

I U C L I D

D a t a s e t

| | |
|-------------------|---------------------------------|
| Existing Chemical | Substance ID: 115-10-6 |
| CAS No. | 115-10-6 |
| EINECS Name | dimethyl ether |
| EINECS No. | 204-065-8 |
| Molecular Formula | C ₂ H ₆ O |

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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1.0.2 Location of Production Site

-

1.0.3 Identity of Recipients

-

1.1 General Substance Information

Substance type: organic
Physical status: gaseous

1.1.1 Spectra

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1.2 Synonyms

Demeon D

Source: Akzo Nobel Chemicals b.v. Amersfoort

Dimethyl oxide

Source: Akzo Nobel Chemicals b.v. Amersfoort

DME

Source: Akzo Nobel Chemicals b.v. Amersfoort

DME, Demeon D, Dymel A, Methyl Ether, Dimethyloxid, Methoxymethane, Methane, oxybis-, Wood Ether

Source: DEA Mineraloel AG Hamburg

Methane, oxybis-

Source: Akzo Nobel Chemicals b.v. Amersfoort

Methane, oxybis. Methyl ether. DME. Wood ether.

Source: CONOCO Limited. Warwick

Methoxymethane

Source: Akzo Nobel Chemicals b.v. Amersfoort

Methyl ether

Source: Akzo Nobel Chemicals b.v. Amersfoort

Wood ether

Source: Akzo Nobel Chemicals b.v. Amersfoort

1.3 Impurities

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1.4 Additives

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1.5 Quantity

-

1.6.1 Labelling

Labelling: as in Directive 67/548/EEC

Symbols: F+
C

Specific limits: no data

R-Phrases: (12) Extremely flammable

S-Phrases: (2) Keep out of reach of children
(9) Keep container in a well-ventilated place
(16) Keep away from sources of ignition - No smoking
(33) Take precautionary measures against static discharges

1.6.2 Classification

Classification: as in Directive 67/548/EEC

Class of danger: extremely flammable

R-Phrases: (12) Extremely flammable

1.7 Use Pattern

-

1.7.1 Technology Production/Use

-

1.8 Occupational Exposure Limit Values

Type of limit: MAC (NL)
Limit value: 1000 ml/m3
Remark: MAC Time weighted average : 1000 ppm or 1910 mg/m3.
Source: Akzo Nobel Chemicals b.v. Amersfoort

(1)

Type of limit: MAK (DE)
Limit value: 1000 ml/m3
Short term expos.
Limit value: 2000 ml/m3
Schedule: 60 minute(s)
Frequency: 3 times
Remark: MAK: 1000 ml/m3 (ppm) or 1910 mg/m3
Short term exposure limit: 2 x MAK 60 min, 3 times/shift.
Skin notation
Source: Akzo Nobel Chemicals b.v. Amersfoort

(2)

Type of limit: MAK (DE)
Limit value: 1000 ml/m3
Short term expos.
Limit value: 2000 ml/m3
Schedule: 60 minute(s)
Frequency: 3 times
Remark: MAK: 1000ml (ppm) or 1910 Mg/m3.
Short term exposure limit: 2 x MAK 60 min, 3 times/shift.
Skin notation.
Source: DEA Mineraloel AG Hamburg

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1.9 Source of Exposure

Remark: Dedicated transport to guarantee safety. All in bulk transport of 20 tonnes (800 times per year) tanklorry. Is used as multipurpose propellant; main application in hairspray.

Source: Akzo Nobel Chemicals b.v. Amersfoort

Remark: a) Production process: Catalytical dehydration of methanol.
b) Manufacturing sites: Germany: DEA Mineraloel AG, Netherlands: Akzo, Great Britain: Du Pont.
c) Production process: closed system.
d) During production: no human exposure, no emission.
During use: exposure to aerosol propellants.
e) During manufacture and use: no emissions to water and soil.

Source: DEA Mineraloel AG Hamburg

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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

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1.14.2 Major Accident Hazards

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1.14.3 Air Pollution

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1.15 Additional Remarks**Remark:** ..**Source:** Akzo Nobel Chemicals b.v. Amersfoort**Remark:** Disposal: may be incinerated, reprocess if feasible.**Source:** Transport: by road. UN NO 1033 Hazchem 2WE₂**Source:** CONOCO Limited. Warwick

Remark:

| | |
|---------------------------|--------------------------------|
| a) Disposal options | : Recover by distillation |
| | : May be incinerated |
| b) Transport information: | GGVS/ADR : Class 2 No. 3b |
| | : GGVE/RID : Class 2 No. 3b |
| | UN-No. 1033 |
| | : ADN/ADNR : Class Id No. 8a |
| | : IMDG/GGVSee-Code : Class 2.1 |
| | EmS : 2-07 |
| | MFAG : 330 |
| | Marine pollutant : -- |
| | IMDG-PACK.GROUP : ---- |

UN-No. : 1033
: ICAO/IATA-DGR : 2.1
ICAO-PACK.GROUP : ----
UN-No. : 1033

Source: DEA Mineraloel AG Hamburg

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: = -141.5 degree C
Decomposition: no
Sublimation: no
Method: other
Year: 1966
GLP: no data
Source: DEA Mineraloel AG Hamburg

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2.2 Boiling Point

Value: = -24.9 degree C at 1013 hPa
Decomposition: no
Method: other
Year: 1941
GLP: no
Source: DEA Mineraloel AG Hamburg

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2.3 Density

Type: density
Value: = 668.3 kg/m3 at 20 degree C
Method: other
Year: 1989
GLP: no
Remark: Relative vapour density (20 degree C) : 1.59
Source: DEA Mineraloel AG Hamburg

2.3.1 Granulometry

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2.4 Vapour Pressure

Value: = 5.12 hPa at 20 degree C
Method: other (calculated): (measured)
Year: 1989
GLP: no
Source: DEA Mineraloel AG Hamburg

(7) (8)

2.5 Partition Coefficient

log Pow: = -.18
Method:
Year:
Source: DEA Mineraloel AG Hamburg

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2.6.1 Water Solubility

Value: = 328 g/l at 20 degree C
Qualitative: soluble
pH: = 7 and 20 degree C
Method: other
Year: 1989
GLP: no
Source: DEA Mineraloel AG Hamburg

(10)

2.6.2 Surface Tension

-

2.7 Flash Point

Value: = -80 degree C
Type: other
Method: other
Year: 1994
GLP: no
Source: DEA Mineraloel AG Hamburg

(11)

2.8 Auto Flammability

Value: = 240 degree C
Method: other
GLP: no
Remark: 240 degrees C.: Nabert/Schön, Sicherheitstechnische
Kennzähle brennbarer Gase und Dämpfe (6. Nachtrag) 1990.
350 degrees C.
Source: DEA Mineraloel AG Hamburg

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2.9 Flammability

Result: extremely flammable
Source: DEA Mineraloel AG Hamburg

2.10 Explosive Properties

Result: not explosive
Remark: Vapours may form explosive mixtures with air
Source: DEA Mineraloel AG Hamburg

2.11 Oxidizing Properties

Result: no oxidizing properties
Source: DEA Mineraloel AG Hamburg

2.12 Additional Remarks

Remark: DME does not tend to form peroxides. DME does not tend to form BCME (Bis-Chloro-Methyl-Ether) in contact with chlorinated compounds.

Source: DEA Mineraloel AG Hamburg

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3.1.1 Photodegradation

Type:**INDIRECT PHOTOLYSIS****Sensitizer:** OH**Conc. of sens.:** 500000 molecule/cm³**Rate constant:** = .000000000000298 cm³/(molecule * sec)**Degradation:** = 63 % after 7.7 day**Method:** other (calculated)**Year:****GLP:****Test substance:** as prescribed by 1.1 - 1.4**Remark:** Calculated from references 1) D. Rhäsa and R. Zellner: Free.
Rad. Res. Comms., Vol. 3 No. 1-5, pp 199-209 (1987)
2) Roger Atkinson, Chem. Rev. 1986, 69-201 (1986).**Source:** DEA Mineraloel AG Hamburg

3.1.2 Stability in Water

Type:**Method:****Year:****GLP:****Test substance:****Source:** DEA Mineraloel AG Hamburg

3.1.3 Stability in Soil

Type:**Radiolabel:****Concentration:****Cation exch.****capac.****Microbial****biomass:****Method:****Year:****GLP:****Test substance:****Remark:** Stable compound at ambient conditions, no further data
available.**Source:** DEA Mineraloel AG Hamburg

3.2 Monitoring Data (Environment)

Type of**measurement:****Medium:****Remark:** No monitoring.**Source:** DEA Mineraloel AG Hamburg

3.3.1 Transport between Environmental Compartments

Type: volatility
Media: water - air
Method: other: calculation from literature data
Year: 1993
Remark: Half life time for volatilisation from water:
Lakes: abt. 4 days
Ponds: abt. 5 days
Stream: abt. 2.5 days
Rivers: abt. 1 day
Currents: abt. ≥ 0.1 days
Source: DEA Mineraloel AG Hamburg

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3.3.2 Distribution

Media: water - air
Method: other (calculation)
Year:
Remark: At MAK-level in air (1000 ppm (V/V)) the DME solubility in water at 20 degrees C is abt. 50 grams per m³.
Source: DEA Mineraloel AG Hamburg

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3.4 Mode of Degradation in Actual Use

Remark: In actual use no degradation.
Source: DEA Mineraloel AG Hamburg

3.5 Biodegradation

Type: aerobic
Inoculum: activated sludge, domestic
Concentration: 2 mg/l related to Test substance
Degradation: = 5 % after 28 day
Result: under test conditions no biodegradation observed
Method: Directive 84/449/EEC, C.4 "Biotic degradation - modified AFNOR test NF T90/302"
Year: **GLP:** no
Test substance: as prescribed by 1.1 - 1.4
Remark: Methane-utilizing microorganisms are capable of oxidizing DME co-metabolically. These microorganisms, abundantly present in nature, play a significant role in the removal of DME from aquatic ecosystems and soils.
Test under GLP working conditions, but not yet certified
Source: DEA Mineraloel AG Hamburg

(17) (18) (19) (20) (21) (22) (23)

3.6 BOD5, COD or BOD5/COD Ratio

Source: DEA Mineraloel AG Hamburg

3.7 Bioaccumulation

Species:

Exposure period:

Concentration:

BCF:

Elimination:

Method:

Year:

GLP:

Test substance:

Source: DEA Mineraloel AG Hamburg

3.8 Additional Remarks

Source: DEA Mineraloel AG Hamburg

AQUATIC ORGANISMS**4.1 Acute/Prolonged Toxicity to Fish**

Type: semistatic
Species: Poecilia reticulata (Fish, fresh water)
Exposure period: 96 hour(s)
Unit: mg/l **Analytical monitoring:** yes
NOEC: > 4000
Method: other: NEN 6504
Year: **GLP:** yes
Test substance: as prescribed by 1.1 - 1.4
Remark: With respect to the rapid volatilization of DME, sealed flasks were used for the testing. Renewal of test solutions after 48 hours. All fishes survived the dosages studied (nominal conc. of test 1900 and 3200 mg/l, maximum concentration DME measured 4100 g/ml)
Source: DEA Mineraloel AG Hamburg

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4.2 Acute Toxicity to Aquatic Invertebrates

Species: Daphnia magna (Crustacea)
Exposure period: 48 hour(s)
Unit: mg/l **Analytical monitoring:** yes
NOEC: > 4000
Method: other: NEN 6501
Year: **GLP:** yes
Test substance: as prescribed by 1.1 - 1.4
Remark: With respect to the rapid volatilization of DME, sealed flasks were used for the testing. All animals survived the dosages studied (nominal conc. of test 1000 and 3200 mg/l, maximum concentration DME measured 4400 mg/l)
Source: DEA Mineraloel AG Hamburg

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4.3 Toxicity to Aquatic Plants e.g. Algae

Species:
Endpoint:
Exposure period:
Unit: **Analytical monitoring:**
Method:
Year: **GLP:**
Test substance:
Source: DEA Mineraloel AG Hamburg

4.4 Toxicity to Microorganisms e.g. Bacteria

Type: aquatic
Species: Pseudomonas putida (Bacteria)
Exposure period:
Unit: mg/l **Analytical monitoring:** no
EC10: > 1600
Method: other: ROBRA
Year: **GLP:** no
Test substance: as prescribed by 1.1 - 1.4
Remark: No distinct inhibition of the respiration has been detected within the concentration range tested (100, 200, 400, 800, and 1600 mg/l)
Source: DEA Mineraloel AG Hamburg

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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:
Source: DEA Mineraloel AG Hamburg

4.5.2 Chronic Toxicity to Aquatic Invertebrates

Species:
Endpoint:
Exposure period:
Unit: **Analytical monitoring:**
Method:
Year: **GLP:**
Test substance:
Source: DEA Mineraloel AG Hamburg

TERRESTRIAL ORGANISMS**4.6.1 Toxicity to Soil Dwelling Organisms**

Type:
Species:
Endpoint:
Exposure period:
Unit:
Method:
Year: GLP:
Test substance:
Source: DEA Mineraloel AG Hamburg

4.6.2 Toxicity to Terrestrial Plants

Species:
Endpoint:
Expos. period:
Unit:
Method:
Year: GLP:
Test substance:
Source: DEA Mineraloel AG Hamburg

4.6.3 Toxicity to other Non-Mamm. Terrestrial Species

Species:
Endpoint:
Expos. period:
Unit:
Method:
Year: GLP:
Test substance:
Source: DEA Mineraloel AG Hamburg

4.7 Biological Effects Monitoring

Source: DEA Mineraloel AG Hamburg

4.8 Biotransformation and Kinetics

Type: animal
Remark: Kinetics: After 60 minutes exposure to 1000 ppm V/V a constant level of 14 - 22 mg/kg rat was reached. 90 Minutes after termination of the exposure the DME levels were 2-5 mg/kg rat. The higher levels refer to fat tissues; the lower figures refer to muscles.
Biotransformation: no data.
Source: DEA Mineraloel AG Hamburg

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4.9 Additional Remarks

Source: DEA Mineraloel AG Hamburg

5.1 Acute Toxicity

5.1.1 Acute Oral Toxicity

Type:**Species:****Sex:****Number of
Animals:****Vehicle:****Value:****Method:****Year:****GLP:****Test substance:****Source:** DEA Mineraloel AG Hamburg

5.1.2 Acute Inhalation Toxicity

Type: LC50**Species:** rat**Sex:****Number of
Animals:****Vehicle:****Exposure time:** 4 hour(s)**Value:** = 308.5 mg/l**Method:** other**Year:****GLP:** no data**Test substance:** as prescribed by 1.1 - 1.4**Source:** DEA Mineraloel AG Hamburg

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Type: LC50**Species:** mouse**Sex:****Number of
Animals:****Vehicle:****Exposure time:** 15 minute(s)**Value:** = 494.36 ppm**Method:** other**Year:****GLP:** no data**Test substance:** as prescribed by 1.1 - 1.4**Source:** DEA Mineraloel AG Hamburg

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Type: LC50
Species: mouse
Sex:
Number of
Animals:
Vehicle:
Exposure time: 30 minute(s)
Value: = 385.94 ppm
Method: other
Year: GLP: no data
Test substance: as prescribed by 1.1 - 1.4
Source: DEA Mineraloel AG Hamburg

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Type: other
Species: rabbit
Sex:
Number of
Animals:
Vehicle:
Exposure time: 15 minute(s)
Value: = 400 ppm
Method: other
Year: GLP: no data
Test substance: as prescribed by 1.1 - 1.4
Source: DEA Mineraloel AG Hamburg

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Type: other
Species: cat
Sex:
Number of
Animals:
Vehicle:
Exposure time:
Value:
Method: other
Year: GLP: no data
Test substance: as prescribed by 1.1 - 1.4
Remark: Cats exposed to DME by way of tracheal tube were anesthetized by a 65% DME/35% oxygen mixture. 85% DME/15% oxygen produces profound anesthesia. Appr. 20 minutes were required for the animals to completely recover from 50 minutes of anesthesia.
Source: DEA Mineraloel AG Hamburg

(32)

Type: other
Species: dog
Sex:
Number of Animals:
Vehicle:
Exposure time:
Value:
Method: other
Year: **GLP:** no data
Test substance: as prescribed by 1.1 - 1.4
Remark: DME is a weak cardiac sensitizer in dogs. In 5-minute exposures, two of 12 dogs exhibited responses at levels of 200.000 ppm and two of six exhibited responses at 300.000 ppm. This latter dose was not well tolerated by the test animals. No response occurred at 100.000 ppm.
Source: DEA Mineraloel AG Hamburg (33) (34) (35)

Type: other
Species: human
Sex:
Number of Animals:
Vehicle:
Exposure time:
Value:
Method: other
Year: **GLP:** no data
Test substance: as prescribed by 1.1 - 1.4
Remark: Experimenters indicate that humans have inhaled DME in the laboratory at up to 500.000 ppm and describe DME as unpleasant to take.
In human subjects, 50.000 and 75.000 ppm of DME caused feelings of mild intoxication after 12-minutes exposure to higher concentration. At 82.000 ppm, some incoordination developed after 21,5 minutes, and a complaint was made of indistinct vision. At 100.000 ppm, no objective symptoms occurred during the first 15 minutes. Distinct signs of incoordination developed after 21 minutes of exposure. The experiment continued for 64 minutes, with the subject unable to do simple tasks. At 144.000 ppm, symptoms first occurred after 7 minutes with the subject losing consciousness after 26 minutes. Inhalation of 200.000 ppm caused unconsciousness in 17 minutes.
Source: DEA Mineraloel AG Hamburg (36) (37)

5.1.3 Acute Dermal Toxicity

Type: other
Species:
Sex:
Number of
Animals:
Vehicle:
Value:
Method:
Year: GLP:
Test substance: as prescribed by 1.1 - 1.4
Remark: Liquid DME will cause severe frostbite if spilled on the skin.
Source: DEA Mineraloel AG Hamburg

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5.1.4 Acute Toxicity, other Routes

Type: other
Species: mouse
Sex:
Number of
Animals:
Vehicle:
Route of admin.: i.p.
Value: = 5 ppm
Method:
Year: GLP: no data
Test substance: as prescribed by 1.1 - 1.4
Remark: DME is less efficient than diethylether as an anesthetic in animals. It does, however, have both vasolidator and hypotensor effects.
Intraperitoneal doses of 5 mg/kg of DME produced reversible anesthesia in Mice.
Source: DEA Mineraloel AG Hamburg

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5.2 Corrosiveness and Irritation

5.2.1 Skin Irritation

Species:

Concentration:

Exposure:

Exposure Time:

Number of

Animals:

PDII:

Result:

EC classificat.:

Method:

Year:

GLP:

Test substance: as prescribed by 1.1 - 1.4

Remark: Liquid DME will cause severe frostbite, if spilled on the skin.

Source: DEA Mineraloel AG Hamburg

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5.2.2 Eye Irritation

Species:

Concentration:

Dose:

Exposure Time:

Comment:

Number of

Animals:

Result:

EC classificat.:

Method:

Year:

GLP:

Test substance:

Source: DEA Mineraloel AG Hamburg

5.3 Sensitization

Type:

Species:

Number of

Animals:

Vehicle:

Result:

Classification:

Method:

Year:

GLP:

Test substance:

Source: DEA Mineraloel AG Hamburg

5.4 Repeated Dose Toxicity

Species: rat **Sex:** male/female
Strain: Wistar
Route of admin.: inhalation
Exposure period: 4 week
Frequency of treatment: 6 hours/day, 5 days/week
Post. obs. period: no
Doses: 0, 100, 1.000 and 10.000 ppm
Control Group: yes
NOAEL: < 10000 ppm
Method: other
Year: **GLP:** no data
Test substance: as prescribed by 1.1 - 1.4
Remark: 1. Observations were made of behaviour, growth, food intake, haematology, urine composition, organ weights and gross as well as microscopic pathology.
2. None of the criteria applied revealed any distinct treatment related effects.
3. It was concluded that it is unlikely that the substance will present inhalation hazard to man, as the present four-week inhalation study in rats did not disclose any adverse effects even at levels of up to 10.000 ppm.
Source: DEA Mineraloel AG Hamburg

(41)

Species: rat **Sex:** male/female
Strain: Wistar
Route of admin.: inhalation
Exposure period: 13 weeks
Frequency of treatment: 6 hours/day, 5 days/week
Post. obs. period: no
Doses: 0, 2.000, 10.000 and 20.000 ppm
Control Group: yes
NOAEL: < 20000 ppm
Method: other
Year: **GLP:** no data
Test substance: as prescribed by 1.1 - 1.4
Remark: Animals exposed did not show significant differences as to behaviour, health condition, food intake and food efficiency. Male rats of the 20.000 ppm group showed a statistically significant increase of neutrophils. The amount of GPT showed a significant increase in the males of the top dose group. The females of that dose group showed a slight but significant increase of the total serum protein. Urine composition was within the range that can be considered normal. No significant differences were found in absolute and relative organ weights amongst the groups, and neither macroscopic nor microscopic examination of a large number of organs revealed changes that were ascribed to treatment. It was concluded that exposure of rats at levels up to 20.000 ppm DME for 6 hours a day, 5 days a week for 13 weeks produced no effects of obvious toxicological

significance.
Source: DEA Mineraloel AG Hamburg (42)

Species: rat **Sex:** male/female
Strain: Wistar
Route of admin.: inhalation
Exposure period: 13 weeks
Frequency of treatment: 6 hours/day, 5 days/week
Post. obs. period: no
Doses: 0, 1.000, 5.000, 10.000 and 20.000 ppm
Control Group: yes
NOAEL: = 10000 ppm
Method: other
Year: **GLP:** no data
Test substance: as prescribed by 1.1 - 1.4
Remark:

Health condition, behaviour and body weights did not change due to DME exposure. No toxicologically relevant significance is ascribed to a temporary difference in white blood cell counts in males. Neutrophil counts were higher in male rats at all test levels. A dose-effect relation could not be found. In view of the fact that increased neutrophil counts were also found in previous sub-chronic study, it was stated in the final conclusion that the no-effect-level in rats is 10.000 ppm.
Source: DEA Mineraloel AG Hamburg (43)

Species: rat **Sex:** male/female
Strain: no data
Route of admin.: inhalation
Exposure period: 30 weeks
Frequency of treatment: 6 hours/day, 5 days /week
Post. obs. period: no
Doses: 0, 200 2.000 and 20.000 ppm
Control Group: yes
NOAEL: = 2000 ppm
LOAEL: = 20000 ppm
Method: other
Year: **GLP:** no data
Test substance: as prescribed by 1.1 - 1.4
Remark: A critical remark about the conclusion drawn by Collins et al: As there is no dose-effect relation with regard to the change of the GOT-value, no great significance can be attached to this symptom. The no-effect level is therefore between 2.000 and 20.000 ppm. The high-dose level male rats showed a significant reduction in liver weight compared with the control group; this was accompanied by raised SGPT levels. In high-dose female rats, there was no significant effect on liver weight, but the SGPT levels were raised above control values. No histological abnormalities were observed in the liver or in any other organ.

Source: DEA Mineraloel AG Hamburg (44) (45)

Species: rat **Sex:** male/female
Strain: no data
Route of admin.: inhalation
Exposure period: 2 years
Frequency of treatment: 6 hours/day, 5 days/week
Post. obs. period: no
Doses: 2.000, 10.000 and 25.000 ppm
Control Group: yes
NOAEL: = 2000 ppm
Method: other
Year: **GLP:** no data

Test substance: as prescribed by 1.1 - 1.4
Remark: DME was not carcinogen and produced no compound-related effects relative to gross signs, body weights, haematology, urine analysis, blood chemistry, gross and histopathologic examination of tissues at any exposure level.

Source: DEA Mineraloel AG Hamburg (46)

Species: hamster **Sex:** male/female
Strain: no data
Route of admin.: inhalation
Exposure period: 13 weeks
Frequency of treatment: 6 hours/day, 5 days/week
Post. obs. period: no
Doses: 0, 1.000, 5.000, 10.000 and 20.000 ppm
Control Group: yes
NOAEL: = 5000 ppm
Method: other
Year: **GLP:** no data

Test substance: as prescribed by 1.1 - 1.4
Remark: Exposures did not effect health condition, behavior and body weights of hamsters. White blood cell counts and in particular absolute lymphocyte counts had decreased both in male and female hamsters, that had been exposed to 20.000 ppm. The difference concerning absolute white blood cell counts were never statistically significant. The difference in absolute lymphocyte counts was only significant on day 56. A number of other measured haematological values showed a significant difference compared with values found in the animals of the control group. For several reasons the investigators considered these differences to be of no importance. Although the sub-chronic study did not confirm the results of the sub-acute study, the investigators concluded that the no-effect level for DME in hamsters is 5.000 ppm, as at concentrations of 20.000 and 10.000 ppm a decrease in white blood cell counts and lymphocyte counts occurred.

Source: DEA Mineraloel AG Hamburg (47)

5.5 Genetic Toxicity 'in Vitro'

Type: Ames test
System of testing: Salmonella/microsome test
Concentration: 119.000 ppm
Metabolic activation: with and without
Result: negative
Method: other
Year: **GLP:** no data
Test substance: as prescribed by 1.1 - 1.4
Remark: DME was not mutagenic when tested with and without activation in Salmonella typhimurium strains TA 1535, TA 1537, TA 1538, TA 98 and TA 100.
Source: DEA Mineraloel AG Hamburg

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Type: Bacterial gene mutation assay
System of testing: V79 Chinese Hamster Cells in suspension
Concentration: 230, 460, 1150, and 3450 mg/l DME
Metabolic activation: with and without
Result: negative
Method: other
Year: **GLP:** no data
Test substance: as prescribed by 1.1 - 1.4
Remark: A mutagenic effect caused by DME could not been shown.
Source: DEA Mineraloel AG Hamburg

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Type: DNA damage and repair assay
System of testing: Primary rat liver cells
Concentration: 230, 460, 1150, 2300 and 3450 mg/l DME
Metabolic activation: without
Result: negative
Method: other
Year: **GLP:** no data
Test substance: as prescribed by 1.1 - 1.4
Remark: No induction of DNA-repair synthesis was observed at any of the concentrations.
Source: DEA Mineraloel AG Hamburg

(49)

Type: Salmonella typhimurium reverse mutation assay
System of testing: Intra-sanguineous host-mediated assay
Concentration: 2x100000000000 bacteria per injection
Metabolic activation: no data
Result: negative
Method: other
Year: 1981 **GLP:** no data
Test substance: as prescribed by 1.1 - 1.4
Source: DEA Mineraloel AG Hamburg

(50)

5.6 Genetic Toxicity 'in Vivo'

Type: Drosophila SLRL test
Species: Drosophila melanogaster **Sex:** male
Strain: no data
Route of admin.: inhalation
Exposure period: 3 days / 14 days
Doses: 8.000 and 28.000 / 28.000 ppm
Result:
Method: other
Year: 1981 **GLP:** no data
Test substance: as prescribed by 1.1 - 1.4
Remark: Progeny examination led to the conclusion that DME is not mutagenic under the test conditions.
Source: DEA Mineraloel AG Hamburg

(51)

Type:
Species: **Sex:**
Strain:
Route of admin.:
Exposure period:
Doses:
Result:
Method:
Year: **GLP:**
Test substance:
Source: DEA Mineraloel AG Hamburg

5.7 Carcinogenicity

Species: rat **Sex:** male/female
Strain: no data
Route of admin.: inhalation
Exposure period: 2 years
Frequency of treatment: 6 hours/day, 5 days/week
Post. obs. period: no
Doses: 2.000, 10.000 and 25.000 ppm
Result:
Control Group: yes
Method: other
Year: 1986 **GLP:** no data
Test substance: as prescribed by 1.1 - 1.4
Remark: DME was not carcinogenic in a two-year inhalation study with rats.
Source: DEA Mineraloel AG Hamburg

(52)

5.8 Toxicity to Reproduction

Type: Fertility
Species: **Sex:**
Strain:
Route of admin.:
Exposure Period:
Frequency of treatment:
Duration of test:
Doses:
Control Group:
Method:
Year: **GLP:**
Test substance:
Source: DEA Mineraloel AG Hamburg

5.9 Developmental Toxicity/Teratogenicity

Species: rat **Sex:** female
Strain: Wistar
Route of admin.: inhalation
Exposure period: days 6-15 of pregnancy
Frequency of treatment: 6 hours/day
Duration of test:
Doses: 0, 1.250, 5.000, 20.000, 28.000 and 40.000 ppm
Control Group: yes
NOAEL Maternalt.: = 28000 ppm
NOAEL Teratogen.: = 28000 ppm
Method: other
Year: 1981 **GLP:** no data
Test substance: as prescribed by 1.1 - 1.4
Remark: DME had no teratogenic effect on the fetuses of pregnant rats, which were exposed to concentrations up to 40.000 ppm during days 6 - 15 of pregnancy. Some foetotoxic effects (i.e. reduced foetal weight and increase in foetal variations) were only observed at dose levels which also produced maternal toxicity (weight gain suppression, 40.000 ppm).
Source: DEA Mineraloel AG Hamburg (53) (54) (55)

5.10 Other Relevant Information

Type: Biochemical or cellular interactions
Remark: "lysis of human red blood celles in the presence of various cosolvents.IIII. The relationship between hemolytic potential and structure."
Source: DEA Mineraloel AG Hamburg (56)

Type: Metabolism
Remark: Human exposure to DME resulting from its use of consumer products in aerosol cans has been determined and related to the toxicity data acquired in experimental animal studies. The no-effect level found in the rat lifetime study is at least 250 times higher than the calculated average daily exposure in man.
Pharmacokinetic studies in rats have shown that after inhalation DME is rapidly taken up by the various organs and tissues. The steady state level in organs is reached within 30 minutes (i.e. 14-22 ppm for most organs after exposure to 1.000 ppm DME). This value dsclines rapidly to background levels (2 ppm) at 90 minutes after termination of exposure. No accumulation of DME in tissues was noticed. Pharmacology of DME was studied by spraying twice (26.6 Mg/spray) into the oral cavity. The plasma concentration three minutes after exposure was 179/2842 ppb. A similar administration 60 minutes later did not increase DME blood concentrations further.
Source: DEA Mineraloel AG Hamburg (57) (58) (59)

Type: other**Remark:** Final conclusion of a series of investigations on the use of DME as an aerosol propellant: There is no indication that, based upon the data presently available, the use of DME as an aerosol propellant presents a danger for the environment or human health.**Source:** DEA Mineraloel AG Hamburg

(60)

5.11 Experience with Human Exposure

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7.1 Risk Assessment

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