

# **SAFETY DATA SHEET**

Based upon Regulation (EC) No 1907/2006, as amended by Regulation (EU) No 2015/830

# 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
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

### 1.3. Details of the supplier of the safety data sheet

## Supplier of the safety data sheet

BALCHEM NV Westvaartdijk 85 B-1850 Grimbergen Belgium +32 2 251 60 87 +32 2 252 17 51 info.grimbergen@balchem.com

#### Distributor of the product

BALCHEM NV Westvaartdijk 85 B-1850 Grimbergen Belgium +32 2 251 60 87 +32 2 252 17 51 info.grimbergen@balchem.com

### 1.4. Emergency telephone number

24h/24h (Telephone advice: English, French, German, Dutch): + 32 14 58 45 45 (BIG)

# SECTION 2: Hazards identification

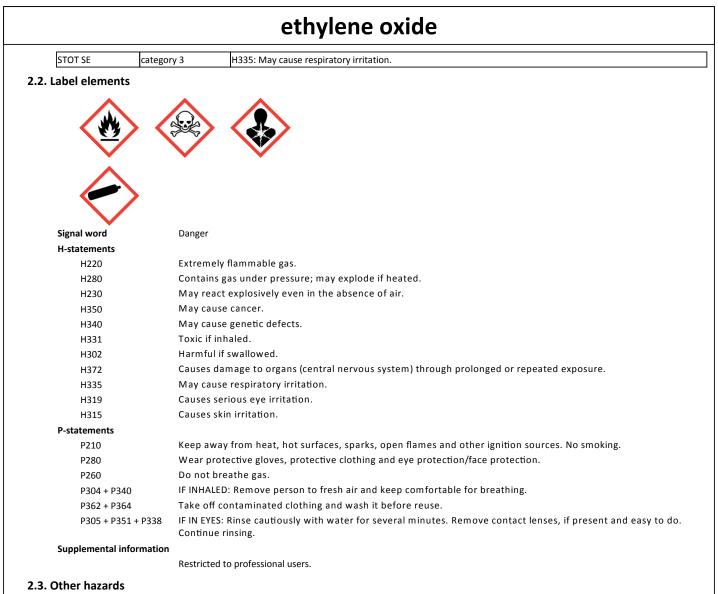
# 2.1. Classification of the substance or mixture

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.
STOT RE	category 1	H372: Causes damage to organs (central nervous system) through prolonged or repeated exposure.
Acute Tox.	category 4	H302: Harmful if swallowed.
Skin Irrit.	category 2	H315: Causes skin irritation.
Eye Irrit.	category 2	H319: Causes serious eye irritation.

Created by: Brandweerinformatiecentrum voor gevaarlijke stoffen vzw (BIG) Technische Schoolstraat 43 A, B-2440 Geel http://www.big.be © BIG vzw Reason for revision: ATP8 Revision number: 0200 Publication date: 2014-10-29 Date of revision: 2017-07-11 Reference number: 1400

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134-16453-567-en



Gas/vapour spreads at floor level: ignition hazard Odour threshold is well above the exposure limit Produces effects on the nervous system May cause frostbites Caution! Substance is absorbed through the skin

# SECTION 3: Composition/information on ingredients

# 3.1. Substances

Name RFACH Registration No	CAS No FC No	Conc. (C)	Classification according to CLP	Note	Remark
REACH Registration No ethylene oxide 01-2119432402-53	EC No 75-21-8 200-849-9	>99.9 %	Press. Gas - Liquefied gas; H280 Chem. Unst. Gas A; H230 Carc. 1B; H350 Muta. 1B; H340 Acute Tox. 3; H331 STOT RE 1; H372 Acute Tox. 4; H302	(1)(2)(6)(10)	Mono-constituent
			Skin Irrit. 2; H315 Eye Irrit. 2; H319 STOT SE 3; H335		

(1) For 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

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#### 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. Remove contact lenses, if present and easy to do. Continue rinsing. 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:

Small fire: Quick-acting ABC powder extinguisher, Quick-acting BC powder extinguisher.

#### 5.1.2 Unsuitable extinguishing media:

Small fire: Quick-acting CO2 extinguisher, Water (water can be used to control jet flame), Foam.

Major fire: Water (water can be used to control jet flame), Foam.

### 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.

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# 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 product, 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.

Belgium
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Deigiuili		
Oxyde d'éthylène	Time-weighted average exposure limit 8 h	1 ppm
	Time-weighted average exposure limit 8 h	1.8 mg/m³
The Netherlands		
Ethyleenoxide	Time-weighted average exposure limit 8 h (Public occupational exposure limit value)	e 0.46 ppm
	Time-weighted average exposure limit 8 h (Public occupational exposure limit value)	e 0.84 mg/m³
France		
Oxyde d'éthylène	Time-weighted average exposure limit 8 h (VL: Valeur non réglementaire indicative)	1 ppm
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<b>UK</b> Ethylene oxide		S	hort time value (VL:	valeur non regiemei	intaire indicative,		5 ppm
			ime-weighted avera EH40/2005))	ge exposure limit 8 h	n (Workplace exp	osure limit	5 ppm
			ime-weighted avera EH40/2005))	ge exposure limit 8 h	n (Workplace exp	osure limit	9.2 mg/m <sup>3</sup>
USA (TLV-ACGIH)							
Ethylene oxide		Т	ime-weighted avera	ge exposure limit 8 h	n (TLV - Adopted	Value)	1 ppm
<u>b) National biological limit valu</u>	ies						
If limit values are applicable and	d available these will	be listed belo	ow.				
2 Sampling methods							
Product name			Test	Number			
Ethylene oxide (organic and ino	rganic gases by Extra	active FTIR)	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 <b>3 Applicable limit values when</b> f limit values are applicable and <b>4 DNEL/PNEC values</b> DNEL/DMEL - Workers	-			50			
Ethylene Oxide <b>3 Applicable limit values when</b> If limit values are applicable and <b>4 DNEL/PNEC values</b> <u>DNEL/DMEL - Workers</u> <u>ethylene oxide</u>	available these will		s intended				
Ethylene Oxide <b>3 Applicable limit values when</b> If limit values are applicable and <b>4 DNEL/PNEC values</b> <u>DNEL/DMEL - Workers</u> <u>ethylene oxide</u> <u>Effect level (DNEL/DMEL)</u>	d available these will Type	be listed belo	s intended	Value		Remark	
Ethylene Oxide <b>3 Applicable limit values when</b> If limit values are applicable and <b>4 DNEL/PNEC values</b> <u>DNEL/DMEL - Workers</u> <u>ethylene oxide</u> <u>Effect level (DNEL/DMEL)</u> DMEL	d available these will           Type           Long-term sys	be listed belo	s intended	Value 2 mg/m <sup>3</sup>		Remark	
Ethylene Oxide <b>3 Applicable limit values when</b> If limit values are applicable and <b>4 DNEL/PNEC values</b> <b>DNEL/DMEL - Workers</b> ethylene oxide Effect level (DNEL/DMEL) DMEL DNEL	d available these will Type	be listed belo	s intended	Value		Remark	
Ethylene Oxide 3 Applicable limit values when If limit values are applicable and 4 DNEL/PNEC values DNEL/DMEL - Workers ethylene oxide Effect level (DNEL/DMEL) DMEL DNEL DNEL PNEC	d available these will           Type           Long-term sys	be listed belo	s intended	Value 2 mg/m <sup>3</sup>		Remark	
Ethylene Oxide 3 Applicable limit values when If limit values are applicable and 4 DNEL/PNEC values DNEL/DMEL - Workers ethylene oxide Effect level (DNEL/DMEL) DMEL DNEL DNEL PNEC ethylene oxide	d available these will           Type           Long-term sys	be listed belo stemic effects ic effects inha	s intended	Value 2 mg/m <sup>3</sup>	Pemark	Remark	
Ethylene Oxide 3 Applicable limit values when if limit values are applicable and 4 DNEL/PNEC values DNEL/DMEL - Workers ethylene oxide Effect level (DNEL/DMEL) DMEL DNEL DNEL PNEC ethylene oxide Compartments	d available these will           Type           Long-term sys	be listed below stemic effects ic effects inha Value	s intended	Value 2 mg/m <sup>3</sup>	Remark	Remark	
Ethylene Oxide 3 Applicable limit values when if limit values are applicable and 4 DNEL/PNEC values DNEL/DMEL - Workers ethylene oxide Effect level (DNEL/DMEL) DMEL DNEL PNEC ethylene oxide Compartments Fresh water	d available these will           Type           Long-term sys	be listed belo stemic effects ic effects inha Value 0.084 mg/	s intended	Value 2 mg/m <sup>3</sup>	Remark	Remark	
Ethylene Oxide 3 Applicable limit values when if limit values are applicable and 4 DNEL/PNEC values DNEL/DMEL - Workers ethylene oxide Effect level (DNEL/DMEL) DMEL DNEL PNEC ethylene oxide Compartments Fresh water Marine water	d available these will           Type           Long-term sys	be listed belo stemic effects ic effects inha 0.084 mg/ 0.0084 mg	s intended	Value 2 mg/m <sup>3</sup>	Remark	Remark	
Ethylene Oxide 3 Applicable limit values when if limit values are applicable and 4 DNEL/PNEC values DNEL/DMEL - Workers ethylene oxide Effect level (DNEL/DMEL) DMEL DNEL PNEC ethylene oxide Compartments Fresh water	d available these will           Type           Long-term sys	be listed belo stemic effects ic effects inha 0.084 mg/ 0.84 mg/I	s intended	Value 2 mg/m <sup>3</sup>	Remark	Remark	
Ethylene Oxide 3 Applicable limit values when if limit values are applicable and 4 DNEL/PNEC values DNEL/DMEL - Workers ethylene oxide Effect level (DNEL/DMEL) DMEL DNEL PNEC ethylene oxide Compartments Fresh water Marine water Aqua (intermittent releases)	d available these will           Type           Long-term sys	be listed below stemic effects ic effects inha 0.084 mg/ 0.84 mg/1 13 mg/1	s intended	Value 2 mg/m <sup>3</sup>	Remark	Remark	
Ethylene Oxide 3 Applicable limit values when If limit values are applicable and 4 DNEL/PNEC values DNEL/DMEL - Workers ethylene oxide Effect level (DNEL/DMEL) DMEL DNEL PNEC ethylene oxide Compartments Fresh water Marine water Aqua (intermittent releases) STP	d available these will           Type           Long-term sys	be listed below stemic effects ic effects inha 0.084 mg/ 0.084 mg/1 13 mg/1 0.329 mg/	s intended s intended w. inhalation lation l kg sediment dw	Value 2 mg/m <sup>3</sup>	Remark	Remark	
Ethylene Oxide 3 Applicable limit values when If limit values are applicable and 4 DNEL/PNEC values DNEL/DMEL - Workers ethylene oxide Effect level (DNEL/DMEL) DMEL DNEL DNEL PNEC ethylene oxide Compartments Fresh water Aqua (intermittent releases) STP Fresh water sediment	d available these will           Type           Long-term sys	be listed belo stemic effects ic effects inha 0.084 mg/ 0.84 mg/l 13 mg/l 0.329 mg/ 0.0329 mg/	s intended	Value 2 mg/m <sup>3</sup>	Remark	Remark	

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.

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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	0.254 mPa.s ; 10 °C ; Liquid	
Kinematic viscosity	Not determined	
Melting point	-111 °C	
Boiling point	10.7 °C ; 1013 hPa	
Flash point	Not applicable	
Evaporation rate	Ether ; Not applicable	
	72 ; Butyl acetate	
Relative vapour density	Not applicable	
Vapour pressure	1458 hPa ; 20 °C	
	3950 hPa ; 50 °C	
	1752 hPa ; 25 °C	
Solubility	Water ; complete	
	Ethanol ; complete	
	Ether ; complete	
	Acetone ; soluble	
Relative density	0.88 ; 10 °C ; Liquid	
Decomposition temperature	>570 °C	
Auto-ignition temperature	429 °C	
Explosive properties	No chemical group associated with explosive properties	
Oxidising properties	No chemical group associated with oxidising properties	
рН	7 ; 10 %	

## 9.2. Other information

. 0		
	Minimum ignition energy	0.065 mJ
	Specific conductivity	4 μS/m
	Critical temperature	196 °C
	Critical pressure	71900 hPa
	Surface tension	0.0267 N/m ; 10 °C ; 1000 g/l
	Absolute density	887 kg/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. May react explosively even in the absence of air. 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.

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## 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	Remark
						determination	
Oral	LD50	Other	330 mg/kg bw		Rat (male)	Experimental value	Aqueous solution
Dermal						Data waiving	
Inhalation (gases)	LC50	Other	2.63 mg/l air	4 h	Rat (male)	Experimental value	
Inhalation (gases)	LC50	Other	1460 ppm	4 h	Rat (male)	Experimental value	

As the substance is a gas, inhalation is the most likely 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	Remark
						determination	
Eye	Irritating	Equivalent to OECD 405		24; 48 hours	Rabbit	Experimental value	Aqueous solution
Skin	Irritating		1 minutes - 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 liquefied gases

#### **Conclusion**

Causes skin irritation.

Causes serious eye 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	· ·	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)		Equivalent to OECD 453	10 ppm	Central nervous system	No effect	104 weeks (6h/day, 5 days/week)	Rat (male/female)	Experimental value
Inhalation (vapours)	NOAEC	Subchronic toxicity test	10 ppm		No effect	10 weeks (6h/day, 5 days/week) - 11 weeks (6h/day, 5	Mouse (male/female)	Experimental value

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

#### **Conclusion**

Causes damage to organs (central 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		Chinese hamster lung fibroblasts (V79)		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
<u>c</u>	onclusion					

May cause genetic defects.

#### Carcinogenicity

ethylene oxide

Route of exposure	Parameter	Method	Value	Exposure time	Species	Effect	- 0-	Value determination
Inhalation (vapours)		Equivalent to OECD 453	10 ppm	104 weeks (6h/day, 5 days/week)		No neoplastic effects		Experimental value

**Conclusion** 

May cause cancer.

#### **Reproductive toxicity**

#### ethylene oxide

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

#### **Conclusion**

Not classified for reprotoxic or developmental toxicity

#### **Toxicity other effects**

ethylene oxide

No (test)data available

#### 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.

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# SECTION 12: Ecological information

# 12.1. Toxicity

## ethylene oxide

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

#### **Conclusion**

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	57.2 day(s)	500000 /cm <sup>3</sup>	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	
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Method	Remark	Value	Temperature	Value determination
			25 °C	

**Conclusion** 

## Not bioaccumulative

# 12.4. Mobility in soil

ethylene oxide

(log) Koc

	Parameter	Method	Value	Value determination
	log Koc	SRC PCKOCWIN v1.66	0.157	QSAR
v	olatility (Henry's Law constant H)			

•	olatility (litelily 5 Eaw collista				-
	Value	Method	Temperature	Remark	Value determination
	12.159 Pa.m³/mol	SRC HENRYWIN v3.10	25 °C		QSAR

Method	Fraction air	 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

Reason for revision: ATP8	Publication date: 2014-10-29	
	Date of revision: 2017-07-11	
	Reference number: 1400	
Revision number: 0200	Product number: 50538	9 / 14

Substance does not meet the criteria of PBT, nor the criteria of vPvB according to Annex XIII of Regulation (EC) No 1907/2006, so is neither PBT nor vPvB.

# 12.6. Other adverse effects

#### ethylene oxide

#### Fluorinated greenhouse gases (Regulation (EU) No 517/2014)

Not included in the list of fluorinated greenhouse gases (Regulation (EU) 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

#### **European Union**

Hazardous waste according to Directive 2008/98/EC, as amended by Regulation (EU) No 1357/2014.

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 hazardous substances). Depending on branch of industry and production process, also other waste codes may be applicable.

#### 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

#### **European Union**

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.	
ail (RID)		
14.1. UN number		
UN number	1040	
14.2. UN proper shipping name	1040	
Proper shipping name	Ethylene oxide with nitrogen	
14.3. Transport hazard class(es)		
Hazard identification number	263	
Class	200	
Classification code	2 2TF	
14.4. Packing group	215	
Packing group		
Labels	2.3+2.1 (+13)	
Laucis	2.5, 2.1 (713)	
	Dublication date: 2014 10 20	
on for revision: ATP8	Publication date: 2014-10-29	

Reason for revision: ATP8	Publication date: 2014-10-29
	Date of revision: 2017-07-11
	Reference number: 1400
Revision number: 0200	Product number: 50538

Environmentally hazardous substance mark	no
.6. Special precautions for user	
Special provisions	342
Limited quantities	none.

# Inland waterways (ADN)

l4.1. UN number		
UN number	1040	
14.2. UN proper shipping name		
Proper shipping name	Ethylene oxide with nitrogen	
4.3. Transport hazard class(es)		
Class	2	
Classification code	2TF	
L4.4. Packing group		
Packing group		
Labels	2.3+2.1	
14.5. Environmental hazards		
Environmentally hazardous substance mark	no	
4.6. 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	
4.3. Transport hazard class(es)		
Class	2.3	
14.4. Packing group		
Packing group		
Labels	2.3 + 2.1	
4.5. Environmental hazards		
Marine pollutant	-	
Environmentally hazardous substance mark	no	
4.6. Special precautions for user		
Special provisions	342	
Limited quantities	none.	
4.7. Transport in bulk according to Annex II of Marpol 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
Limited quantities: maximum net quantity per packaging	

 Reason for revision: ATP8
 Publication date: 2014-10-29

 Date of revision: 2017-07-11
 Date of revision: 2017-07-11

 Revision number: 0200
 Product number: 1400

# 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.

• ethylene oxide	2 or 3, flammable solids category 1 or 2,	2001/83/EC; (b) cosmetic products as defined by Directive 76/768/EEC; (c) the following fuels and oil products: — motor fuels which are covered by Directive 98/70/EC, — mineral oil products intended for use as fuel in mobile or fixed combustion plants, — fuels sold in closed systems (e.g. liquid gas bottles); (d) artists' paints covered by Directive 1999/45/EC; (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 derogati shall apply until the said date. 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: — metallic glitter intended mainly for decoration, — artificial snow and frost, — "whoopee" cushions, — silly string aerosols, — imitation excrement, — horns for parties, — decorative flakes and foams, — artificial cobwebs, — stink bombs.2. Without prejudice to the application of other Community provisions on Publication date: 2014-10-29 Date of revision: 2017-07-11
	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	<ul> <li>(b) cosmetic products as defined by Directive 76/768/EEC;</li> <li>(c) the following fuels and oil products: <ul> <li>motor fuels which are covered by Directive 98/70/EC,</li> <li>mineral oil products intended for use as fuel in mobile or fixed combustion plants,</li> <li>fuels sold in closed systems (e.g. liquid gas bottles);</li> <li>(d) artists' paints covered by Directive 1999/45/EC;</li> <li>(e) the substances listed in Appendix 11, column 1, for the applications or uses listed in Appendix 11, column 2 of Appendix 11, the derogatis shall apply until the said date.</li> </ul> </li> <li>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: <ul> <li>metallic glitter intended mainly for decoration,</li> <li>artificial snow and frost,</li> <li>imitation excrement,</li> <li>horns for parties,</li> <li>decorative flakes and foams,</li> <li>artificial cobwebs,</li> <li>stink bombs.2. Without prejudice to the application of other Community provisions on</li> </ul> </li> </ul>
· ethylene oxide	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	<ul> <li>(b) cosmetic products as defined by Directive 76/768/EEC;</li> <li>(c) the following fuels and oil products: <ul> <li>motor fuels which are covered by Directive 98/70/EC,</li> <li>mineral oil products intended for use as fuel in mobile or fixed combustion plants,</li> <li>fuels sold in closed systems (e.g. liquid gas bottles);</li> <li>(d) artists' paints covered by Directive 1999/45/EC;</li> <li>(e) the substances listed in Appendix 11, column 1, for the applications or uses listed in Appendix 11, column 2 of Appendix 11, the derogati shall apply until the said date.</li> </ul> </li> <li>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: <ul> <li>metallic glitter intended mainly for decoration,</li> <li>artificial snow and frost,</li> <li>"whoopee" cushions,</li> <li>silly string aerosols,</li> <li>mitation excrement,</li> <li>horns for parties,</li> <li>decorative flakes and foams,</li> <li>artificial cobwebs,</li> </ul> </li> </ul>
· ethylene oxide	category 1 or 2, flammable liquids categories 1, 2 or 3, flammable solids category 1 or 2, substances and mixtures which, in contact with	<ul> <li>(b) cosmetic products as defined by Directive 76/768/EEC;</li> <li>(c) the following fuels and oil products: <ul> <li>motor fuels which are covered by Directive 98/70/EC,</li> <li>mineral oil products intended for use as fuel in mobile or fixed combustion plants,</li> <li>fuels sold in closed systems (e.g. liquid gas bottles);</li> <li>(d) artists' paints covered by Directive 1999/45/EC;</li> <li>(e) the substances listed in Appendix 11, column 1, for the applications or uses listed in Appendix 11, column 2 of Appendix 11, the derogati shall apply until the said date.</li> </ul> </li> <li>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: <ul> <li>metallic glitter intended mainly for decoration,</li> </ul> </li> </ul>
athulana avida		<ul> <li>(b) cosmetic products as defined by Directive 76/768/EEC;</li> <li>(c) the following fuels and oil products: <ul> <li>motor fuels which are covered by Directive 98/70/EC,</li> <li>mineral oil products intended for use as fuel in mobile or fixed combustion plants,</li> <li>fuels sold in closed systems (e.g. liquid gas bottles);</li> <li>(d) artists' paints covered by Directive 1999/45/EC;</li> <li>(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 derogat shall apply until the said date.</li> </ul> </li> </ul>
· ethylene oxide	Substances which appear in Part 3 of Annex VI to Regulation (EC) No 1272/2008 classified as germ cell mutagen category 1 A 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	
• ethylene oxide	Designation of the substance, of the group of substances or of the mixture Substances which appear in Part 3 of Annex VI to Regulation (EC) No 1272/2008 classified as carcinogen category 1 A 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 2 (Table 3.2) listed in Appendix 2	Conditions of restriction Without prejudice to the other parts of this Annex the following shall apply to entries 28 t 30:1. Shall not be placed on the market, or used, — as substances, — as constituents of other substances, or, — in mixtures, for supply to the general public when the individual concentration in the substance or mixture is equal to or greater than: — either the relevant specific concentration limit specified in Part 3 of Annex VI to Regulation (EC) No 1272/2008, or, — 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. 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 war derogation, paragraph 1 shall not apply to: (a) medicinal or veterinary products as defined by Directive 2001/82/EC and Directive 2001/83/EC; (b) cosmetic products as defined by Directive 98/70/EC, — mineral oil products: — motor fuels which are covered by Directive 98/70/EC, — mineral oil products intended for use as fuel in mobile or fixed combustion plants, — fuels sold in closed systems (e.g. liquid gas bottles); (d) artists' paints covered by Directive 1999/45/EC; (e) the substances listed in Appendix 11, column 1, for the applications or uses listed in Appendix 11, column 2 of Appendix 11, the derogat

		ethylene oxide					
		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 mark visibly, legibly and indelibly with: "For professional users only". 3. By way of derogation, paragraphs 1 and 2 shall not apply 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 ur they conform to the requirements indicated.					
National legislation B	elgium						
Additional classi	fication	Oxyde d'éthylène; C; La mention "C" signifie que l'agent en question relève du champ d'application de l'arrêté royal du décembre 1993 concernant la protection des travailleurs contre les risques liés à l'exposition à des agents cancérigènes mutagènes au travail.					
National legislation T	he Netherland	ds					
Waterbezwaarlij	jkheid	Z (2)					
SZW - Lijst van		Ethyleenoxide; Listed in SZW-list of carcinogenic substances					
kankerverwekke							
SZW - Lijst van n stoffen	nutagene	Ethyleenoxide; Listed in SZW-list of mutagenic substances					
SZW - Lijst van v voortplanting gi (vruchtbaarheid	ftige stoffen	Ethyleenoxide; 1B; May damage fertility.					
National legislation F	rance						
Catégorie cancé		Oxyde d'éthylène					
Catégorie mutag	-	Oxyde d'éthylène; M1B					
	-						
National legislation G	ermany	2. Classification water polluting based on the D physics in compliance with Verweltung water polluting based on the D					
WGK		3; Classification water polluting based on the R-phrases in compliance with Verwaltungsvorschrift wassergefährdender Stoffe (VwVwS) of 27 July 2005 (Anhang 3)					
TA-Luft		5.2.7.1.1; II					
National legislation U	Inited Kingdon						
Carcinogen		Ethylene oxide; Carc					
Other relevant data		1					
IARC - classificat	ion	1; Ethylene oxide					
	n	Ethylene oxide; A2					
TLV - Carcinoger	ty assessme	ent					
L5.2. Chemical safet	ty assessme assessment ha	ent as been performed.					
L5.2. Chemical safet A chemical safet TION 16: Othe Full text of any H-stat H220 Extremely f H230 May react H280 Contains g H302 Harmful if H315 Causes skir H319 Causes seri H331 Toxic if inh H335 May cause H340 May cause H350 May cause	ty assessment hat assessment hat tements referr flammable gas explosively eves as under pressi swallowed. n irritation. ious eye irritati aled. respiratory irri genetic defect cancer.	ent as been performed. Dation red to under headings 2 and 3:  en in the absence of air. ure; may explode if heated. ion. itation.					
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STP	Sludge Treatment Process
vPvB	very Persistent & very Bioaccumulative

Specific concentration limits CLP

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

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