NEWSTERi SRL Sterilization Products

# SAFETY DATA SHEET

Based upon Regulation (EC) No. 1907/2006, as amended by Regulation (EC) No. 453/2010

# ethylene oxide

## SECTION 1: Identification of the substance/mixture and of the company/undertaking

### 1.1 Product identifier:

| | |
|---|---|
| **Product name** | : ethylene oxide |
| **Synonyms** | : ethene oxide; oxirane |
| **Registration number REACH** | : 01-2119432402-53 |
| **Product type REACH** | : Substance/mono-constituent |
| **CAS number** | : 75-21-8 |
| **EC index number** | : 603-023-00-X |
| **EC number** | : 200-849-9 |
| **RTECS number** | : KX2450000 |
| **Molecular mass** | : 44.05 g/mol |
| **Formula** | : C2H4O |

### 1.2 Relevant identified uses of the substance or mixture and uses advised against:

**1.2.1 Relevant identified uses**

Industrial use

Chemical raw material

Biocide

**1.2.2 Uses advised against**

No uses advised against



## SECTION 2: Hazards identification

### 2.1 Classification of the substance or mixture:

**2.1.1 Classification according to Regulation EC No 1272/2008**

Classified as dangerous according to the criteria of Regulation (EC) No 1272/2008

| Class | Category | Hazard statements |
|---|---|---|
| Flam. Gas | category 1 | H220: Extremely flammable gas. |
| Press. Gas | Liquefied gas | H280: Contains gas under pressure; may explode if heated. |
| Chem. Unst. Gas | Category A | H230: May react explosively even in the absence of air. |
| Carc. | category 1B | H350: May cause cancer. |
| Muta. | category 1B | H340: May cause genetic defects. |
| Acute Tox. | category 3 | H331: Toxic if inhaled. |
| Acute Tox. | category 4 | H302: Harmful if swallowed. |
| STOT RE | category 1 | H372: Causes damage to the central nervous system through prolonged or repeated exposure. |
| STOT SE | category 3 | H335: May cause respiratory irritation. |

| | | |
|---|---|---|
| Eye Irrit. | category 2 | H319: Causes serious eye irritation. |
| Skin Irrit. | category 2 | H315: Causes skin irritation. |

**2.1.2 Classification according to Directive 67/548/EEC-1999/45/EC**

Classified as dangerous in accordance with the criteria of Directives 67/548/EEC and 1999/45/EC

F+; R12 - Extremely flammable.

Carc. Cat. 2; R45 - May cause cancer.

Muta. Cat. 2; R46 - May cause heritable genetic damage.

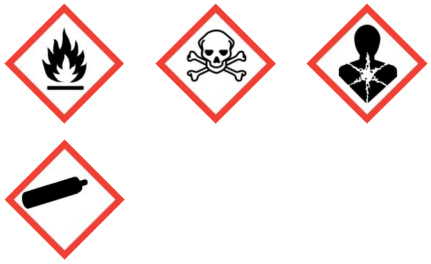
T; R23 - 48/23 - Toxic by inhalation. Toxic: danger of serious damage to health by prolonged exposure through inhalation.

Xi; R36/37/38 - Irritating to eyes, respiratory system and skin.

R6 - Explosive with or without contact with air.

## 2.2 Label elements:

**Labelling according to Regulation EC No 1272/2008 (CLP)**



**Signal word** Danger

**H-statements**

| | |
|---|---|
| H220 | Extremely flammable gas. |
| H280 | Contains gas under pressure; may explode if heated. |
| H230 | May react explosively even in the absence of air. |
| H350 | May cause cancer. |
| H340 | May cause genetic defects. |
| H331 | Toxic if inhaled. |
| H302 | Harmful if swallowed. |
| H372 | Causes damage to the central nervous system through prolonged or repeated exposure. |
| H335 | May cause respiratory irritation. |
| H319 | Causes serious eye irritation. |
| H315 | Causes skin irritation. |

**P-statements**

| | |
|---|---|
| P210 | Keep away from heat, hot surfaces, sparks, open flames and other ignition sources. No smoking. |
| P280 | Wear protective gloves, protective clothing and eye protection/face protection. |
| P260 | Do not breathe gas. |
| P304 + P340 | IF INHALED: Remove person to fresh air and keep comfortable for breathing. |
| P362 + P364 | Take off contaminated clothing and wash it before reuse. |
| P311 | Call a POISON CENTER/doctor. |

**Supplemental information**

Restricted to professional users.

## 2.3 Other hazards:

**CLP**

May be ignited by sparks

Gas/vapour spreads at floor level: ignition hazard

Heat may cause pressure rise in tanks/drums: explosion risk

Odour threshold is well above the exposure limit

Produces effects on the nervous system

May cause frostbites

Caution! Substance is absorbed through the skin

Causes damage to the central nervous system

Probably human mutagenic

Harmful to fishes

# SECTION 3: Composition/information on ingredients

## 3.1 Substances:

| Name<br>REACH Registration No | CAS No<br>EC No | Conc. (C) | Classification according to DSD/DPD | Classification according to CLP | Note | Remark |
|---|---|---|---|---|---|---|
| ethylene oxide<br>01-2119432402-53 | 75-21-8<br>200-849-9 | C>99 % | F+; R12<br>Carc. Cat. 2; R45<br>Muta. Cat. 2; R46<br>T; R23 - 48/23<br>Xi; R36/37/38<br>R6 | Flam. Gas 1; H220<br>Press. Gas - Liquefied gas; H280<br>Chem. Unst. Gas A; H230<br>Carc. 1B; H350<br>Muta. 1B; H340<br>Acute Tox. 3; H331<br>Acute Tox. 4; H302<br>STOT RE 1; H372<br>STOT SE 3; H335<br>Eye Irrit. 2; H319<br>Skin Irrit. 2; H315 | (1)(2)(10) | Mono-constituent |

(1) For R-phrases and H-statements in full: see heading 16
(2) Substance with a Community workplace exposure limit
(6) Enumerated in Annex VI of Regulation (EC) No. 1272/2008 but the classification has been adapted after evaluation of available test data
(10) Subject to restrictions of Annex XVII of Regulation (EC) No. 1907/2006

### 3.2 Mixtures:

Not applicable

## SECTION 4: First aid measures

### 4.1 Description of first aid measures:

**General:**

Check the vital functions. Unconscious: maintain adequate airway and respiration. Respiratory arrest: artificial respiration or oxygen. Cardiac arrest: perform resuscitation. Victim conscious with laboured breathing: half-seated. Victim in shock: on his back with legs slightly raised. Vomiting: prevent asphyxia/aspiration pneumonia. Prevent cooling by covering the victim (no warming up). Keep watching the victim. Give psychological aid. Keep the victim calm, avoid physical strain. Depending on the victim's condition: doctor/hospital. Never give alcohol to drink.

**After inhalation:**

Remove the victim into fresh air. Immediately consult a doctor/medical service. Do not apply mouth-to-mouth resuscitation.

**After skin contact:**

Wash immediately with lots of water. Soap may be used. Do not apply (chemical) neutralizing agents. Take victim to a doctor if irritation persists. In case of frostbites: Wash immediately with lots of water (15 minutes)/shower. Do not remove clothing if it sticks to the skin. Cover wounds with sterile bandage. Consult a doctor/medical service.

**After eye contact:**

Rinse immediately with plenty of water for 15 minutes. Do not apply neutralizing agents. Take victim to an ophthalmologist.

**After ingestion:**

Immediately after ingestion: give lots of water to drink. Do not induce vomiting. Consult a doctor/medical service if you feel unwell.

### 4.2 Most important symptoms and effects, both acute and delayed:

**4.2.1 Acute symptoms**

**After inhalation:**

Dry/sore throat. Irritation of the respiratory tract. Irritation of the nasal mucous membranes. Central nervous system depression. Nausea. Vomiting. Headache. Dizziness. Disturbances of consciousness. EXPOSURE TO HIGH CONCENTRATIONS: Disturbances of heart rate. Respiratory difficulties. FOLLOWING SYMPTOMS MAY APPEAR LATER: Cramps/uncontrolled muscular contractions. Risk of lung oedema.

**After skin contact:**

Frostbites. Tingling/irritation of the skin. FOLLOWING SYMPTOMS MAY APPEAR LATER: Swelling of the skin. Red skin. Blisters. May stain the skin. AFTER CONTACT WITH WATER: Caustic burns/corrosion of the skin.

**After eye contact:**

Irritation of the eye tissue. Frostbites.

**After ingestion:**

Not applicable.

**4.2.2 Delayed symptoms**

No effects known.

### 4.3 Indication of any immediate medical attention and special treatment needed:

If applicable and available it will be listed below.

## SECTION 5: Firefighting measures

### 5.1 Extinguishing media:

**5.1.1 Suitable extinguishing media:**

Water spray. Alcohol-resistant foam. BC powder. Carbon dioxide.

**5.1.2 Unsuitable extinguishing media:**

Solid water jet ineffective as extinguishing medium.

### 5.2 Special hazards arising from the substance or mixture:

Upon combustion: CO and CO2 are formed. On heating: explosive decomposition. Polymerizes on exposure to temperature rise, on exposure to impurities, on exposure to light, on exposure to (some) metals and on exposure to (strong) acids/bases with heat release resulting in increased fire or explosion risk. Reacts slowly on exposure to water (moisture): heat release resulting in increased fire or explosion risk.

### 5.3 Advice for firefighters:

**5.3.1 Instructions:**

If no hazard for/from the surroundings: controlled burning. If hazardous substances are nearby: consider extinguishment. Extinguish only if gas supply/leak can be shut afterwards. Cool tanks/drums with water spray/remove them into safety. Physical explosion risk: extinguish/cool from behind cover. Do not move the load if exposed to heat. After cooling: persistant risk of physical explosion. Take account of toxic fire-fighting water. Use water moderately and if possible collect or contain it.

**5.3.2 Special protective equipment for fire-fighters:**

Insulating gloves. Head/neck protection. Protective clothing. Compressed air/oxygen apparatus.

## SECTION 6: Accidental release measures

### 6.1 Personal precautions, protective equipment and emergency procedures:

Keep upwind. Seal off low-lying areas. Close doors and windows of adjacent premises. Stop engines and no smoking. No naked flames or sparks. Spark- and explosionproof appliances and lighting equipment. Protect substance against light. Avoid ingress of water in the containers.

**6.1.1 Protective equipment for non-emergency personnel**

See heading 8.2

**6.1.2 Protective equipment for emergency responders**

Insulating gloves. Head/neck protection. Protective clothing.

Suitable protective clothing

See heading 8.2

### 6.2 Environmental precautions:

Contain released substance, pump into suitable containers. Plug the leak, cut off the supply. Dam up the liquid spill. Tip the container on one side to stop the leakage. Try to reduce evaporation. Take account of toxic/corrosive precipitation water. Prevent soil and water pollution. Prevent spreading in sewers.

### 6.3 Methods and material for containment and cleaning up:

Damaged/cooled tanks must be emptied. Do not use compressed air for pumping over spills. Prevent evaporation by covering with: foam. Take collected spill to manufacturer/competent authority. Wash clothing and equipment after handling.

### 6.4 Reference to other sections:

See heading 13.

## SECTION 7: Handling and storage

The information in this section is a general description. If applicable and available, exposure scenarios are attached in annex. Always use the relevant exposure scenarios that correspond to your identified use.

### 7.1 Precautions for safe handling:

Use spark-/explosionproof appliances and lighting system. Use earthed equipment. Keep away from naked flames/heat. Keep away from ignition sources/sparks. Gas/vapour heavier than air at 20°C. Observe very strict hygiene - avoid contact. Remove contaminated clothing immediately.

### 7.2 Conditions for safe storage, including any incompatibilities:

**7.2.1 Safe storage requirements:**

Storage temperature: <50 °C. Store in a cool area. Store in a dark area. Ventilation at floor level. Fireproof storeroom. Provide for an automatic sprinkler system. Provide for a tub to collect spills. Provide the tank with earthing. Unauthorized persons are not admitted. Under a shelter/in the open. Detached building. Keep only in the original container. Limited time of storage. May be stored under inert gas. Meet the legal requirements.

**7.2.2 Keep away from:**

Heat sources, ignition sources, combustible materials, oxidizing agents, (strong) acids, (strong) bases, highly flammable materials, metals, halogens, alcohols, amines, water/moisture.

**7.2.3 Suitable packaging material:**

Stainless steel, carbon steel, polypropylene.

**7.2.4 Non suitable packaging material:**

Aluminium, iron, copper, tin.

### 7.3 Specific end use(s):

If applicable and available, exposure scenarios are attached in annex. See information supplied by the manufacturer.

## SECTION 8: Exposure controls/personal protection

### 8.1 Control parameters:

**8.1.1 Occupational exposure**

a) Occupational exposure limit values

If limit values are applicable and available these will be listed below.

**The Netherlands**

| | | |
|---|---|---|
| Ethyleenoxide | Time-weighted average exposure limit 8 h (Public occupational exposure limit value) | 0.46 ppm |
| | Time-weighted average exposure limit 8 h (Public occupational exposure limit value) | 0.84 mg/m³ |

**Belgium**

| | | |
|---|---|---|
| Oxyde d'éthylène | Time-weighted average exposure limit 8 h | 1 ppm |
| | Time-weighted average exposure limit 8 h | 1.8 mg/m³ |

**USA (TLV-ACGIH)**

| | | |
|---|---|---|
| Ethylene oxide | Time-weighted average exposure limit 8 h (TLV - Adopted Value) | 1 ppm |

**France**

| | | |
|---|---|---|
| Oxyde d'éthylène | Time-weighted average exposure limit 8 h (VL: Valeur non réglementaire indicative) | 1 ppm |
| | Short time value (VL: Valeur non réglementaire indicative) | 5 ppm |

**UK**

| | | |
|---|---|---|
| Ethylene oxide | Time-weighted average exposure limit 8 h (Workplace exposure limit (EH40/2005)) | 5 ppm |
| | Time-weighted average exposure limit 8 h (Workplace exposure limit (EH40/2005)) | 9.2 mg/m³ |

b) National biological limit values

If limit values are applicable and available these will be listed below.

**8.1.2 Sampling methods**

| Product name | Test | Number |
|---|---|---|
| Ethylene oxide (organic and inorganic gases by Extractive FT | NIOSH | 3800 |
| Ethylene Oxide (Qazi-Ketcham) | NON | 14 |
| Ethylene Oxide | NIOSH | 1614 |
| Ethylene Oxide | NIOSH | 3702 |
| Ethylene Oxide | OSHA | 1010 |
| Ethylene Oxide | OSHA | 30 |
| Ethylene Oxide | OSHA | 49 |
| Ethylene Oxide | OSHA | 50 |

**8.1.3 Applicable limit values when using the substance or mixture as intended**

If limit values are applicable and available these will be listed below.

**8.1.4 DNEL/PNEC values**

**DNEL - Workers**

ethylene oxide

| Effect level (DNEL/DMEL) | Type | Value | Remark |
|---|---|---|---|
| DMEL | Long-term systemic effects inhalation | 2 mg/m³ | |
| DNEL | Acute systemic effects inhalation | 10 mg/m³ | |

**PNEC**

ethylene oxide

| Compartments | Value | Remark |
|---|---|---|
| Fresh water | 0.084 mg/l | |
| Marine water | 0.0084 mg/l | |
| Aqua (intermittent releases) | 0.84 mg/l | |
| STP | 13 mg/l | |
| Fresh water sediment | 0.329 mg/kg sediment dw | |
| Marine water sediment | 0.0329 mg/kg sediment dw | |
| Soil | 0.0165 mg/kg soil dw | |

**8.1.5 Control banding**

If applicable and available it will be listed below.

## 8.2 Exposure controls:

The information in this section is a general description. If applicable and available, exposure scenarios are attached in annex. Always use the relevant exposure scenarios that correspond to your identified use.

**8.2.1 Appropriate engineering controls**

Use spark-/explosionproof appliances and lighting system. Use earthed equipment. Keep away from naked flames/heat. Keep away from ignition sources/sparks. Measure the concentration in the air regularly. Work under local exhaust/ventilation. Exhaust gas must be neutralised.

**8.2.2 Individual protection measures, such as personal protective equipment**

Observe very strict hygiene - avoid contact. Do not eat, drink or smoke during work.

a) Respiratory protection:

Gas mask with filter type AX. Self-contained breathing apparatus if conc. in air > 5 ppm.

b) Hand protection:

Insulated gloves.

- materials (good resistance)

Butyl rubber.

- materials (less resistance)

Neoprene, natural rubber.

- materials (poor resistance)

Polyethylene, PVC, nitrile rubber, leather.

c) Eye protection:

Protective goggles.

d) Skin protection:

Head/neck protection. Protective clothing.

**8.2.3 Environmental exposure controls:**

See headings 6.2, 6.3 and 13

## SECTION 9: Physical and chemical properties

### 9.1 Information on basic physical and chemical properties:

| | |
|---|---|
| Physical form | Gas |
| Odour | Sweet odour |
| | Ether-like odour |
| Odour threshold | 257 - 690 ppm |
| | 470 - 1263 mg/m³ |
| Colour | Colourless |
| Particle size | Not applicable (gas) |
| Explosion limits | 2.6 - 100 vol % |
| | 47 - 1820 g/m³ |
| Flammability | Extremely flammable gas. |
| Log Kow | -0.3 ; 25 °C |
| Dynamic viscosity | 0.254mPa.s ; 10°C ; Liquid |
| Kinematic viscosity | Not determined |
| Melting point | -111°C |
| Boiling point | 10.7°C ; 1013hPa |
| Flash point | -57°C ; 1013.25hPa |
| Evaporation rate | Not applicable ; ether |
| | 72 ; butyl acetate |
| Relative vapour density | Not applicable |
| Vapour pressure | 1458hPa ; 20°C |
| | 3950hPa ; 50°C |
| | 1752hPa ; 25°C |
| Solubility | water ; Complete |
| | ethanol ; Complete |
| | ether ; Complete |
| | acetone ; soluble |
| Relative density | 0.9 ; 10°C ; Liquid |
| Decomposition temperature | > 500 °C |
| Auto-ignition temperature | 429°C |
| Explosive properties | No chemical group associated with explosive properties |
| Oxidising properties | No chemical group associated with oxidising properties |
| pH | 7 ; 10% |

### 9.2 Other information:

| | |
|---|---|
| Minimum ignition energy | 0.065mJ |
| Specific conductivity | 4µS/m |
| Critical temperature | 196°C |
| Critical pressure | 71900hPa |

| | |
|---|---|
| Surface tension | 0.0267N/m ; 10°C ; 1000g/l |
| Absolute density | 887kg/m³ ; 10°C |

## SECTION 10: Stability and reactivity

### 10.1 Reactivity:

May be ignited by sparks. Gas/vapour spreads at floor level: ignition hazard. Substance has neutral reaction.

### 10.2 Chemical stability:

Unstable on exposure to heat. Unstable on exposure to light. Unstable on exposure to air.

### 10.3 Possibility of hazardous reactions:

Reacts slowly on exposure to water (moisture): heat release resulting in increased fire or explosion risk. Reacts violently with many compounds e.g.: with (strong) oxidizers: (increased) risk of fire/explosion. Prolonged storage: polymerizes slowly.

### 10.4 Conditions to avoid:

Use spark-/explosionproof appliances and lighting system. Use earthed equipment. Keep away from naked flames/heat. Keep away from ignition sources/sparks.

### 10.5 Incompatible materials:

Combustible materials, oxidizing agents, (strong) acids, (strong) bases, highly flammable materials, metals, halogens, alcohols, amines, water/moisture.

### 10.6 Hazardous decomposition products:

Upon combustion: CO and CO2 are formed.

## SECTION 11: Toxicological information

### 11.1 Information on toxicological effects:

#### 11.1.1 Test results

**Acute toxicity**

ethylene oxide

| Route of exposure | Parameter | Method | Value | Exposure time | Species | Value determination | Remark |
|---|---|---|---|---|---|---|---|
| Oral | LD50 | Other | 330mg/kg bw | | Rat (male) | Experimental value | Aqueous solution |
| Dermal | | | | | | Data waiving | |
| Inhalation (gases) | LC50 | Other | 2.63mg/l air | 4 h | Rat (male) | Experimental value | |
| Inhalation (gases) | LC50 | Other | 1460ppm | 4 h | Rat (male) | Experimental value | |

As the substance is a gas, inhalation is the most appropriate route of exposure

**Conclusion**

Harmful if swallowed.

Toxic if inhaled.

**Corrosion/irritation**

ethylene oxide

| Route of exposure | Result | Method | Exposure time | Time point | Species | Value determination | Remark |
|---|---|---|---|---|---|---|---|
| Eye | Irritating | Equivalent to OECD 405 | | 24; 48 hours | Rabbit | Experimental value | Aqueous solution |
| Skin | Irritating | | 1-60 minutes | | Rabbit | Experimental value | Aqueous solution |
| Inhalation | Irritating | | | | | Annex VI | |

Insufficient data available. Classification according to Regulation (EC) No 1272/2008 - Annex VI

The liquid form can cause frostbites, typical for all liquified gases

**Conclusion**

Causes serious eye irritation.

Causes skin irritation.

May cause respiratory irritation.

Specific target organ toxicity, single exposure: classified as irritant to respiratory organs

**Respiratory or skin sensitisation**

ethylene oxide

| Route of exposure | Result | Method | Exposure time | Observation time point | Species | Value determination | Remark |
|---|---|---|---|---|---|---|---|
| Skin | | | | | | Data waiving | |

The study on skin sensitisation does not need to be conducted as the substance is a gas

**Conclusion**

Not classified as sensitizing for skin

No respiratory sensitization data available

**Specific target organ toxicity**

ethylene oxide

| Route of exposure | Parameter | Method | Value | Organ | Effect | Exposure time | Species | Value determination |
|---|---|---|---|---|---|---|---|---|
| Dermal | | | | | | | | Data waiving |
| Inhalation (vapours) | NOAEC | Equivalent to OECD 453 | 10ppm | Central nervous system | No effect | 104 weeks (6h/day, 5 days/week) | Rat (male/female) | Experimental value |
| Inhalation (vapours) | NOAEC | Subchronic toxicity test | 10ppm | | No effect | 10-11 weeks (6h/day, 5 | Mouse (male/female) | Experimental value |

As the substance is a gas, inhalation is the most appropriate route of exposure

**Conclusion**

Causes damage to the nervous system through prolonged or repeated exposure.

**Mutagenicity (in vitro)**

ethylene oxide

| Result | Method | Test substrate | Effect | Value determination |
|---|---|---|---|---|
| Positive without metabolic activation | Equivalent to OECD 471 | Bacteria (S.typhimurium) | | Experimental value |
| Positive without metabolic activation | Equivalent to OECD 476 | Chinese hamster lung fibroblasts | | Experimental value |

**Mutagenicity (in vivo)**

ethylene oxide

| Result | Method | Exposure time | Test substrate | Organ | Value determination |
|---|---|---|---|---|---|
| Positive | Other | 4 h | Rat (male/female) | | Experimental value |

**Carcinogenicity**

ethylene oxide

| Route of exposure | Parameter | Method | Value | Exposure time | Species | Value determination | Organ | Effect |
|---|---|---|---|---|---|---|---|---|
| Inhalation (vapours) | NOAEC | Equivalent to OECD 453 | 10ppm | 104 weeks (6h/day, 5 days/week) | Rat (male/female) | Experimental value | | No neoplastic effects |

**Reproductive toxicity**

ethylene oxide

| | Parameter | Method | Value | Exposure time | Species | Effect | Organ | Value determination |
|---|---|---|---|---|---|---|---|---|
| Developmental toxicity | NOAEC | Equivalent to OECD 414 | 0.18mg/l air | 6-15 days (gestation, daily) | Rat (female) | No effect | | Experimental value |
| Maternal toxicity | NOAEC | Equivalent to OECD 414 | 0.18mg/l air | 6-15 days (gestation, daily) | Rat (female) | No effect | | Experimental value |
| Effects on fertility | NOAEC (P) | Equivalent to OECD 415 | 0.054mg/l air | 14 weeks (6h/day, 5 days/week) | Rat (male/female) | No effect | | Experimental value |

**Conclusion CMR**

May cause genetic defects.

May cause cancer.

Not classified for reprotoxic or developmental toxicity

**Chronic effects from short and long-term exposure**

ethylene oxide

ON CONTINUOUS/REPEATED EXPOSURE/CONTACT: Dry skin. Red skin. Itching. Inflammation/damage of the eye tissue. Nausea. Vomiting. Sensorial disturbances. Headache. Impairment of the nervous system. Movement disturbances. Impairment of the blood forming system. Coordination disorders. Myasthenia. Change in the haemogramme/blood composition. Degeneration of heart tissue. Tumours of the gastrointestinal tract. Possible bladder tumours. Brain affection. Possible premature birth.

## SECTION 12: Ecological information

### 12.1 Toxicity:

ethylene oxide

| | Parameter | Method | Value | Duration | Species | Test design | Fresh/salt water | Value determination |
|---|---|---|---|---|---|---|---|---|
| Acute toxicity fishes | LC50 | EPA 660/3 - 75/009 | 84mg/l | 96 h | Pimephales promelas | Static system | Fresh water | Experimental value |
| Acute toxicity invertebrates | LC50 | EPA 600/3-75/009 | 137mg/l - 300mg/l | 48 h | Daphnia magna | Static system | Fresh water | Experimental value |
| Toxicity algae and other aquatic plants | EC50 | Equivalent to OECD 201 | 240mg/l | 96 h | Pseudokirchneriella subcapitata | Static system | Fresh water | Experimental value |
| Toxicity aquatic micro-organisms | EC10 | OECD 209 | 130mg/l | 180 minutes | | Static system | Fresh water | Experimental value |

**Conclusion**

Harmful to fishes

Slightly harmful to invertebrates (Daphnia)

Not harmful to algae

Slightly harmful to bacteria

Not classified as dangerous for the environment according to the criteria of Regulation (EC) No 1272/2008

### 12.2 Persistence and degradability:

ethylene oxide

**Biodegradation water**

| Method | Value | Duration | Value determination |
|---|---|---|---|
| OECD 301C: Modified MITI Test (I) | 93% - 98% | 28 day(s) | Read-across |
| OECD 301D: Closed Bottle Test | 69% | 20 day(s) | Experimental value |

**Phototransformation air (DT50 air)**

| Method | Value | Conc. OH-radicals | Value determination |
|---|---|---|---|
| SRC AOP v1.92 | 57.2day(s) | 500000 /cm³ | QSAR |

**Half-life soil (t1/2 soil)**

| Method | Value | Primary degradation/mineralisation | Value determination |
|---|---|---|---|
| Not applicable | | | |

**Conclusion**

Readily biodegradable in water

### 12.3 Bioaccumulative potential:

ethylene oxide

**Log Kow**

| Method | Remark | Value | Temperature | Value determination |
|---|---|---|---|---|
| | | -0.3 | 25 °C | |

**Conclusion**

Bioaccumulation: not applicable

### 12.4 Mobility in soil:

ethylene oxide

**(log) Koc**

| Parameter | Method | Value | Value determination |
|---|---|---|---|
| log Koc | SRC PCKOCWIN v1.66 | 0.157 | QSAR |

**Volatility (Henry's Law constant H)**

| Value | Method | Temperature | Remark | Value determination |
|---|---|---|---|---|
| 12.159Pa.m³/mol | SRC HENRYWIN v3.10 | 25°C | | QSAR |

**Percent distribution**

| Method | Fraction air | Fraction biota | Fraction sediment | Fraction soil | Fraction water | Value determination |
|---|---|---|---|---|---|---|
| Mackay level I | 7.75% | | 0% | 0% | 92.23% | QSAR |

**Conclusion**

Low potential for adsorption in soil

### 12.5 Results of PBT and vPvB assessment:

Substance does not meet the screening criteria for persistency nor bioaccumulation so is neither PBT nor vPvB.

### 12.6 Other adverse effects:

ethylene oxide

**Global warming potential (GWP)**

Not included in the list of fluorinated greenhouse gases (Regulation (EC) No 517/2014)

**Ozone-depleting potential (ODP)**

Not classified as dangerous for the ozone layer (Regulation (EC) No 1005/2009)

## SECTION 13: Disposal considerations

The information in this section is a general description. If applicable and available, exposure scenarios are attached in annex. Always use the relevant exposure scenarios that correspond to your identified use.

### 13.1 Waste treatment methods:

**13.1.1 Provisions relating to waste**

Waste material code (Directive 2008/98/EC, Decision 2000/0532/EC).
16 05 04* (gases in pressure containers and discarded chemicals: gases in pressure containers (including halons) containing dangerous substances).
Depending on branch of industry and production process, also other waste codes may be applicable. Hazardous waste according to Directive 2008/98/EC.

**13.1.2 Disposal methods**

Refer to manufacturer/supplier for information on recovery/ recycling. Remove waste in accordance with local and/or national regulations. Hazardous waste shall not be mixed together with other waste. Different types of hazardous waste shall not be mixed together if this may entail a risk of pollution or create problems for the further management of the waste. Hazardous waste shall be managed responsibly. All entities that store, transport or handle hazardous waste shall take the necessary measures to prevent risks of pollution or damage to people or animals. Do not discharge into drains or the environment.

**13.1.3 Packaging/Container**

Waste material code packaging (Directive 2008/98/EC).
15 01 10* (packaging containing residues of or contaminated by dangerous substances).

## SECTION 14: Transport information

### Road (ADR)

14.1 UN number:

| | |
|---|---|
| UN number | 1040 |

14.2 UN proper shipping name:

| | |
|---|---|
| Proper shipping name | Ethylene oxide with nitrogen |

14.3 Transport hazard class(es):

| | |
|---|---|
| Hazard identification number | 263 |
| Class | 2 |
| Classification code | 2TF |

14.4 Packing group:

| | |
|---|---|
| Packing group | |
| Labels | 2.3+2.1 |

14.5 Environmental hazards:

| | |
|---|---|
| Environmentally hazardous substance mark | no |

14.6 Special precautions for user:

| | |
|---|---|
| Special provisions | 342 |
| Limited quantities | none. |

### Rail (RID)

14.1 UN number:

| | |
|---|---|
| UN number | 1040 |

14.2 UN proper shipping name:

| | |
|---|---|
| Proper shipping name | Ethylene oxide with nitrogen |

14.3 Transport hazard class(es):

| | |
|---|---|
| Hazard identification number | 263 |
| Class | 2 |
| Classification code | 2TF |

14.4 Packing group:

| | |
|---|---|
| Packing group | |
| Labels | 2.3+2.1 (+13) |

14.5 Environmental hazards:

| | |
|---|---|
| Environmentally hazardous substance mark | no |

14.6 Special precautions for user:

| | |
|---|---|
| Special provisions | 342 |
| Limited quantities | none. |

### Inland waterways (ADN)

14.1 UN number:

| | |
|---|---|
| UN number | 1040 |

14.2 UN proper shipping name:

| | |
|---|---|
| Proper shipping name | Ethylene oxide with nitrogen |

14.3 Transport hazard class(es):

| | |
|---|---|
| Class | 2 |
| Classification code | 2TF |

14.4 Packing group:

| | |
|---|---|
| Packing group | |
| Labels | 2.3+2.1 |

14.5 Environmental hazards:

| | |
|---|---|
| Environmentally hazardous substance mark | no |

14.6 Special precautions for user:

| | |
|---|---|
| Special provisions | 342 |
| Limited quantities | none. |

### Sea (IMDG/IMSBC)

14.1 UN number:

| | |
|---|---|
| UN number | 1040 |

14.2 UN proper shipping name:

| | |
|---|---|
| Proper shipping name | ethylene oxide with nitrogen |

14.3 Transport hazard class(es):

| | |
|---|---|
| Class | 2.3 |

14.4 Packing group:

| | |
|---|---|
| Packing group | |
| Labels | 2.3 + 2.1 |

14.5 Environmental hazards:

| | |
|---|---|
| Marine pollutant | - |
| Environmentally hazardous substance mark | no |

14.6 Special precautions for user:

| | |
|---|---|
| Special provisions | 342 |
| Limited quantities | none. |

14.7 Transport in bulk according to Annex II of MARPOL 73/78 and the IBC Code:

| | |
|---|---|
| Annex II of MARPOL 73/78 | Not applicable |

### Air (ICAO-TI/IATA-DGR)

14.1 UN number:

| | |
|---|---|
| Transport | Forbidden |
| UN number | 1040 |

14.2 UN proper shipping name:

| | |
|---|---|
| Proper shipping name | Ethylene oxide with nitrogen |

14.3 Transport hazard class(es):

| | |
|---|---|
| Class | 2.3 |

14.4 Packing group:

| | |
|---|---|
| Packing group | |
| Labels | |

14.5 Environmental hazards:

| | |
|---|---|
| Environmentally hazardous substance mark | no |

14.6 Special precautions for user:

| | |
|---|---|
| Special provisions | A2 |
| Passenger and cargo transport: limited quantities: maximum net quantity per packaging | |

## SECTION 15: Regulatory information

### 15.1 Safety, health and environmental regulations/legislation specific for the substance or mixture:

**European legislation:**

VOC content Directive 2010/75/EU

| VOC content | Remark |
|---|---|
| 100% | |

REACH Annex XVII - Restriction

Subject to restrictions of Annex XVII of Regulation (EC) No. 1907/2006: restrictions on the manufacture, placing on the market and use of certain dangerous substances, mixtures and articles.

| | Designation of the substance, of the group of substances or of the mixture | Conditions of restriction |
|---|---|---|
| · ethylene oxide | Substances which appear in Part 3 of Annex VI to Regulation (EC) No 1272/2008 classified as carcinogen category 1A or 1B (Table 3.1) or carcinogen category 1 or 2 (Table 3.2) and listed as follows: - Carcinogen category 1A (Table 3.1)/carcinogen category 1 (Table 3.2) listed in Appendix 1 - Carcinogen category 1B (Table 3.1)/carcinogen category 2 (Table 3.2) listed in Appendix 2 | Without prejudice to the other parts of this Annex the following shall apply to entries 28 to 30:1. Shall not be placed on the market, or used,<br>— as substances,<br>— as constituents of other substances, or,<br>— in mixtures, for supply to the general public when the individual concentration in the substance or mixture is equal to or greater than:<br>— either the relevant specific concentration limit specified in Part 3 of Annex VI to Regulation (EC) No 1272/2008, or,<br>— the relevant concentration specified in Directive 1999/45/EC where no specific concentration limit is set out in Part 3 of Annex VI to Regulation (EC) No 1272/2008.<br>Without prejudice to the implementation of other Community provisions relating to the classification, packaging and labelling of substances and mixtures, suppliers shall ensure before the placing on the market that the packaging of such substances and mixtures is marked visibly, legibly and indelibly as follows: “Restricted to professional users”.2. By way of derogation, paragraph 1 shall not apply to:<br>(a) medicinal or veterinary products as defined by Directive 2001/82/EC and Directive 2001/83/EC;<br>(b) cosmetic products as defined by Directive 76/768/EEC;<br>(c) the following fuels and oil products:<br>— motor fuels which are covered by Directive 98/70/EC,<br>— mineral oil products intended for use as fuel in mobile or fixed combustion plants,<br>— fuels sold in closed systems (e.g. liquid gas bottles);<br>(d) artists’ paints covered by Directive 1999/45/EC;<br>(e) the substances listed in Appendix 11, column 1, for the applications or uses listed in Appendix 11, column 2. Where a date is specified in column 2 of Appendix 11, the derogation shall apply until the said date. |
| · ethylene oxide | Substances which appear in Part 3 of Annex VI to Regulation (EC) No 1272/2008 classified as germ cell mutagen category 1A or 1B (Table 3.1) or mutagen category 1 or 2 (Table 3.2) and listed as follows: - Mutagen category 1A (Table 3.1)/mutagen category 1 (Table 3.2) listed in Appendix 3 - Mutagen category 1B (Table 3.1) /mutagen category 2 (Table 3.2) listed in Appendix 4 | Without prejudice to the other parts of this Annex the following shall apply to entries 28 to 30:1. Shall not be placed on the market, or used,<br>— as substances,<br>— as constituents of other substances, or,<br>— in mixtures, for supply to the general public when the individual concentration in the substance or mixture is equal to or greater than:<br>— either the relevant specific concentration limit specified in Part 3 of Annex VI to Regulation (EC) No 1272/2008, or,<br>— the relevant concentration specified in Directive 1999/45/EC where no specific concentration limit is set out in Part 3 of Annex VI to Regulation (EC) No 1272/2008.<br>Without prejudice to the implementation of other Community provisions relating to the classification, packaging and labelling of substances and mixtures, suppliers shall ensure before the placing on the market that the packaging of such substances and mixtures is marked visibly, legibly and indelibly as follows: “Restricted to professional users”.2. By way of derogation, paragraph 1 shall not apply to:<br>(a) medicinal or veterinary products as defined by Directive 2001/82/EC and Directive 2001/83/EC;<br>(b) cosmetic products as defined by Directive 76/768/EEC;<br>(c) the following fuels and oil products:<br>— motor fuels which are covered by Directive 98/70/EC,<br>— mineral oil products intended for use as fuel in mobile or fixed combustion plants,<br>— fuels sold in closed systems (e.g. liquid gas bottles);<br>(d) artists’ paints covered by Directive 1999/45/EC;<br>(e) the substances listed in Appendix 11, column 1, for the applications or uses listed in Appendix 11, column 2. Where a date is specified in column 2 of Appendix 11, the derogation shall apply until the said date. |
| · ethylene oxide | Substances classified as flammable gases category 1 or 2, flammable liquids categories 1, 2 or 3, flammable solids category 1 or 2, substances and mixtures which, in contact with water, emit flammable gases, category 1, 2 or 3, pyrophoric liquids category 1 or pyrophoric solids category 1, regardless of whether they appear in Part 3 of Annex VI to that Regulation or not. | 1. Shall not be used, as substance or as mixtures in aerosol dispensers where these aerosol dispensers are intended for supply to the general public for entertainment and decorative purposes such as the following:<br>— metallic glitter intended mainly for decoration,<br>— artificial snow and frost,<br>— “whoopee” cushions,<br>— silly string aerosols,<br>— imitation excrement,<br>— horns for parties,<br>— decorative flakes and foams,<br>— artificial cobwebs,<br>— stink bombs.2. Without prejudice to the application of other Community provisions on the classification, packaging and labelling of substances, suppliers shall ensure before the placing on the market that the packaging of aerosol dispensers referred to above is marked visibly, legibly and indelibly with:<br>“For professional users only”.3. By way of derogation, paragraphs 1 and 2 shall not apply to the aerosol dispensers referred to Article 8 (1a) of Council Directive 75/ 324/EEC.4. The aerosol dispensers referred to in paragraphs 1 and 2 shall not be placed on the market unless they conform to the requirements indicated. |

**National legislation The Netherlands**

| | |
|---|---|
| Waste identification (the Netherlands) | LWCA (the Netherlands): KGA category 06 |
| SZW - List of carcinogenic substances | Listed in SZW-list of carcinogenic substances |
| SZW - List of mutagenic substances | Listed in SZW-list of mutagenic substances |
| SZW - List of reprotoxic substances (fertility) | May have an effect on fertility |
| Waterbezwaarlijkheid | 2 |

**National legislation Germany**

| | |
|---|---|
| MAK - Krebserzeugend Kategorie | 2 |
| MAK - Keimzellmutagen Kategorie | 2 |
| WGK | 2; Classification water polluting in compliance with Verwaltungsvorschrift wassergefährdender Stoffe (VwVwS) of 27 July 2005 (Anhang 2) |
| TA-Luft | 5.2.7.1.1; II |

**National legislation France**

| | |
|---|---|
| Catégorie cancérogène | C1B |

**National legislation Belgium**

| | |
|---|---|
| Additional classification | C; La mention “C” signifie que l’agent en question relève du champ d’application de l’arrêté royal du 2 décembre 1993 concernant la protection des travailleurs contre les risques liés à l’exposition à des agents cancérigènes et mutagènes au travail. |

**Other relevant data**

| | |
|---|---|
| TLV - Carcinogen | Ethylene oxide; A2 |
| IARC - classification | 1; Ethylene oxide |

### 15.2 Chemical safety assessment:

A chemical safety assessment has been performed.

## SECTION 16: Other information

**Labelling according to Directive 67/548/EEC-1999/45/EC (DSD/DPD)**

Labelling according to Directive 2009/2/EC (31th adaptation of Directive 67/548/EEC)

**Labels**

Extremely flammable

Toxic

**R-phrases**

| | |
|---|---|
| 45 | May cause cancer |
| 46 | May cause heritable genetic damage |
| 06 | Explosive with or without contact with air |
| 12 | Extremely flammable |
| 23 | Also toxic by inhalation |
| 36/37/38 | Irritating to eyes, respiratory system and skin |
| 48/23 | Also toxic: danger of serious damage to health by prolonged exposure through inhalation |

**S-phrases**

| | |
|---|---|
| 53 | Avoid exposure - obtain special instructions before use |
| 45 | In case of accident or if you feel unwell, seek medical advice immediately (show the label where possible) |

**Additional recommendations**

Restricted to professional users.

**Full text of any R-phrases referred to under headings 2 and 3:**

R06 Explosive with or without contact with air
R12 Extremely flammable
R23 Toxic by inhalation
R36/37/38 Irritating to eyes, respiratory system and skin
R45 May cause cancer
R46 May cause heritable genetic damage
R48/23 Toxic: danger of serious damage to health by prolonged exposure through inhalation

**Full text of any H-statements referred to under headings 2 and 3:**

H220 Extremely flammable gas.
H230 May react explosively even in the absence of air.
H280 Contains gas under pressure; may explode if heated.
H302 Harmful if swallowed.
H315 Causes skin irritation.
H319 Causes serious eye irritation.
H331 Toxic if inhaled.
H335 May cause respiratory irritation.
H340 May cause genetic defects.
H350 May cause cancer.
H372 Causes damage to the central nervous system through prolonged or repeated exposure.

(*) = INTERNAL CLASSIFICATION BY BIG

PBT-substances = persistent, bioaccumulative and toxic substances

DSD Dangerous Substance Directive
DPD Dangerous Preparation Directive
CLP (EU-GHS) Classification, labelling and packaging (Globally Harmonised System in Europe)

**Specific concentration limits CLP**

| | | | |
|---|---|---|---|
| ethylene oxide | C ≥ 30 % | Chem. Unst. Cat. A; H230 | UN Manual of Tests and Criteria |

**Specific concentration limits DSD**

The information in this safety data sheet is based on data and samples provided to BIG. The sheet was written to the best of our ability and according to the state of knowledge at that time. The safety data sheet only constitutes a guideline for the safe handling, use, consumption, storage, transport and disposal of the substances/preparations/mixtures mentioned under point 1. New safety data sheets are written from time to time. Only the most recent versions may be used. Old versions must be destroyed. Unless indicated otherwise word for word on the safety data sheet, the information does not apply to substances/preparations/mixtures in purer form, mixed with other substances or in processes. The safety data sheet offers no quality specification for the substances/preparations/mixtures in question. Compliance with the instructions in this safety data sheet does not release the user from the obligation to take all measures dictated by common sense, regulations and recommendations or which are necessary and/or useful based on the real applicable circumstances. BIG does not guarantee the accuracy or exhaustiveness of the information provided and cannot be held liable for any changes by third parties. This safety data sheet is only to be used within the European Union, Switzerland, Iceland, Norway and Liechtenstein. Any use outside of this area is at your own risk. Use of this safety data sheet is subject to the licence and liability limiting conditions as stated in your BIG licence agreement or when this is failing the general conditions of BIG. All intellectual property rights to this sheet are the property of BIG and its distribution and reproduction are limited. Consult the mentioned agreement/conditions for details.