

Type: other: Developmental Toxicity/Teratogenicity (HMT)
Remark: Doses: 15, 31 mg/kg/d (600, 1250 ppm)
Result: The effects of hexamethylenetetramine (HMT), which releases formaldehyde in vivo, on reproduction was studied in 30 female dogs. The dogs were fed normal diet (control, 11 mated, 9 pregnant) or diet containing HMT (9 mated and 8 pregnant in the low dose group; 10 mated and 9 pregnant in the high dose group) on days 4 to 56 of pregnancy. On day 56, the dogs were transferred into a whelping room and were allowed to litter. The treatment did not affect the pregnancy rate, the weight gain of the pregnant dogs, the length of gestation or the size of the 28 litters (9, 8, and 8 litters in the control,low dose, and high dose group, respectively). Mean length of gestation was 65.8, 63.3, and 63.5 days in the untreated,low dose, and high dose group, respectively. The high dose led to a slight decrease of survival and growth of the pups. No malformations (either external of skeletal) were observed in the 150 live-born and 8 still-born pups (56, 48, and 46 live-born in the control, low dose, and high dose group, respectively; 4, 2, and 2 still-born pups in control, low, and high dose group, respectively).
Source: BASF AG Ludwigshafen
Test substance: hexamethylenetetramine (HMT; in vivo release of formaldehyde); no data on purity of the compound
Reliability: (2) valid with restrictions

(446) (458)

Type: other: Multi Generation Carcinogenity (HMT)
Result: Rats were given 1% hexamethylenetetramine in the drinking water for 3 consecutive generation, up to the ages of 40 weeks in F1 and F2 generation and up to the age of 20 weeks of the F3 generation. The P, F1, F2, and F3 group consisted of 1 male and 2 females, 13 males and 7 females, 15 males and 11 females, and 12 males and 12 females, respectively.
Findings:
P: 10 pups per dam, 7f/13m
F1: 1 dam died during delivery, 36 pups out of 6 dams, 10 pups died during lactation period, surviving pups constituted F2
F2: 99 pups out of 11 dams, 12f and 12m constituted F3. No malformations or pathological findings.
Aditionally, a group of offsprings of 5 females treated with 2% of hexamethylenetetramine (16 males and 16 females) were treated with 2% of the test substance for 50 weeks and was observed up to week 130.
Findings:
49 pups out of 5 dams from which F1 was chosen. No abnormalities detected
Source: BASF AG Ludwigshafen
Test substance: hexamethylenetetramine (HMT; in vivo formation of formaldehyde); no data on purity of the compound
Reliability: (2) valid with restrictions

(510)

Type: other: Repeated dose toxicity (HMT)
Remark: Species/Strain : Rat wistar
Sex: male/female
Route of admin.: oral feed
Exposure period: until natural death
Doses: 0.16 % hexamethylenetetramine in the diet
Control group: yes, concurrent no treatment
Result: Sixteen 2-month-old animals/sex were treated with hexamethylenetetramine in the diet which is converted to formaldehyde in vivo. Another 16 animals/sex were given normal diet (control). Voluntary muscular activity was determined after 11 days, 3, 7, and 14 months of treatment. According to the authors, the mean values for the voluntary activity were slightly decreased in the treated rats. However, considering the great individual variations, these differences were very small and they were not statistically significant.
These experiments were part of a fertility study.
Source: BASF AG Ludwigshafen
Test substance: hexamethylenetetramine (HMT; in vivo formation of formaldehyde); no data on purity of the compound
Reliability: (2) valid with restrictions

(517)

Type: other: Repeated dose toxicity (HMT)
Remark: Species/Strain : Rat wistar
Sex: male/female
Route of admin.: oral feed
Exposure period: until natural death
Doses: 0.16 % hexamethylenetetramine in the diet
Control group: yes, concurrent no treatment
Result: Twenty-four rats (12 males, 12 females) were offered both control diet (diet without any contaminant) and test diet (diet containing the test substance). The animals were allowed to choose their diet. The aim of the test was to evaluate whether the rats would avoid the food containing the test substance or not. Food consumption was recorded; the amounts of the test and control diet consumed over a 28-day period were calculated.
In the first part of the first 28-day trial, the rats ate more food containing the test substance, but in the latter part, the females, but not the males ate a little more of the control food. According to the authors, over the entire period, both sexes consumed little more test diet than control diet; however, the differences were negligible and not significant. The total amount of food eaten was fairly constant throughout the study; ca. 26 g/day for the males and ca. 18 g/day for the females.
These experiments were part of a fertility study.
Source: BASF AG Ludwigshafen
Test substance: hexamethylenetetramine (HMT; in vivo formation of formaldehyde); no data on purity of the compound
Reliability: (2) valid with restrictions

(517)

Type: other: Reproduction (HMT)
Result: Wistar rats 1% HMT in drinking water from 8 weeks of age to 20 weeks post partum (including pregnancy and lactation period of F1), 12 females and 6 males were used per group, treated group and control group). After 2 weeks of treatment, the rats were mated; the females were kept under treatment during pregnancy and lactation. Twelve treated and eleven controls became pregnant and gave birth to 124 and 118 pups, respectively. Out of these, 24 males and 24 females were treated with the test substance up to an age of 20 weeks, another 24/sex were used as untreated controls. At the end of treatment, the groups were sacrificed and examined macroscopically and histopathologically.
According to the authors, no adverse effects were observed when the rats were treated with hexamethylenetetramine which is formaldehyde releaser in vivo. No malformations were observed in the offsprings. The body weights of treated animals was significantly reduced compared to controls. In offsprings, this finding was recorded up to the 9th and 13th week of age in males and females, respectively.
Original in Italian with English abstract.
Source: BASF AG Ludwigshafen
Test substance: hexamethylenetetramine (HMT; in vivo formation of formaldehyde); no data on purity of the compound
Reliability: (2) valid with restrictions
(510) (442)

Type: other: Reproduction (HMT)
Result: Sixteen 2-month-old animals/sex were treated with 0.16% hexamethylenetetramine in the diet which is a formaldehyde releaser in vivo. Another 16 animals/sex were given normal diet (control). After 3 months of treatment (at the age of 5 months), females were mated with males of the same group and the numbers of offspring were recorded. In both, the test group and the control group, 16 males and 16 females of this F1 generation were fed the same diet as the parents from weaning onwards. They were weighed at the age of 7 and 15 weeks. At the age of 123 days, half of these rats were sacrificed and autopsied; livers, kidneys, adrenals, and gonads were weighed.
No significant differences in body weights and relative organ weights was observed between treated and untreated animals of both parents and offsprings. The post-mortem examinations revealed no signs of any disease attributable to the test substance. No significant differences in fertiliy were found in both parents and offsprings.
Source: BASF AG Ludwigshafen
Test substance: hexamethylenetetramine (HMT; in vivo release of formaldehyde); no data on purity of the compound
Reliability: (2) valid with restrictions
(446) (442) (517)

Type: other: Reviews
Source: BASF AG Ludwigshafen
Reliability: (2) valid with restrictions
(446) (443) (442)

5.11 Experience with Human Exposure

Remark: Review; assessment of data on the effects of FA on humans.
Source: BASF AG Ludwigshafen
Reliability: (4) not assignable
4.2; review
(518)

Remark: Review of mutagenic and carcinogenic potential.
Source: BASF AG Ludwigshafen
Reliability: (4) not assignable
4.2; review
(519)

Remark: Review; up–date of report 1 and 2.
Source: BASF AG Ludwigshafen
Reliability: (4) not assignable
4.2; review
(520)

Remark: Review of mutagenicity and carcinogenicity.
Source: BASF AG Ludwigshafen
Reliability: (4) not assignable
4.2; review
(521)

Remark: Review; evaluation of the carcinogenic risk
Source: BASF AG Ludwigshafen
Reliability: (4) not assignable
4.2; review
(522)

Remark: Review of carcingenicity, mutagenicity, irritation, reproductive effects/teratology, behavioral effects, immunotoxicity/sensitization, neurotoxicity, biochemistry/metabolism, and histopathology.
Source: BASF AG Ludwigshafen
Reliability: (4) not assignable
4.2; review
(523)

Remark: Review
Source: BASF AG Ludwigshafen
Reliability: (4) not assignable
4.2; review
(524)

Remark: Review of respiratory cancer
Source: BASF AG Ludwigshafen
Reliability: (4) not assignable
4.2; review
(525)

Remark: Review; data evaluation for MAK value and classification
Source: BASF AG Ludwigshafen
Reliability: (4) not assignable
4.2; review
(526)

Remark: Review; overall evaluation of the carcinogenic risk, up-date.
Source: BASF AG Ludwigshafen
Reliability: (4) not assignable
4.2; review
(527)

Remark: Review of the potential cancer risk to anatomists and other related health professionals.
Source: BASF AG Ludwigshafen
Reliability: (4) not assignable
4.2; review
(528) (529)

Remark: Review; data evaluation for risk in pregancy.
Source: BASF AG Ludwigshafen
Reliability: (4) not assignable
4.2; review
(530)

Remark: Review; data evaluation for MAK value and classification.
Source: BASF AG Ludwigshafen
Reliability: (4) not assignable
4.2; review
(531)

Remark: Review of human exposure, kinetics and metabolism, effects on man, incl. sensory, toxic, respiratory, sensitization, skin irritation, genotoxic, reproductive, and carcinogenic effects.
Source: BASF AG Ludwigshafen
Reliability: (4) not assignable
4.2; review
(532)

Remark: Review; documentation of threshold limit value.
Source: BASF AG Ludwigshafen
Reliability: (4) not assignable
4.2; review
(533)

Remark: Review of oral toxicity of FA and its derivates.
Source: BASF AG Ludwigshafen
Reliability: (4) not assignable
4.2; review
(534)

Remark: Review of animal and human toxicology and occupational exposure.
Source: BASF AG Ludwigshafen
Reliability: (4) not assignable
4.2; review
(535)

Remark: Review of risk assessment.
Source: BASF AG Ludwigshafen
Reliability: (4) not assignable
4.2; review
(536)

Remark: Review of epidemiological data.
Source: BASF AG Ludwigshafen
Reliability: (4) not assignable
4.2; review
(537)

Remark: Review of human cancer risk.
Source: BASF AG Ludwigshafen
Reliability: (4) not assignable
4.2; review
(538)

Remark: Review of the evaluation of the carcinogenic risk.
Source: BASF AG Ludwigshafen
Reliability: (4) not assignable
4.2; review
(539)

Remark: FA conc. in human blood were determined by analyzing venous blood samples before and after exp. of six volunteers to 1.9 +/– 0.1 ppm for 40 mminutes. Av. conc. (óg/g blood) were 2.61 +/– 0.14 before exp. and 2.77 +/– 0.28 after exposure. The effect was statistically not significant.
Source: BASF AG Ludwigshafen
Reliability: (2) valid with restrictions
2.1; acceptable study, meets basic scientific principles
(540)

Remark: 70 persons occupationally exposed to FA, 30 medical students with short but intensive inhalational exp. during anatomic dissection and 8 pathological–anatomical laboratory employees were investigated for formic acid excretion. A value of 23 mg formic acid(g creatinine is given as the upper normal level for adults. Short but intensive FA exp. (0.32–3.48 ppm) did not change significantly the av. formic acid conc.. Continous exp. (0.03–0.83 ppm) during the working week was related to a continous increase from 8.7 mg/g creat. to 22.3 mg/g creat.. The change proved to be not significant and no linear correlation was detected.
Source: BASF AG Ludwigshafen
Reliability: (2) valid with restrictions
2.1; acceptable study, meets basic scientific principles
(541)

Remark: Odor threshold 1.0 ppm in four selected test persons.
Source: BASF AG Ludwigshafen
Reliability: (2) valid with restrictions
2.1; acceptable study, meets basic scientific principles
(542)

Remark: Odor threshold was 0.3 ppm in 24 test persons exp. for 4 h on each of 4 consecutive days.
Source: BASF AG Ludwigshafen
Reliability: (2) valid with restrictions
2.1; acceptable study, meets basic scientific principles
(543)

Remark: Odor threshold was 0.25-0.83 ml/m3 in 11 test persons.
Source: BASF AG Ludwigshafen
Reliability: (2) valid with restrictions
2.1; acceptable study, meets basic scientific principles
(544)

Remark: Odor threshold was 0.06-0.09 ppm in 12 test persons.
Source: BASF AG Ludwigshafen
Reliability: (2) valid with restrictions
2.1; acceptable study, meets basic scientific principles
(545)

Remark: Odor threshold was 0.06-0.08 ppm in 15 test persons.
Source: BASF AG Ludwigshafen
Reliability: (2) valid with restrictions
2.1; acceptable study, meets basic scientific principles
(546)

Remark: Odor threshold was 0.05-0.89 ppm in 64 test persons.
Source: BASF AG Ludwigshafen
Reliability: (2) valid with restrictions
2.1; acceptable study, meets basic scientific principles
(547)

Remark: Eye and nose irritation at 13.8 ppm in 12 test persons exp. for 30 minutes.
Source: BASF AG Ludwigshafen
Reliability: (2) valid with restrictions
2.1; acceptable study, meets basic scientific principles
(548)

Remark: Eye irritation at 1-5.2 ppm in 13-20 test persons exp. repeadly for 5-12 min..
Source: BASF AG Ludwigshafen
Reliability: (2) valid with restrictions
2.1; acceptable study, meets basic scientific principles
(549)

Remark: Eye irritation at 0.33-0.58 ppm in 3/53 test persons exp. for 3 h.
Source: BASF AG Ludwigshafen
Reliability: (2) valid with restrictions
2.1; acceptable study, meets basic scientific principles
(547)

Remark: Irritation of the eyes, nose, and throat at 1.2-2.1 ppm in 33 test persons exposed contineously for 35 min. and in 48 test persons exp. discontinously (5 x 1.5 min.).
Source: BASF AG Ludwigshafen
Reliability: (2) valid with restrictions
2.1; acceptable study, meets basic scientific principles
(550)

Remark: Eye irritation at 0.25 – 0.83 ppm in 16 test persons exp. for 5 h.
Source: BASF AG Ludwigshafen
Reliability: (2) valid with restrictions
2.1; acceptable study, meets basic scientific principles
(551)

Remark: Threshold conc. of 0.2 ppm for eye irritation in 10 – 22 test persons exp. for 5 min..
Source: BASF AG Ludwigshafen
Reliability: (2) valid with restrictions
2.1; acceptable study, meets basic scientific principles
(552)

Remark: Threshold conc. of 1 ppm for eye irritation in 5-28 test persons exp. for 6 min..
Source: BASF AG Ludwigshafen
Reliability: (2) valid with restrictions
2.1; acceptable study, meets basic scientific principles
(553)

Remark: Initial eye irritation with rapid decline at 1 ppm in 15/18 test persons exposed for 90 min., irritation of the nose in 18 test persons with rapid acclimatization.
Source: BASF AG Ludwigshafen
Reliability: (2) valid with restrictions
2.1; accepatable study, meets basic scientific principles
(554)

Remark: Two groups of male workers who were exp. to FA (45 batt making and 18 tissue fixation) were studied for work-related neuro-behavioral, respiratory, and dermatological symptoms. Av. frequency of combined symptoms was 17.3 for batt making – hot areas, 14.7 for batt making – cold areas, 7.3 for tissue fixation, and 4.8 for the unexp. control group.
Source: BASF AG Ludwigshafen
Reliability: (2) valid with restrictions
2.1; acceptable study, meets basic scientific principles
(555)

Remark: Irriation of the eyes in 8/15, of the nose in 6/15, and the throat in 5/15 test persons at 2 ppm exp. for 40 min. at rest and with exercise.
Source: BASF AG Ludwigshafen
Reliability: (2) valid with restrictions
2.1; accepatable study, meets basic scientific principles
(556)

Remark: Eye, nose, and throat irritation in 9 test persons exp. at 3 ppm for 3 h.
Source: BASF AG Ludwigshafen
Reliability: (2) valid with restrictions
2.1; acceptable study, meets basic scientifc principles
(557)

Remark: Eye irritation at 1.0 ppm and nose and throat irritation at 0.5 ppm in healthy nonsmokers.
Source: BASF AG Ludwigshafen
Reliability: (2) valid with restrictions
2.1; acceptable study, meets basic scientific principles
(558)

Remark: Eye irritation in 66 % of 38 acid-hardening lacquer workers and nose and throat irritation in 39 % ($p<0.01$ vs. 18 contr.) at 0.33-0.58 ppm in a 8 h workday.
Source: BASF AG Ludwigshafen
Reliability: (2) valid with restrictions
2.1; acceptable study, meets basic scientific principles
(559)

Remark: Cross-sectional study in particle board workers. Nose irriatation in 2 % of workers, sore throat in 8 % at 0.1 ppm; nose irriatation in 4 %, sore throat in 8 % at 0.2 ppm; nose irritation in 21 %, sore throat in 20 % at 0.5 ppm; nose irriatation in 32 %, sore throat in 20 % at 0.8 ppm.
Source: BASF AG Ludwigshafen
Reliability: (2) valid with restrictions
2.1; acceptable study, meets basic scientific principles
(560)

Remark: Study in 84 funeral service workers reported more frequently nasal and eye irritation than 38 controls. Exp. level 0.36 +/- 0.19 ppm during 22 embalming procedures.
Source: BASF AG Ludwigshafen
Reliability: (2) valid with restrictions
2.1; acceptable study, meets basic scientific principles
(561)

Remark: Prospective evaluation in 103 medical students over a 7 months period. Eye and upper rspiratory tract irritation were significantly associated with exposure. Exp. level was generally <1 ppm and peak level <5 ppm.
Source: BASF AG Ludwigshafen
Reliability: (2) valid with restrictions
2.1; acceptable study, meets basic scientific principles
(562)

Remark: Increased ill health complaints in workers in fabric stores at >= 0.13 ppm for 30-50 h/wk..
Source: BASF AG Ludwigshafen
Reliability: (2) valid with restrictions
2.1; acceptable study, meets basic scientific principles
(563)

Remark: Case report on a 47-year-old diary foreman, who had been exp. for 9 years to FA emitted from a milk-packing machine situated underneath his office. Under normal process conditions FA level was 0.03 mg/m3. A specific laryngeal provocation-test with FA was positive. His laryngitis was so serious that he retired.
Source: BASF AG Ludwigshafen
Reliability: (2) valid with restrictions
2.2; basic data given, restrictions

(564)

Remark: Pilot study on ill health complaints, physiology, and histology of the upper airways in two groups of MDF board workers. The frequency of ill health complaints was higher, the sense of smell was poorer, and the frequency of nasal obstruction was higher for the MDF board workers in comparison to traditional borad workers and the reference group. Mucociliary activity was lower in the traditional board workers. Forced vital capacity was low in both groups when compared to expected values. Histologic changes did not differ significantly between the groups.
Source: BASF AG Ludwigshafen
Reliability: (2) valid with restrictions
2.1; acceptable study, meets basic scientific principles

(565)

Remark: 34 workers in a gross anatomy laboratory were evaluated for pulmonary response. FA conc. ranged from 0.07 – 2.94 ppm during dissecting operations. Reported symptoms included irritation of eyes (88 %), nose (74 %), throat (29 %), and airways (21 %).
Source: BASF AG Ludwigshafen
Reliability: (2) valid with restrictions
2.1; acceptable study, meets basic scientific principles

(566)

Remark: Report of one case of upper respiratory tract irritation after accidental inhalation of FA, which was sent to the clinic for further treatment.
Source: BASF AG Ludwigshafen
Reliability: (2) valid with restrictions
2.1; basic data given, restrictions

(567)

Remark: Review of health risks in homes insulated with urea formaldehyde foam and details of 48 patients contacting a poison center.
Source: BASF AG Ludwigshafen
Reliability: (4) not assignable
4.2; review

(568)

Remark: Review of health risks in homes insulated with urea formaldehyde foam and details of 48 patients contacting a poison center.
Source: BASF AG Ludwigshafen
Reliability: (4) not assignable
4.2; review
(569)

Remark: Sixty–five mobile home households volunteered for an assessment of indoor FA gas. Sixty–one teenage and adult occupants completed health questionnaires. FA conc. ranged from <0.1 – 0.8 ppm. Ocular discomfort showed a positive dose–response relationship.
Source: BASF AG Ludwigshafen
Reliability: (2) valid with restrictions
2.1; acceptable study, meets basic scientific principles
(570)

Remark: Review of health risks in homes insulated with urea formaldehyde foam.
Source: BASF AG Ludwigshafen
Reliability: (4) not assignable
4.2; review
(571)

Remark: Review; health risks in homes insulated with urea formaldeyhde foam.
Source: BASF AG Ludwigshafen
Reliability: (4) not assignable
4.2; review
(571)

Remark: Prevalence of selected symptoms were determined in 54 residents from 22 UFFI homes, 26 residents in 16 non–UFFI homes and 10 laboratory technicians. FA conc. were in UFFI homes 0.054 ppm, 0.051 in non–UFFI homes, and 0.125 ppm in the labs. Residents of UFFI homes reported a significantly higher prevalence of non–specific symptoms compared to the two other groups.
Source: BASF AG Ludwigshafen
Reliability: (2) valid with restrictions
2.1; acceptable study, meets basic scientific principles
(572)

Remark: Positive dose–response of ill health complaints (eye irritation, nose/throat irritation, headache and skin rash) at FA conc. of 0.1 ppm and above was demonstrated in 2000 residents living in mobile and conventional homes.
Source: BASF AG Ludwigshafen
Reliability: (2) valid with restrictions
2.1; acceptable study, meets basic scientific principles
(573)

Remark: Improvement of ill health complaints in a survey of 762 control and urea formaldehyde foam insulated houses 1 year after removal or remedial of the foam was not associated with changes in indoor FA levels.
Source: BASF AG Ludwigshafen
Reliability: (2) valid with restrictions
2.1; acceptable study, meets basic scientific principles
(574) (575) (576)

Remark: Case report of a 27-year-old neurology resident who noted progressive dyspnea and chest tightness after preparing formaldehyde-fixated tissues.
Source: BASF AG Ludwigshafen
Reliability: (2) valid with restrictions
2.2; basic data given, restrictions
(577)

Remark: Questionnaire and lung function tests were performed in five groups of phenol-formaldehyde resin workers. A slight excess of chronic cough and sputum production and a small decrease in lung function was seen.
Source: BASF AG Ludwigshafen
Reliability: (2) valid with restrictions
2.1; acceptable study, meets basic scientific principles
(578)

Remark: Cross-sectional study in 73 men and women exp. to phenolic resin dust and/or processed cotton dust. There was a statisitically significant acute drop in FEV1 and FVC over the shift in workers exp. to dust containing phenolic resin; workers exp. to processed cotton dust only, showed no significant changes.
Source: BASF AG Ludwigshafen
Reliability: (2) valid with restrictions
2.1; acceptable study, meets basic scientific principles
(579)

Remark: 47 subjects and 20 controls employed in a carpenter shop were studied for symptoms and lung function. Exp. level was 0.45 mg(m3 (mean). Changes in lung function suggesting bronchoconstriction were seen after a day of work and exp. to FA.
Source: BASF AG Ludwigshafen
Reliability: (2) valid with restrictions
2.1; acceptable study, meets basic scientific principles
(580)

Remark: Morbidity study in 199 employees in Fa manufacturing and its processing to resins for up to 42 years. Exp. level before 1971 <5 ppm, after 1971 <1 ppm. (average shift). No changes in lung function in comparison to a control group of 91 steel construction workers were seen.
Source: BASF AG Ludwigshafen
Reliability: (2) valid with restrictions
2.1; acceptable study, meets basic scientific principles
(581)

Remark: A population-based, retrosepctive survey of 395 urea-formaldehyde foam unsulated households and 400 controls showed a significant excess in two specific symptoms, "burning skin" and "wheezing or difficult breezing".
Source: BASF AG Ludwigshafen
Reliability: (2) valid with restrictions
2.1; acceptable study, meets basic scientific principles
(582)

Remark: No significant changes in lung function in 18 subjects exp. to 1-2 ppm FA for 90 min..
Source: BASF AG Ludwigshafen
Reliability: (2) valid with restrictions
2.1; acceptable study, meets basic scientific principles
(583)

Remark: No chronic bronchitis or lung function disorders in embalmers occupationally exp. to FA (0.4-2.1 peak conc.).
Source: BASF AG Ludwigshafen
Reliability: (2) valid with restrictions
2.1; acceptable study, meets basic scientific principles
(584)

Remark: No increase in airway resistance, neither at rest or during exercise in test persons with symptoms of asthma during exp. up to 3 ppm for 10 min..
Source: BASF AG Ludwigshafen
Reliability: (2) valid with restrictions
2.1; acceptable study, meets basic scientific principles
(585)

Remark: No changes in breathing capacity during working weeks in laboratory technicians. Ex. level up to 5.86 ppm (av. 0.125 ppm).
Source: BASF AG Ludwigshafen
Reliability: (2) valid with restrictions
2.1; acceptable study, meets basic scientific principles
(586)

Remark: Symptoms of astham in 5 of 15 test persons exp. up to 25 ppm and 30 min..
Source: BASF AG Ludwigshafen
Reliability: (2) valid with restrictions
2.2; basic data given, restrictions
(587)

Remark: Positive bronchial provocation test (1-2 ppm for 30 min.) in 12 of 230 persons exp. to FA and suffering asthma-like symptoms.
Source: BASF AG Ludwigshafen
Reliability: (2) valid with restrictions
2.2; basic data given, restrictions
(588)

Remark: No airway onbstruction in steel foundry workers occupationally exp. to up to 4 ppm FA in comparison to controls.
Source: BASF AG Ludwigshafen
Reliability: (2) valid with restrictions
2.1; acceptable study, meets basic scientific principles
(589)

Remark: Slight changes in lung function parameters in test persons after 30 min. exp. at 3 ppm for 3 h; reversible within 1-3 hrs; no changes in asthmatic subjects.
Source: BASF AG Ludwigshafen
Reliability: (2) valid with restrictions
2.1; acceptable study, meets basic scientific principles
(590) (557) (591)

Remark: No changes in lung function parameters in 15 test persons with bronchial hypersensitivity at 0.12 and 0.85 mg/m3 for 90 min..
Source: BASF AG Ludwigshafen
Reliability: (2) valid with restrictions
2.1; acceptable study, meets basic scientific principles
(592)

Remark: No changes in lung function in 30 test persons including 15 having asthma exp. to 2 ppm for 40 mi. at rest and exercise.
Source: BASF AG Ludwigshafen
Reliability: (2) valid with restrictions
2.1; acceptable study, meets basic scientific principles
(593) (594) (556)

Remark: No significant decrements in lung function or increase in bronchial reactivity with exp. to 3 ppm at rest or to 2 ppm at exercise in healthy nonsmokers.
Source: BASF AG Ludwigshafen
Reliability: (2) valid with restrictions
2.1; acceptable study, meets basic scientific principles
(595)

Remark: No changes in lung function in 15 hospital laboratory workers exp. to 2.0 ppm for 40 min. on four occasions (two at rest and two during exercise).
Source: BASF AG Ludwigshafen
Reliability: (2) valid with restrictions
2.1; acceptable study, meets basic scienticfic principles
(596)

Remark: No chronic decrements in lung function in 38 acid-hardening paint workers in comparison to 18 conrols. Mean exp. conc. wa 0.4 mg/m3 FA.
Source: BASF AG Ludwigshafen
Reliability: (2) valid with restrictions
2.1; acceptable study, meets basic scientific principles
(559)

Remark: No changes in lung function in residents of mobile and conventional homes and mobile offices exp. to 0.006–1.6 ppm Fa.
Source: BASF AG Ludwigshafen
Reliability: (2) valid with restrictions
2.1; acceptable study, meets basic scientific principles
(597) (597) (575) (598)

Remark: Cross–sectional study in 109 particle board workers and 254 controls. No evidence of a chronic decrement in lung function after a mean exp. of 0.17–2.93 ppm for ten years.
Source: BASF AG Ludwigshafen
Reliability: (2) valid with restrictions
2.1; acceptable study, meets basic scientific principles
(599)

Remark: Cross–sectional study in three groups (70 chemical plant workers, 100 furniture production workers, 36 clerks). No signs that duration of exp. or level of exp. (0.05–0.5, 02–0.3, or 0.09 mg/m3) to FA had any influence on the severity or symptoms or impairment of lung function parameters.
Source: BASF AG Ludwigshafen
Reliability: (2) valid with restrictions
2.1; acceptable study, meets basic scientific principles
(600)

Remark: Cross–sectional study in 176 strandboard production workers. Ex. to FA was low (<0.01 – 0.06 ppm). measured dust was low to moderate (.01 – 0.57 mg/m3). No evidence of an acute effect on lung function.
Source: BASF AG Ludwigshafen
Reliability: (2) valid with restrictions
2.1; acceptable study, meets basic scientific principles
(601)

Remark: Prospective study in 47 woodworkers and 20 controls first examined in 1980. A dose–response relationship was found between exp. to FA (0.3 – 0.7 mg/m3) and decrease in lung function. The impairment, however, can be reversed within 4 weeks of no exposure.
Source: BASF AG Ludwigshafen
Reliability: (2) valid with restrictions
2.1; acceptables study, meets basic scientific principles
(602)

Remark: Small, but not clinically significant pulmonary response in 24 healthy volunteers exposed while exercising for 2 h to 3 ppm or a mixture of FA and 0.5 mg/m3 of respirable dust.
Source: BASF AG Ludwigshafen
Reliability: (2) valid with restrictions
2.1; acceptable study, meets basic scientific principles
(603) (604) (605)

Remark: Cross–sectional study in 84 funeral service workers revealed no significant change in lung function in comparison to controls. Exp. level was 0.36 +/– 0.19 ppm during 22 embalming procedures.
Source: BASF AG Ludwigshafen
Reliability: (2) valid with restrictions
2.1; acceptables study, meets basic scientific principles
(561)

Remark: Prospective study in 103 medical students (TWA < 1 ppm, peak < 5 ppm) showed no pattern of bronchoconstriction in response to exp. after either 2 weeks or 7 months. Twelve subjects had a history of asthma; they were no more likely to have smyptoms than those without such a history.
Source: BASF AG Ludwigshafen
Reliability: (2) valid with restrictions
2.1; acceptable study, meets basic scientific principles
(606)

Remark: No changes in lung function or increase in bronchial reactivity in 15 asthmatic subjects exp. to 0.008 – 0.85 mg/m3 for 90 min..
Source: BASF AG Ludwigshafen
Reliability: (2) valid with restrictions
2.1; acceptable study, meets basic scientific principles
(607)

Remark: The respiratory health status of 186 male plywood workers was evaluated by spirometric tests, repsiratory questionnaires, and chest x–ray. Area con. ranged from 0.28 – 3.48 ppm. The av. personal exp. was 1.13 ppm. Exp. was associated with decrements in the baseline spirometric values and with several respiratory symptoms and diseases, incl. cough, phlegm, asthma, chronic bronchitis, and chest colds.
Source: BASF AG Ludwigshafen
Reliability: (2) valid with restrictions
2.1; acceptable Study, meets basic scientific principles
(608)

Remark: The long term effects on the respiratory tract have been investigated in a group of 164 workers exp. daily during the production of urea formaldehyde resin together with 129 workers not exp. to free FA. Exp. was classified as high (TWA > 2 ppm), medium (TWA 0.6 – 2 ppm), or low (0.1 – 0.5 ppm). the proportion with self reported respiratory symptoms was similar in the two groups. The initial FEV1 was within 0.5 l of the predicted value for both groups. The mean decline in FEV1 was 42 ml a year for the exp. and 41 ml for the controls.
Source: BASF AG Ludwigshafen
Reliability: (2) valid with restrictions
2.1; acceptable study, meets basic scientific principles
(609)

Remark: Case report on airways obstruction after exp. to FA.
Source: BASF AG Ludwigshafen
Reliability: (2) valid with restrictions
2.2; basic data given, restrictions
(610)

Remark: Hypersensitivity was shown by inhalation provocation tests in two nurses with attacks of wheezing accomponied by productive cough. Two ot three firther members of the staff of 28 who had developed similar recurrent but less frequent episodes did not produce these symptoms under inhalative provocation. Single episodes of these symptoms had been notes by three additional staff members. The exp. did not seem to be directly responsible in all cases, it might have increased susceptibility to other provoking agents or induced a hyperreactive responsiveness of the airways.
Source: BASF AG Ludwigshafen
Reliability: (2) valid with restrictions
2.1; basic data given, restrictions
(611)

Remark: Case report; bronchial challenge at 3 ppm was negative in a patient with severs asthma after use of urea–formaldehyde foam.
Source: BASF AG Ludwigshafen
Reliability: (2) valid with restrictions
2.1; acceptable study, meets basic scientific principles
(612)

Remark: Reinvestigation of two nurses who have shown positive inhalation provocation tests. In one nurse a 15 min. exp. to 6 ppm provoked no reaction; in the other a 5 min. exp. to 3 ppm provoked a late asthmatic reaction.
Source: BASF AG Ludwigshafen
Reliability: (2) valid with restrictions
2.1; acceptable study, meets basic scientific principles
(613)

Remark: 13 selected patients with symptoms suggestive of asthma and exp. to FA at their homes or at work (0.1 – 1.2 ppm) were tested with bronchial challenges of 0.1, 1, and 3 ppm for 20 min.. In no case asthmatic symptoms were caused or aggrevated.
Source: BASF AG Ludwigshafen
Reliability: (2) valid with restrictions
2.1; acceptable study, meets basic scientific principles
(614)

Remark: Bronchial provocation (0.1, 1, 10, 20, and 25 %) was performed in 15 workers occupationally exp. to FA were performed. Three showed asthma with late asthmatic reactions and six immediate reactions, which were likely to be due to direct irritant effects. FA conc. required to elicit these irritant reactions was 4.8 mg/m3 (mean).
Source: BASF AG Ludwigshafen
Reliability: (2) valid with restrictions
2.1; acceptable study, meets basic scientific principles

(587)

Remark: Immunological test in 23 asthmatic subjects who lived in urea-formaldehyde foam-insulated homes and on 4 asthmatic subjects living in conventionally insulated homes showed after long-term exp. no , and at short-term exp. minor changes.
Source: BASF AG Ludwigshafen
Reliability: (2) valid with restrictions
2.1; acceptables study, meets basic scientific principles

(615)

Remark: No IgE-mediated sensitization could be attributed to FA in 86 subjects living or working in rooms or places were formaldheyde-containing construction materials were used.
Source: BASF AG Ludwigshafen
Reliability: (2) valid with restrictions
2.2; basic data given, restrictions

(616)

Remark: Clinical and immunological evaluation or 37 workers exp. to gaseous FA. None of the workers had IgE or IgG antibody to F-HAS or an immunologically mediated respiratory or ocular disease by FA; however some of the workers appeared to experience irritant symptoms.
Source: BASF AG Ludwigshafen
Reliability: (2) valid with restrictions
2.1; acceptable study, meets basic scientific principles

(617)

Remark: Report on 61 serum samples analyzed for IgG antibodies against F-HSA. There is no evidence that gaseous FA meets the criteria for causation of inhalational IgG-mediated lung disease by clincial or serological studies.
Source: BASF AG Ludwigshafen
Reliability: (2) valid with restrictions
2.1; acceptables study, meets basic scientific principles

(618)

Remark: 55 subjects were studied to determine if the presence of IgE or IgG antidbodies to F-HSA was associated with exp. to gaseous FA or with respiratory or cunjunctival symptoms. IgE antibody specific for FA-HSA was deteced by ELISA in three subjects; immediate-type skin testing was negative in two of these subjects, and not interpretables in one. A respiratory challenge at 2 ppm in one of these subjects with history or respiratory symptoms showed no changes in lung function. A relationship between presence of antibodies or respiratory or conjunctival symptoms and histroy of gaseous FA exp. could not be defined.
Source: BASF AG Ludwigshafen
Reliability: (2) valid with restrictions
2.1; acceptable study, meets basic scientific principles

(619)

Remark: Study on prevalence of atopy and hypersensitivity to FA in pathologists. None of 63 subjects had allergen-specific IgE, although 29 subejcts complained of sensitivity.
Source: BASF AG Ludwigshafen
Reliability: (2) valid with restrictions
2.1; acceptable study, meets basic scientific principles
(620)

Remark: Case report of 4 patients and experiment in 14 volunteers of contact urticaria to FA. The contact urticaria appeared on healthy skin only following repeated open applications or after single application on slightly diseased skin.
Source: BASF AG Ludwigshafen
Reliability: (2) valid with restrictions
2.1; acceptable study, meets basic scientific principles
(621)

Remark: Prevalence rate of FA sensitivity in 4553 male and 6479 female patients tested from 1984-1989 was 2.2 % for the men and 4.0 % for the women. Source of exp. in men was occupational (31 %), domestic (10 %), and unknown (48 %). 95 of the female cases were sensitized by FA donators and 117 cases by FA itself.
Source: BASF AG Ludwigshafen
Reliability: (2) valid with restrictions
2.2; basic data given, restrictions
(622)

Remark: 23 patients with a history of a positive epicutaneous test to FA were studied for specific IgE antidbodies. On rats test, only two nonatopic patients had specific IgE antibodies. No support that specific IgE antidbodies are active in the pathogenesis of contact sensitivity either in atopic or in nonatopic patients was found.
Source: BASF AG Ludwigshafen
Reliability: (2) valid with restrictions
2.1; acceptable study, meets basic sceintific principles
(623)

Remark: Case report on contact urticaria in a pathology laboratory worker (open patch test: 1 % and 2 % pruritic flares, 0.5 % neg.).
Source: BASF AG Ludwigshafen
Reliability: (2) valid with restrictions
2.1; acceptables study, meets basic scientific principles
(624)

Remark: Case report on contact urticaria from FA treated leather (pos. patch-test at 2 %).
Source: BASF AG Ludwigshafen
Reliability: (2) valid with restrictions
2.1; acceptable study, meets basic scientific principles
(625)

Remark: Questionnaire study among 70 employees at day care centers and 34 controls. Median exp. level was 0.43 mg/m3, resp. 0.08 mg/m3. Exp. employees showed a significantly higher frequency of mucous membran irriatation, headache, abnormal tiredness, menstrual irregularities, and use of analgetics.
Source: BASF AG Ludwigshafen
Reliability: (2) valid with restrictions
2.1; basic data given, restrictions

(626)

Remark: Two groups of male worker exp. to phenol-FA-plastic foam and tissue fixation for histology were studied for work-related neuro-behavioral, respiratory, and dermatological symptoms. Av. combined frequency were 17.3 and 14.3 for the plastic foam workers, 7.3 for the histology technicians, and 4.8 for unexp. hospital workers.
Source: BASF AG Ludwigshafen
Reliability: (2) valid with restrictions
2.2; basic data given, restrictions

(555)

Remark: Case report of a 26-year-old female who had accidentally ingested 45 ml of a 37 % (v/v) FA solution. Examination of the oropharynx after reference to the clinic four days after ingestion revealed ulceration and sloughing of soft palate and posterior pharyngeal wall. Gastrointestinal endoscopy showed oedematous and ulceration of the oesophagal mucosa with patches of black slough along its whole length.
Source: BASF AG Ludwigshafen
Reliability: (2) valid with restrictions
2.1; acceptable study, meets basic scientific principles

(627)

Remark: Case report of four cases of nephrotic syndrome after exposure to FA in newly built homes. Membranous nephropathy was confirmed by biopsy. The four patients shared a particular histocompatibility leukocyte antigen (HLA). FA conc. ranged from 0.10-0.49 ppm.
Source: BASF AG Ludwigshafen
Reliability: (2) valid with restrictions
2.2; basic data given, restrictions

(628)

Remark: Impaired nervous system function was seen in three patients using FA an phenol in fixation of animals for 14-30 years and a fourth patient covered several times in FA and phenol spills. They had elevated mood state and symptom frequency scores compared to controls. There was excessive fatigue, somnolence, headache, difficulty remembering, irritability, and instability of mood.
Source: BASF AG Ludwigshafen
Reliability: (2) valid with restrictions
2.2; basic data given, restrictions

(629)

Remark: Nasal lavage fluid was investigated in 11 healthy subjects and 9 patients with specific skin sensitization after provocation with FA (0.5 mg/m3 for 2 h). An increase in eosinophiles and elevated albumin and total protein levels were observed. No difference was found between healthy subjects and patients.
Source: BASF AG Ludwigshafen
Reliability: (2) valid with restrictions
2.1; acceptable study, meets basic scientific principles
(630)

Remark: Eight symtomatic subjects exp. to indoor FA at 0.07-0.55 ppm were compared to 8 nonexposed with respect to immunological parameters. Anti-FA-HAS IgG, but no IgE antibodies were detected in the 8 exposed; none were found in 7 of the unexposed. Proportion of peripheral T cells were decreased in the exposed in comparison to the controls.
Source: BASF AG Ludwigshafen
Reliability: (2) valid with restrictions
2.2; basic data given, restrictions
(631) (632) (633)

Remark: 6 patients with multiple subjective ill health complaints and exp. to FA during education and occupation showed changes in immunological parameters; two showed IgE, 3/4 tested IgM and 5 IgG. All 6 had elevated t cells (antigen memory cells).
Source: BASF AG Ludwigshafen
Reliability: (2) valid with restrictions
2.2; basic data given, restrictions
(631) (634) (635)

Remark: Four groups of patients with long-term inhalation exp. showed significantly higher antibody titers to FA-HAS and significant increases in Ta1+, IL2+, and B cell lymphocytes compared to controls with short term periodic exp..
Source: BASF AG Ludwigshafen
Reliability: (2) valid with restrictions
2.2; basic data given, restrictions
(636)

Remark: Three years following exp. to emissions from a overheated tanker containing urea-FA resin immunological parameters were investigated in 42 exp. subjects and 29 controls. There was a significant difference for CD26 cells, autoantibodies, and titers of IgG and IgM to FA-HSA.
Source: BASF AG Ludwigshafen
Reliability: (2) valid with restrictions
2.2; basic data given, restrictions
(637)

Remark: Cytogenetic evaluation of 15 employees exp. in FA manufacturing and processing for 23 to 35 years (28 years average) revealed no statistically significant increase in chromosome aberration rates in lymphocytes as compared with a matched control group. Exp. level <1971: 5 ppm and >1971: 1 ppm.

Source: BASF AG Ludwigshafen
Reliability: (2) valid with restrictions
2.1; acceptable study, meets basic sceintific principles
(638)

Remark: No significant difference in chromosome aberrations or SCE frequencies in lymphocytes between 6 exp. pathology workers and 5 controls. Ex. level 1.8-3.9 ppm.
Source: BASF AG Ludwigshafen
Reliability: (2) valid with restrictions
2.1; acceptable study, meets basic scientific principles
(639)

Remark: Elven hospital autopsy service workers and 11 mated controls were evaluated for sperm count, abnormal sperm morphology and frequency of one or two fluorescent bodies. No sigficant difference was observed. Exp. was intermittent, with a TWA of 0.61-1.32 ppm.
Source: BASF AG Ludwigshafen
Reliability: (2) valid with restrictions
2.1; acceptable study, meets basic scientific principles
(640)

Remark: Significant difference in some cytogenetic measures (dicentrics or ring chromosomes), but not in SCE, in lymphocytes in 20 exp. paper factory workers and 20 controls. Exp. level 1-3 ppm.
Source: BASF AG Ludwigshafen
Reliability: (2) valid with restrictions
2.1; acceptable study, meets basic scientific principles
(641)

Remark: Small but significant increase in SCE in lymphocytes in 8 exp. anatomy students when compared to samples obtained before exp.. Exp. level 1.2 ppm.
Source: BASF AG Ludwigshafen
Reliability: (2) valid with restrictions
2.1; acceptable study, meets basic scientific principles
(642)

Remark: Cytologic examination of exfoliated nasal mucosa cells in 42 phenol-FA and Fa process workers showed no statistical realtionship to FA exp. in compariosn to 38 controls. Ex. level was 0.02-2 ppm.
Source: BASF AG Ludwigshafen
Reliability: (2) valid with restrictions
2.1; acceptable study, meets bsic scientific principles
(643)

Remark: A significant difference of histology index in the nasal musosa but no relation to dose or duration of FA exp. was found in 75 particle board workers and 25 controls. Exp. level was 0.08-1.0 ppm.
Source: BASF AG Ludwigshafen
Reliability: (2) valid with restrictions
2.1; acceptable study, meets basic scientific principles
(644) (645)

Remark: A significant difference of histology index in nasal mucosa but no relation to dose and duration of FA exp. was found in 62 resin manufacturing workers and 32 controls. Exp. level was 0.04-0.4 and 0.17-0.25 ppm.
Source: BASF AG Ludwigshafen
Reliability: (2) valid with restrictions
2.1; acceptable study, meets basic scientific principles
(646)

Remark: No significant difference of histology index in nasal mucosa in 37 workers and 37 controls. Fa exp. level 0.5->2 ppm.
Source: BASF AG Ludwigshafen
Reliability: (2) valid with restrictions
2.1; acceptable study, meets basic scientific principles
(647)

Remark: Cross-sectional study in 16 MDF- and 29 traditional board workers and 36 controls. Nasal epithelial dysplasia were seen in a few cases of the traditional board group, but histological changes in terms of scoring did not differ significantly between the groups.
Source: BASF AG Ludwigshafen
Reliability: (2) valid with restrictions
2.1; acceptable study, meets basic scientific principles
(648)

Remark: The frequency of MN and cytology of respiratory nasal mucosa cells were evaluated in 15 workers in a plywood factory compared to a control group. Exp. level ranged from 0.1 to 0.39 mg/m3 for FA and contemporary wood dust (0.23-0.73 mg/m3). A higher frequency of MN and a chronic phlogosis in the nasal mucosa with metaplasia cells was observed in the exposed versus controls, but no dose-response effect.
Source: BASF AG Ludwigshafen
Reliability: (2) valid with restrictions
2.1; acceptable study, meets basic scientific principles
(649)

Remark: Workers of a plywood production plant (n=9), a chipboard impregnation facility (n=10), and a fiber glass factory (n=9) exp. appr. to 0.1, 0.2, and 0.3 resp. were studied for MN in buccal mucosa cells. For comparison MN were also scored in blood lymphocytes. The exp. workers showed more than twice as much MN-buccal mucosa cells than a control group (n=34). A dose-response relationship could not be demonstrated. MN in lymphocytes were only related to age.
Source: BASF AG Ludwigshafen
Reliability: (4) not assignable
4.1; abstract
(650)

Remark: Metaplasia of nasal mucosa with corresponding retardation of mucociliar clearance were detected in 9 of 18 workers and in 6 a deterioration of olfactory function. FA exp. duration was 11.3 years (mean); conc. was 2.54 ppm (mean out of several single measurements during one year).
Source: BASF AG Ludwigshafen

Reliability: (2) valid with restrictions
2.2; basic data given, restrictions
(651)

Remark: 20 workers in manufacture of wood splinter materials were investigated for chromosomal aberrations. Significant differences were observed in mitogen-induced proliferation of lymphocytes between the exposed and controls. FA conc. ranged from 0.55-10.36 mg/m3.
Source: BASF AG Ludwigshafen
Reliability: (2) valid with restrictions
2.2; basic data given, restrictions
(652)

Remark: Exfoliated buccal and nasal cells from 35 mortuary science students exposed to embalming fluid containing FA were examined before and after a 90 days course. In buccal cells, total MN frequency was significantly increased, whereas in nasal cells it was not.
Source: BASF AG Ludwigshafen
Reliability: (2) valid with restrictions
2.1; acceptable study, meets basic scientific principles
(653)

Remark: Significantly increased MN from biccal area cells and blood lymphocytes, but not from nasal cells in a 85 day study period in 29 mortuary students. Results differ for men and women.
Source: BASF AG Ludwigshafen
Reliability: (2) valid with restrictions
2.2; basic data given, restrictions
(654)

Remark: Morbidity study in 199 employees in FA manufacturing and its processing to resins for up to 42 years. Exp. level before 1971: <5 ppm, after 1971 <1 ppm (average shift). No nasal or lung tumors were observed.
Source: BASF AG Ludwigshafen
Reliability: (2) valid with restrictions
2.1; acceptable study, meets basic scientific principles
(655)

Remark: Retrospective cohort mortality study with 26,561 subjects first employed before 1966 and followed until 1980 for vital status, which included plants reported on previously by other researchers. Job exp. matrix was developed for 6,700 job titles. There was no overall cancer excess (SMR 101, 95 % CI: 93-109). Nasal cancer showed no excess risk (2 obs. vs. 2.2 expect.) as for buccal cavity and phrynx (SMR=96, 95 % CI: 57-152), brain (SMR=81, 95 % CI:47-130), and leukemia (SMR=80, 95 % CI: 47-130). Lung cancer was slightly but not significantly above expectation (SMR=112, 95 % CI: 97-128), and was not correlated with intensity or duration of exp., cumulative exp., or peak exp.. Although mortality for buccal cavitiy and pharynx cancer was not elveated (SMR=96), when the numerous subsites were examined, an excess risk for nsaopharyngeal cancer (NPC) was seen (7 obs. vs. 2.2

expect.). Of the 7 NPSCs, 6 were associated with exp. to FA (SMR=300). There was a suggestive non-significant trend with cumulative exp.. However, for the other sited of the pharynx there was an inverse association with the level of esp.. Only 1 unspecified oral/pharyngeal cancer death was found in the FA cohort vs. 4.4 expected. Correction for the differnces in diagnostic criteria used and misclasification reduced the significance of the excess risk of NPC. Further analysis found that although short term workers had higher total cancer risk,their exp. was not greater than long-term workers.

Source: BASF AG Ludwigshafen

Reliability: (2) valid with restrictions
2.1; acceptable study, meets basic scientific principles
(656) (657) (658) (659) (660) (661) (662) (663) (664) (665)

Remark: Retrospective cohort mortality study from 1959 to 1980 and follow-up to 1986 in 1,332 subjects of a resin manufacturing plant. Mean level exp. was 0.2-3.8 ppm. No nasal cancers or NPC were reported. SMR on oral/phyrngeal cancer, brein cancer or leukemia were not presented. A SMR for hematologic cancer (SMR=154, 95 % CI: 50-359, 5 deaths) was presented. A statistically siginificant SMR of 186 for lung cancer (SMR 136, 95 % CI: 44-318) was at lower risk than those with "other" or "unknown" exp.. For the FA group there was no relation between risk of lung cancer and duration of employment or latency. In an update of this cohort, overall lung cancer mortality was no longer in excess.

Source: BASF AG Ludwigshafen

Reliability: (2) valid with restrictions
2.1; acceptable study, meets basic scientific principles
(666) (667)

Remark: Cohort study in 521 workers in the abrasive manufacturing industry. Exp. was 5 mg/m3 total dust, silica 0.1 mg/m3, FA 0.1-1 mg/m3 with intermittent peaks uo to 20-30 mg/m3 in 59 workers. No excess of cancer incidence or mortality; no nasal or nasopharyngeal cancer reported.

Source: BASF AG Ludwigshafen

Reliability: (2) valid with restrictions
2.1; acceptable study, meets basic scientific principles
(668)

Remark: Cohort study in 11,030 female textile workers in three plants starting use fo FA in 1955 and 1959. No deaths of nasal cancer or NPC were observed. The SMR for brain cancer was 71 (90 % CI: 28-149) and for leukemia was 114 (90 % CI: 60-200). There was a non-significant elevation in lung cancer mortality (SMR=114, 90 % CI: 86-149) according to an eleveated risk among short-term workers where exp. to FA was recent and much lower than in the past. A statistically significant elevation of buccal cavity cancer, 4 obs. vs. 1.2 expect. (SMR=343, 90 % CI: 118-786) was reported. The SMR is no longer significant calculating conventional 95 % CI. Snuff dipping has to be considered. There was no excess of pharyngeal cancer deaths.

Source: BASF AG Ludwigshafen

Reliability: (2) valid with restrictions
2.1; acceptable study, meets basic scientific principles
(669) (670)

Remark: Reanalysis of lung cancer mortality study among industrial workers exp. to FA. No statistically significant positive trend for lung cancer with cumulative FA exp. was found.
Source: BASF AG Ludwigshafen
Reliability: (2) valid with restrictions
2.1; acceptable study, meets basic scientific principles
(671)

Remark: Extended cohort study of mortality and incidence in 14,017 Fa industry workers foloowed up to 1989 in 6 plants, 7,660 employed before 1965 and 6,357 first employed after 1964. There was one death from nasal cancer vs. 1.74 expect. in the low exp. category (0.1 –0.5 ppm). ther were no deaths from NPC (vs. 1.3 expect.). There was a slight non-significant excess risk of oral/pharyngeal cancer (SMR=110, 95 % CI: 59-189), 21 brain cancer deaths vs. 23 expect., and 19 leukemia deaths vs. 21.2 expect.. Forlung cancer a slight siginficant SMR of 112 (95 % CI: 100-124) were seen for workers employed before 1965, while the slight excess in SMR (113, 95 % CI: 85-147) in workers employed after 1964 was not statistically significant.
Source: BASF AG Ludwigshafen
Reliability: (2) valid with restrictions
2.1; acceptable study, meets basic scientific principles
(672) (673)

Remark: Meta-analysis of epidemiologic studies on FA exp. and respiratory cancer did not indicate an excess risk or an exposure-response gradient forlung cancer. An exposure-response gradient was seen for both sinonasal and nasopharyngeal cancers.
Source: BASF AG Ludwigshafen
Reliability: (2) valid with restrictions
2.1; acceptable study, meets basic scientific principles
(674)

Remark: A mortality study in a subcohort of 3,929 workers in an automotive iron foundry with exp. to FA found no relation to cancer risk. There were no deaths reported from nasal cancer, and one death from NPC in a non-exp. worker.
Source: BASF AG Ludwigshafen
Reliability: (2) valid with restrictions
2.1; acceptable study, meets basic scientific principles
(675) (676)

Remark: An updated historical cohort mortality study in 7359 chemical plant workers exp. to FA and particulates was performed. Long-term workers showed a generally similar to more favourable mortality than that of the general public. For several causes including lung cancer, death rates among short-term workers were significantly increased. Overall and in the seperate year of hire subgroups, consistently higher percentages of long-term workers were ever exposed to

pigment, FA and pigment, FA>=0.2 ppm, and FA>=0.7 ppm.
Source: BASF AG Ludwigshafen
Reliability: (2) valid with restrictions
2.1; acceptable study, meets basic scientific principles
(677) (678)

Remark: Updated meta-analysis of 47 eoidemiologic studies and upper respiratory tract cancers showed for the cohort studies a relative risk of 1.0 and 1.3 for the case-control studies.
Source: BASF AG Ludwigshafen
Reliability: (2) valid with restrictions
2.1; acceptable study, meets basic scientific principles
(679)

Remark: Mortality study in 2,079 pathologists and 12,944 medical laboratory assistants studied from 1955 to 1973 (path.) and 1963 to 1973 (ass.). No deaths from nasal cancer, oral/pharyngeal cancer, NPC or brain cancer were reported. Lung cancer risk was low (path.: SMR=39, 95 %CI: 20-70; ass.: 59, 95 % CI: 30-100). Only cancer with increases risk was that of lymphoma and hematoma (SMR=200, 95 % CI: 86-394). Follow-up of the pathologists from 1974 through 1980 showed no deaths from nasal cancer, oral/pharyngeal cancer or NPC. Lung cancer deaths were still significantly low. There was an excess of brain cancer deaths (SMR=331, 95 %CI: 90-847). In contrast to the earlier report, there was no excess of deaths from lymphtic or hematopoetic cancers (9 vs. 11.7). A further follow-up reported no cases of nasal or nasopharyngeal cancer; and no cancer sites were observed to be significantly in excess of expected.
Source: BASF AG Ludwigshafen
Reliability: (2) valid with restrictions
2.1; acceptable study, meets basic scientific principles
(680) (681) (682)

Remark: Association in 84 cases of lung cancer in Danish physicians were xamined compared to 252 controls. No lung cancer cases were found in pathologists, and the risk in other medical specialities did not differ significantly from the risk in general practitioners. The lung cancer risk associated with employment at some time during professional carrer was not increased either.
Source: BASF AG Ludwigshafen
Reliability: (2) valid with restrictions
2.1; acceptable study, meets basic scientific principles
(683)

Remark: Proportional mortality study in 1,132 embalmers died between 1925 and 1980. No nasal cancers or NPC were reported. There were 8 deaths from oral and pharyngeal cancer compared with 7.1 expected (PMR=113, 95 % CI: 49-222). For lung cancer, there were 72 deaths vs. 66.8 expected (PMR=108, 95 %CI: 85-136). There were 9 deaths from brain cancer compared with 5.8 expected (PMR=156, 95 % CI: 72-296); and 12 leukemia deaths compared with 8.5 expected (PMR=140, 95 % CI: 72-244). For colon cancer PMR was 143 (95 % CI: 96-205) and 221 for skin cancer (95 % CI: 95-435).

Source: BASF AG Ludwigshafen
Reliability: (2) valid with restrictions
2.1; acceptable study, meets basic scientific principles
(684)

Remark: Proportional mortality study in 1,007 embalmers started in 1925 and lasted through 1980. No nasal cancer deaths occured and no NPC deaths were reported. Eight oral and pharyngeal cancer deaths occured vs. 6.1 expected (PMR=131, 95 % CI: 56-258). There were 41 lung cancer deaths compared with 42.9 expected (PMR=96, 95 % CI: 69-130). Nine deaths from brain cancer were seen vs. 4.7 expected (PMR=194, 95 % CI: 89-368). Leukemia deaths were also greater than expected (12 observed vs. 6.9 expected, PMR=175, 95 % CI: 90-305). PMR for colon cancer was significantly raised at PMR=187 (30 vs. 16.0 expected) and for prostate cancer at PMR=175 (23 vs. 13.1 expected).
Source: BASF AG Ludwigshafen
Reliability: (2) valid with restrictions
2.1; acceptable study, meets basic scientific principles
(685)

Remark: Retrospective cohort mortality study of 1,477 morticians examined for the period 1950 through 1977. There were no nasal or NPC deaths. One death from oral and pharyngeal cancer was observed vs. 2.1 expected. Nineteen lung cancer deaths were seen vs. 20.2 expected (SMR=94, 95 % CI: 57-147). Three brain cancer deaths were reported compared with 2.6 expected (SMR=115, 95 % CI: 23-336). For leukemia 8 deaths were reported vs. 6.5 expected (SMR=160, 95 % CI: 44-409). The most striking cause of deaths was cirrhosis of the liver (SMR=238, significantly increased, 18 deaths vs. 7.6 expected).
Source: BASF AG Ludwigshafen
Reliability: (2) valid with restrictions
2.1; acceptables study, meets basic scientific principles
(686)

Remark: Retrospective cohort mortality study of 2,317 anatomists. The mortality follow-up was for the period 1925 through 1979. Overall cancer mortality was remarkably low (SMR=64, 95 % CI: 53-76). There were no deaths from nasal cancer or NPC. There was only one death from all oral and pharyngeal cancers combined compared with 6.8 expected (SMR=20, 95 % CI: 0-80). For lung cancer 13 deaths were observed with 43.1 expected (SMR=30, 95 % CI: 10-50). Leukemia showed some increases with an SMR=150 (95 % CI: 70-270). One cancer site was significantly elevated indicating brain cancer with a SMR=270 (95 % CI: 130-500).
Source: BASF AG Ludwigshafen
Reliability: (2) valid with restrictions
2.; acceptable study, meets basic scientific principles
(687)

Remark: Proportional mortality study in 4,046 embalmers and funeral directors for the period 1975 to 1985. No nasal cancer deaths were observed compared with 1.7 expected. Four NPC were seen vs. 1.85 expected (PMR=216, 95 % CI: 59-554). For oral and pharyngeal cancer deaths, 30 were seen vs. 25 expected (PMR=120, 95 % CI: 81-171). There was no excess of lung cancer deaths (308 vs. 324.5, PMR =95, 95 % CI: 85-106). For brain cancer deaths, 24 were observed vs. 19.4 expected (PMR=123, 95 % CI: 80-184). A significantly high proportion of lympathic and hematologic malignancies was reported (PMR=157, 95 % CI: 115-167), mostly as a result of an excess of deaths from myeloid leukemia (PMR=157, 95 % CI: 101-234) and "other and unspecified leukemias" (PMR=228, 95 % CI: 139-352).
Source: BASF AG Ludwigshafen
Reliability: (2) valid with restrictions
2.1; acceptable study, meets basic scientific principles
(688)

Remark: Retrospective cohort study of 6,411 pathologists followed for vital status from 1925 to 1978. The overlap between this study population and that of Logue et al. (1986) is unknown. There were no nasal or NPC deaths reported. There were significantly fewer ora/pharyngeal cancer deaths than expected (13 vs. 25, SMR=52, 95 % CI: 28-89). Lung cancer occurrred at almost half the expected rate (77 vs. 137.5, SMR=56, 95 % CI: 44-70). A non-significant increase in brain cancer was seen (SMR=134, 95 % CI: 71-229). There were elevated but non-significant SMRs for some lymphatic-hematopoetic malignancies. SMR for hypopharybgeal cancer was elevated (not NPC) (3 vs. 0.64, SMR=470, 95 % CI: 97-1370). particularly since total oral/pharyngeal cancer deaths were significantly reduced (SMR=52, 95 % CI: 28-89).
Source: BASF AG Ludwigshafen
Reliability: (2) valid with restrictions
2.1; acceptable study, meets basic scientific principles
(689)

Remark: Proportional morbidity study of cancer. SPIR=1.0 (410 cases) forlung , SPIR=1.2 (166 cases) for colon, SPIR=1.3 (60 cases) for kidney, and SPIR=1.2 (13 cases) for sino-nasal cavities. RR 3.0 (95 % CI: 1.4-5.7) for sino-nasal cancer.
Source: BASF AG Ludwigshafen
Reliability: (2) valid with restrictions
2.1; acceptable study, meets basic scientific principles
(690)

Remark: Case-control study of cancer mortality among FA workers. Deaths from 1957 through 1979 were studied. 142 of 481 cancer deaths were among workers with potential exp. to FA. RR of cancer was not significantly greater than 1.0 ($p>0.05$). There were no nasal cancer deaths and no lung cancer excesses. Slightly but nonsignificant elevations were observed for prostatic and bladder cancer.
Source: BASF AG Ludwigshafen
Reliability: (2) valid with restrictions
2.1; acceptable study, meets basic scientific principles

(691)

Remark: Hospital-based case-control study of cancers of the nasal cavity and paranasal sinuses (160 vs. 290 controls). RR=0.35 (95 % CI: 0.1-1.8) for ever exposed to FA.
Source: BASF AG Ludwigshafen
Reliability: (2) valid with restrictions
2.1; acceptable study, meets basic scientific principles

(692)

Remark: Death certificate-based case-control study of lung and bladder cancer (598 and 287 cases, 1,758 controls). RR=1.5 (95 CI: 1.2-1.8) for lung and RR=1.0 (95 % CI: 0.7-1.3) for bladder cancer and ever exp., and RR= 0.9 (95 % CI: 0.6-1.4) and lung and RR=1.5 (95 % CI: 0.9-2.5) and bladder cancer and heavy exposure.
Source: BASF AG Ludwigshafen
Reliability: (2) valid with restrictions
2.1; acceptable study, meets basic scientific principles

(693)

Remark: Linked-registery study with cancer controls of nasal and nasopharyngeal cancer (488 and 266 cases, 2465 controls). RR=2.8 (95 % CI:1.8-4.3) for nasal and ever exp. in men, RR=2.8 (95 % CI: 0.5-14.3) for nasal and ever exp. in women, RR=0.7 (95 % CI: 0.3-1.7) for nasopharyngeal and ever exp. in men, RR=2.6 (95 % CI: 0.3-21.9) for nasopharyngeal and ever exp. in women, RR=1.6 (95 % CI: 0.7-3.6) for nasal and exp.>10 years previously (adjusted for wood dust).
Source: BASF AG Ludwigshafen
Reliability: (2) valid with restrictions
2.1; acceptable study, meets basic scientific principles

(694)

Remark: Linked-registry study with controls on nasal and nasopharyngeal (466 and 293 cases, 2,465 controls). RR=2.3 (95 % CI: 0.9-5.8) for nasal squamous cell carcinoma and ever exp., RR=2.2 (95 % CI: 0.7-7.2) for nasal adenocarcinoma and ever exposed. No association with histologically verified naspharyngeal cancers.
Source: BASF AG Ludwigshafen
Reliability: (2) valid with restrictions
2.1; acceptable study, meets basic scientific principles

(695)

Remark: Population-based study of nasal, nasopharyngeal and other pharynx cancers (53, 27, and 205 cases, 552 controls). RR=0.3 (95 % CI: 0-1.3) for nasal and medium or high occup. exp., RR=1.4 (95 % CI: 0.4-4.7) for nasopharynx and medium or high exp., RR=0.6 (95 % CI: 0.1-2.7) for other pharynx and medium or high exp., RR=0.6 (95 % CI: 0.2-1.7) for nasal and mobil home residence >10 years, RR=5.5 (95 % CI: 1.6-19.4) for nasopharynx and mobile home residence >10 years, and RR=0.8 (95 % CI: 0.2-2.7) for other pharynx and mobile home residence >10 years.
Source: BASF AG Ludwigshafen
Reliability: (2) valid with restrictions

2.1; acceptable study, meets basic scientific principles
(696)

Remark: Case-control study of nasal cancer (91 cases, 195 controls). RR=2.5 (90 % CI: 1.2-5.0) for ever exp. low wood dust, and assessment A,a nd RR=1.6 (90 % CI: 0.9-2.8) for ever exp., low wood dust, and assessment B.
Source: BASF AG Ludwigshafen
Reliability: (2) valid with restrictions
2.2; basic data given, restrictions
(697)

Remark: Nested-case control study of lung cancer among among FA workers (308 cases, 2 x 308 controls). OR=0.62 (95 % CI: 0.29-1.34) for ever exp. workers.
Source: BASF AG Ludwigshafen
Reliability: (2) valid with restrictions
2.1; acceptable study, meets basic scientific principles
(698)

Remark: Case-control study of nasal and nsaopharyngeal cancer (198 and 173 cases, 605 controls). RR=0.8 (95 % CI: 0.5-1.3) for nasal and probably exp., RR=1.0 (95 % CI: 0.6-1.7) for nasopharynx and probably exp., RR=1.5 (95 % CI: 0.6-3.9) for nasal and probably exp. to high levels >20 years before death, and RR=2.3 (95 % CI: 0.9-6.0) for nasopharynx and probablay exp. to high level >20 years before death.
Source: BASF AG Ludwigshafen
Reliability: (2) valid with restrictions
2.2; basic data given, restrictions
(699)

Remark: Multiple site case-control study (3726 cases, 533 controls) showed quite low exp. levels of FA. There was no persuasive evidence of an increased risk of any type of cancer.
Source: BASF AG Ludwigshafen
Reliability: (2) valid with restrictions
2.1; acceptable study, meets basic scientific principles
(700)

Remark: Nested case-control study of nasal, ora(pharyngeal, larynx, and lung cancer among FA workers (1, 5, 12, and 118 cases, 408 controls). RR=0.69 (95 % CI: 0.21-2.24) of ever exp. and RR=0.89 (95 % CI: 0.26-3.00) of exp. with 10 years latency.
Source: BASF AG Ludwigshafen
Reliability: (2) valid with restrictions
2.1; acceptable study, meets basic scientific principles
(701)

Remark: Population-based case-control study of laryngeal cancer (235 cases, 547 controls). RR=1.0 (95 % CI: 0.6-1.7) for low, RR=1.0 (95 % CI: 0.4-2.1) for medium, and RR=2.0 (95 % CI: 0.2-1.95) for high exposure.
Source: BASF AG Ludwigshafen
Reliability: (2) valid with restrictions
2.1; acceptable study, meets basic scientific principles
(702)

Remark: Hospital-based case-control study of sinonasal cancer (207 cases, 409 controls). RR=0.96 (95 % CI: 0.38-2.42) for possible and RR=0.68 (95 % CI: 0.27-1.75) for >20 years exposure.
Source: BASF AG Ludwigshafen
Reliability: (2) valid with restrictions
2.1; acceptable study, meets basic scientific principles
(703)

Remark: Nested case-control study of Hodgkin's, Non-Hodgkin's disease, and leukemias (4, 8, and 12 cases, 152 controls). RR=2.27 (95 % CI: 0.64-7.98) for ever exposed.
Source: BASF AG Ludwigshafen
Reliability: (2) valid with restrictions
2.1; acceptable study, meets basic scientific principles
(704)

Remark: Nested case-control study of lung cancer (220 cases, 2220 controls). RR=1.31 (95 % CI: 0.83-2.07) for zero, RR=0.95 (95 % CI: 0.57-1.57) for ten, RR=0.85 (95 % CI: 0.50-1.45) for 15, and RR=0.84 (95 % CI: 0.44-1.60) for 20 year lag period.
Source: BASF AG Ludwigshafen
Reliability: (2) valid with restrictions
2.1; acceptable study, meets basic scientific principles
(705)

Remark: Population-based case-control study of nasopharyngeal cancer (104 cases, 104 and 101 controls). RR=2.7 (95 % CI: 1.1-6.6) for duration of exposure < 15 years and RR=1.2 (95 % CI: 0.48-32) for duration >=15 years.
Source: BASF AG Ludwigshafen
Reliability: (2) valid with restrictions
2.1; acceptable study, meets basic scientific principles
(706)

Remark: Population-based case-control study of oral/pharyngeal cancer 86 cases, 373 controls). RR=1.6 (95 % CI: 0.92-2.8) for ever exp. and RR=1.8 (95 % CI: 0.6-5.5) for probable or definite exposure.
Source: BASF AG Ludwigshafen
Reliability: (2) valid with restrictions
2.1; acceptable study, meets basic scientific principles
(707)

Remark: Report of three cases of nasal melanoma. All three were ocupationally exp. to FA (FA spraying in a chicken farm, histological preparations with FA, handling or urea formaldehyde foam in construction building).
Source: BASF AG Ludwigshafen
Reliability: (2) valid with restrictions
2.2; basic data given, restrictions
(708)

Remark: As part of a case-control study of subjects with nasal and nasopharyngeal cancer, nine of fourteen cases of nasal and nasopharyngeal melanoma were interviewed. None reported knowledge of specific occupational exposure to FA.
Source: BASF AG Ludwigshafen
Reliability: (2) valid with restrictions
2.2; basic data given, restrictions

(709)

Remark: The incidence of spontaneous abortion was studied among hospital staff in sterilizing units. The rate associated with FA, with or without other agents, was 8.4 %, which was comparable to the reference level of 10.5 %.
Source: BASF AG Ludwigshafen
Reliability: (2) valid with restrictions
2.1; acceptable study, meets basic scientific principles

(710)

Remark: Record linkage study in nurses. 217 women treated for spontaneous abortion and 46 notified to the register of Congenital Malformations were matched on age and hospital with three controls. Exp. to FA during pregnancy was reported for 3.7 % of the nurses who were later treated for abortion and for 5.2 % of their controls, yielding a crude odds ration of 0.7 (95 % CI: 0.28-1.7) and for 8.8 % of the nurses who gave birth to a malformed child and for 5.3 % of the controls (OR=1.7, 95 % CI: 0.39-7.7).
Source: BASF AG Ludwigshafen
Reliability: (2) valid with restrictions
2.1; acceptable study, meets basic scientific principles

(711)

Remark: Retrospective case-control study of spontaneous malformation (206 cases, 329 controls) and congenital malformations (36 cases, 105 controls). OR=3.5 (95 % CI: 1.1-11) for spontaneous abortion. Most of the cases were also exp. to xylene. No association was observed for congenital malformations.
Source: BASF AG Ludwigshafen
Reliability: (2) valid with restrictions
2.2; basic data given, restrictions

(712)

Remark: FA-based disinfection products use was associated with an elevated risk for spontaneous abortion in 96 cosmetologists (OR=1.7, 95 % CI: 1.0-3.0).
Source: BASF AG Ludwigshafen
Reliability: (2) valid with restrictions
2.2; basic data given, restrictions

(713)

Remark: Pas de données disponibles
Source: PROTEX S.A LEVALLOIS PERRET

Remark: WE ARE ONLY NOW STARTING TO MONITOR THE HEALTH OF OUR OPERATORS WHO ARE INVOLVED IN FORMALDEHYDE MANUFACTURE AND DISTRIBUTION.
TO THE BEST OF OUR KNOWLEDGE ONLY ONE PERSON IN THE LAST 40 YEARS OF PRODUCTION HAS DIED AS A RESULT OF CANCER. HE WAS WITH US A SHORT PERIOD OF TIME AFTER TAKING EARLY RETIREMENT FROM HIS PREVIOUS EMPLOYMENT. NO EFFORT WAS MADE BY LOCAL HEALTH AUTHORITIES TO LINK THE CAUSE OF HIS CANCER TO FORMALDEHYDE.
THERE ARE A LARGE NUMBER OF STUDIES SHOWN IN "ENVIRONMENTAL HEALTH CRITERIA 1989" PUBLISHED BY THE WORLD HEALTH ORGANISATION– GENEVA– 1989.

Source: STRATHCLYDE CHEMICAL COMPANY LIMITED JOHNSTONE

(1) Chemline/Copyright 1993 by ACS and NLM

(2) INRS, Valeurs limites d'exposition professionnelle aux substances dangereuses de l'ACGIH et de la commission MAK, Cah. Notes Doc. 1992, 147, 195-225

(3) DFG (1993): MAK-Liste, 48 (01.09.1993)

(4) Hoechst AG (1993): Sicherheitsdatenblatt Formaldehydlösung 37 Gew.-%, U. S. P., stabilisiert mit ca. 10 % Methanol (15.11.1993)

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(14) ACGIH (1991-1992)

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(16) Circulaire DRT n° 93-18 du 12-07-93 modifiant et complétant la circulaire du 19-07-82 modifiée relative aux valeurs admises pour les concentrations de certaines substances dangereuses dans l'atmosphère des lieux de travail.

(17) Circulaire DRT n¿ 93-18 du 12-07-93 modifiant et complÚtant la circulaire du 19-07-82 modifiÚe relative aux valeurs admises pour les concentrations de certaines substances dangereuses dans l'atmosph¿re des lieux de travail.

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ACGIH TLV CL: 0.3 ppm suspected carcinogen
MSHA STD. air CL 2 ppm
OSHA PEL TWA: 1 ppm (8h.)
CL: 5 ppm
PK: 10 ppm (30m/8h)
OEL ARAB (Egypt) TWA: 2 ppm
OEL AUSTRALIA TWA: 1 ppm
OEL BELGIUM TWA: 1 ppm
STEL: 2 ppm (carcinogen)
OEL CZECHOSLOVAKIA TWA: 0.5 ppm
STEL: 2 ppm
OEL DENMARK STEL: 0.3 ppm (carcinogen)
OEL FINLAND STEL: 1 ppm (skin)
OEL FRANCE STEL: 2 ppm
OEL GERMANY TWA: 0.5 ppm (carcinogen)
OEL HUNGARY STEL: 0.6 mg/m3 (carcinogen)
OEL JAPAN TWA: 0.5 ppm (carcinogen)
OEL THE NETHERLANDS TWA: 1 ppm
STEL: 2 ppm
OEL THE PHILIPPINES TWA: 5 ppm
OEL POLAND TWA: 2 mg/m3
OEL RUSSIA TWA: 0.5 ppm
STEL: 0.5 mg/m3 (skin)
OEL SWEDEN TWA: 0.5 ppm
STEL: 0.5 mg/m3
OEL SWITZERLAND TWA: 3 ppm
STEL: 1 ppm
OEL THAILAND TWA: 3 ppm
STEL: 5 ppm
OEL TURKEY TWA: 5 ppm
OEL UK TWA: 2 ppm
STEL: 2 ppm
OEL BULGARIA, COLOMBIA, JORDAN, KOREA, NEW ZEALAND, SINGAPORE, VIETNAM Check ACGIH TLV

(22) ACGIH TLV CL: 0.3 ppm suspected carcinogen
MSHA STD. air CL: 2 ppm
OSHA PEL TWA: 1ppm (8h)
CL: 5 ppm
PK: 10 ppm (30m/8h)
OEL ARAB (Egypt) TWA: 2 ppm
OEL AUSTRALIA TWA: 1 ppm
OEL BELGIUM TWA: 1 ppm
STEL: 2 ppm (carcinogen)
OEL CZECHOSLOVAKIA TWA: 0.5 ppm
STEL: 2 ppm
OEL DENMARK STEL: 0.3 ppm (carcinogen)

OEL FINLAND STEL: 1 ppm (Skin)
OEL FRANCE STEL: 2 ppm
OEL GERMANY TWA: 0.5 ppm (carcinogen)
OEL HUNGARY STEL: 0.6 mg/m3 (carcinogen)
OEL JAPAN TWA: 0.5 ppm (carcinogen)
OEL THE NETHERLANDS TWA: 1 ppm
STEL: 2 ppm
OEL THE PHILIPPINES TWA: 5 ppm
OEL POLAND TWA: 2 mg/m3
OEL RUSSIA TWA: 0.5 ppm
STEL: 0.5 mg/m3 (skin)
OEL SWEDEN TWA: 0.5 ppm
STEL: 0.5 mg/m3
OEL SWITZERLAND TWA: 3 ppm
STEL: 1 ppm
OEL THAILAND TWA: 3 ppm
STEL: 5 ppm
OEL TURKEY TWA: 5 ppm
OEL UK TWA: 5 ppm
STEL: 2 ppm
OEL BULGARIA, COLOMBIA, JORDAN, KOREA, NEW ZEALAND, SINGAPORE, VIETNAM: Check ACGIH TLV

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7.1 Risk Assessment

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