

## SAFETY DATA SHEET

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

## >58% Ethylene oxide ≤87% / Carbon dioxide

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

#### 1.1. Product identifier

Product name : >58% Ethylene oxide ≤87% / Carbon dioxide

: carbon dioxide/ethylene oxide, mixtures, 58%<conc ethylene oxide≤87%; ethylene oxide/carbon dioxide, mixtures, 58% Synonyms

<conc ethylene oxide≤87%

Registration number REACH : Not applicable (mixture)

Product type REACH : Mixture Formula : C2H4O+CO2

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

#### 1.2.1 Relevant identified uses

Industrial use 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

(iii) +32 2 252 17 51

info.grimbergen@balchem.com

#### Manufacturer 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

Classified as dangerous according to the criteria of Regulation (EC) No 1272/2008 Class Category Hazard statements Flam. Gas H220: Extremely flammable gas. category 1 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 category 1B H350: May cause cancer Carc. Muta. category 1B H340: May cause genetic defects. Acute Tox. category 3 H331: Toxic if inhaled. H372: Causes damage to organs (central nervous system) through prolonged or repeated exposure. STOT RE category 1 H302: Harmful if swallowed Acute Tox. category 4 Skin Irrit. category 2 H315: Causes skin irritation. H319: Causes serious eye irritation. Eve Irrit. category 2 STOT SE H335: May cause respiratory irritation. category 3

### 2.2. Label elements







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Contains: ethylene oxide.

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.

H372 Causes damage to organs through prolonged or repeated exposure.

H302 Harmful if swallowed.
 H315 Causes skin irritation.
 H319 Causes serious eye irritation.
 H335 May cause respiratory 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.

P305 + P351 + P338 IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do.

Continue rinsing.

Supplemental information

Restricted to professional users.

#### 2.3. Other hazards

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

Not applicable

#### 3.2. Mixtures

Name REACH Registration No	CAS No EC No	Conc. (C)	Classification according to CLP	Note	Remark
ethylene oxide 01-2119432402-53	75-21-8 200-849-9		Flam. Gas 1; H220 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 Skin Irrit. 2; H315 Eye Irrit. 2; H319 STOT SE 3; H335	(1)(2)(6)(10)	Constituent
carbon dioxide	124-38-9 204-696-9	13% <c≤42%< td=""><td>Press. Gas - Liquefied gas; H280</td><td>(1)(2)(I)</td><td>Constituent</td></c≤42%<>	Press. Gas - Liquefied gas; H280	(1)(2)(I)	Constituent

<sup>(1)</sup> For H-statements in full: see heading 16

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<sup>(2)</sup> Substance with a Community workplace exposure limit

<sup>(6)</sup> Enumerated in Annex VI of Regulation (EC) No. 1272/2008 but the classification has been adapted after evaluation of available test data

<sup>(10)</sup> Subject to restrictions of Annex XVII of Regulation (EC) No. 1907/2006

<sup>(</sup>I) Exempted from registration under REACH according to Annex IV (Regulation (EC) No 1907/2006)

## 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.

#### After inhalation

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

#### After skin contact:

Wash immediately with lots of water. Soap may be used. Take victim to a doctor if irritation persists. In case of frostbites: Wash immediately with lots of water (15 minutes)/shower. Do not apply (chemical) neutralizing agents without medical advice. Remove clothing while washing. Do not remove clothing if it sticks to the skin. Cover wounds with sterile bandage. Consult a doctor/medical service. If burned surface > 10%: take victim to hospital.

#### After eve contact:

Rinse immediately with plenty of water for 15 minutes. Remove contact lenses, if present and easy to do. Continue rinsing. Do not apply (chemical) neutralizing agents without medical advice. Take victim to an ophthalmologist.

#### After ingestion:

Not applicable.

#### 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:

No effects known.

#### 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. Polymerizes on exposure to temperature rise. Contains gas under pressure; may explode if heated.

### 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. Protective goggles. Head/neck protection. Protective clothing. Large spills/in enclosed spaces: gas-tight suit. 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 explosion proof appliances and lighting equipment. 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. Protective goggles. Head/neck protection. Protective clothing. Large spills/in enclosed spaces: gas-tight suit.

Suitable protective clothing

See heading 8.2

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#### 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. 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 based upon the risk analysis of the mixture. If applicable and available, SUMI's (Safe Use Mixture Information) are attached in annex. Always use the relevant SUMI that corresponds to your identified use.

### 7.1. Precautions for safe handling

Use spark-/explosionproof appliances and lighting system. Take precautions against electrostatic charges. Keep away from naked flames/heat. Keep away from ignition sources/sparks. Gas/vapour heavier than air at 20°C. Observe strict hygiene. 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. 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. Keep only in the original container. Meet the legal requirements.

#### 7.2.2 Keep away from:

Heat sources, ignition sources, combustible materials, oxidizing agents, metals.

#### 7.2.3 Suitable packaging material:

Steel, stainless steel, synthetic material.

#### 7.2.4 Non suitable packaging material:

Aluminium, iron, copper, tin.

#### 7.3. Specific end use(s)

If applicable and available, SUMI's (Safe Use Mixture Information) are attached in annex.

## 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.

#### FU

	Time-weighted average exposure limit 8 h (Indicative occupational exposure limit value)	5000 ppm
	Time-weighted average exposure limit 8 h (Indicative occupational exposure limit value)	9000 mg/m³
· ·	Time-weighted average exposure limit 8 h (Indicative occupational exposure limit value)	1 ppm
	Time-weighted average exposure limit 8 h (Indicative occupational exposure limit value)	1.8 mg/m³

#### Belgium

Carbone (dioxyde de)	Time-weighted average exposure limit 8 h	5000 ppm (A)
	Time-weighted average exposure limit 8 h	9131 mg/m³ (A)
	Short time value	
	Short time value	54784 mg/m³ (A)
Oxyde d'éthylène	Time-weighted average exposure limit 8 h	1 ppm
	Time-weighted average exposure limit 8 h	1.8 mg/m³

La mention "A" signifie que l'agent libère un gaz ou une vapeur qui n'ont en eux-mêmes aucun effet physiologique mais peuvent diminuer le taux d'oxygène dans l'air. Lorsque le taux d'oxygène descend en dessous de 17-18 % (vol/vol) le manque d'oxygène provoque des suffocations qu'aucun symptôme préalable n'annonce

## 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
Kooldioxide	Time-weighted average exposure limit 8 h (Public occupational exposure limit value)	4919 ppm
	Time-weighted average exposure limit 8 h (Public occupational exposure limit value)	9000 mg/m³

## France

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Carbone (dioxyde de)	Time-weighted average exposure limit 8 h (VRI: Valeur réglementaire indicative)	5000 ppm
	Time-weighted average exposure limit 8 h (VRI: Valeur réglementaire indicative)	9000 mg/m³
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

#### Germany

Kohlenstoffdioxid	Time-weighted average exposure limit 8 h (TRGS 900)	5000 ppm
	Time-weighted average exposure limit 8 h (TRGS 900)	9100 mg/m <sup>3</sup>

#### UK

Carbon dioxide	Time-weighted average exposure limit 8 h (Workplace exposure limit (EH40/2005))	5000 ppm
	Time-weighted average exposure limit 8 h (Workplace exposure limit (EH40/2005))	9150 mg/m <sup>3</sup>
	Short time value (Workplace exposure limit (EH40/2005))	15000 ppm
	Short time value (Workplace exposure limit (EH40/2005))	27400 mg/m <sup>3</sup>
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/m <sup>3</sup>

## USA (TLV-ACGIH)

Carbon dioxide	Time-weighted average exposure limit 8 h (TLV - Adopted Value)	5000 ppm
	Short time value (TLV - Adopted Value)	30000 ppm
Ethylene oxide	Time-weighted average exposure limit 8 h (TLV - Adopted Value)	1 ppm

## b) National biological limit values

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

#### **USA (BEI-ACGIH)**

Ethyleen oxide (N-(2-hydroxyethyl) valine (HEV) hemoglobin adducts)	Globin: not critical	5000 pmol/g	
Ethyleen oxide (S-(2-hydroxyethyl) mercapturic acid (HEMA))	Urine: end of shift	5 μg/g creatinine	

### c) Nationale Akzeptanz- und Toleranzkonzentrationen

#### Germany

Ethylenoxid	Akzeptanzkonzentration (TRGS 910)	0.2 mg/m³ (b, e)
	Toleranzkonzentration (TRGS 910)	2 mg/m³ (ÜF: 2)
	Akzeptanzkonzentration (TRGS 910)	0.1 ppm (b, e)
	Toleranzkonzentration (TRGS 910)	1 ppm (ÜF: 2)

b, e: Akzeptanzkonzentration assoziiert mit Risiko 4:10.000

die Akzeptanzkonzentration ist assoziiert mit der endogenen Bildungsrate, eine weitere Absenkung erfolgt nicht

ÜF: Überschreitungsfaktor

#### 8.1.2 Sampling methods

2 Jamping methods			
Product name	Test	Number	
Carbon Dioxide	NIOSH	6603	
Carbon Dioxide	OSHA	ID 172	
Ethylene oxide (organic and inorganic gases by Extractive 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	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 Threshold values

## **DNEL/DMEL - Workers**

ethylene oxide

Effect level (DNEL/DMEL)	Туре	Value	Remark
DMEL	Long-term systemic effects inhalation	2 mg/m³	
DNEL	Acute systemic effects inhalation	10 mg/m <sup>3</sup>	

### **PNEC**

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#### 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 based upon the risk analysis of the mixture. If applicable and available, SUMI's (Safe Use Mixture Information) are attached in annex. Always use the relevant SUMI that corresponds to your identified use.

#### 8.2.1 Appropriate engineering controls

Use spark-/explosionproof appliances and lighting system. Take precautions against electrostatic charges. Keep away from naked flames/heat. Keep away from ignition sources/sparks. Measure the concentration in the air regularly. Work under local exhaust/ventilation.

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

Observe strict hygiene. Do not eat, drink or smoke during work.

#### a) Respiratory protection:

Full face mask with filter type A at conc. in air > exposure limit. High vapour/gas concentration: self-contained respirator.

#### b) Hand protection:

Insulated gloves.

- materials (good resistance)

Butyl rubber.

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	Medicinal odour
	Ether-like odour
Odour threshold	No data available
Colour	Colourless
Particle size	Not applicable (gas)
Explosion limits	No data available
Flammability	Extremely flammable gas.
Log Kow	Not applicable (mixture)
Dynamic viscosity	No data available
Kinematic viscosity	No data available
Melting point	No data available
Boiling point	No data available
Evaporation rate	No data available
Relative vapour density	No data available
Vapour pressure	No data available
Solubility	Ethanol ; soluble
	Ether ; soluble
Relative density	No data available
Decomposition temperature	No data available
Auto-ignition temperature	No data available
Flash point	No data available
Explosive properties	No chemical group associated with explosive properties
Oxidising properties	No chemical group associated with oxidising properties
рН	No data available

## 9.2. Other information

Critical temperature	l-10 °C - 70 °C
	F10 C-70 C

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## SECTION 10: Stability and reactivity

#### 10.1. Reactivity

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

#### 10.2. Chemical stability

Unstable on exposure to heat.

#### 10.3. Possibility of hazardous reactions

May react explosively even in the absence of air. Reacts violently with many compounds e.g.: with (strong) oxidizers: (increased) risk of fire/explosion.

#### 10.4. Conditions to avoid

#### Precautionary measures

Use spark-/explosionproof appliances and lighting system. Take precautions against electrostatic charges. Keep away from naked flames/heat. Keep away from ignition sources/sparks.

#### 10.5. Incompatible materials

Combustible materials, oxidizing agents, metals.

### 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**

#### >58% Ethylene oxide ≤87% / Carbon dioxide

No (test)data on the mixture available

Classification is based on the relevant ingredients

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

<u>ethylene oxide</u>

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.

Not classified as acute toxic in contact with skin

## Corrosion/irritation

#### >58% Ethylene oxide ≤87% / Carbon dioxide

No (test)data on the mixture available

Classification is based on the relevant ingredients

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

ethylene oxide

Route of exposure	Result	Method	Exposure time	Time point		Value determination	Remark
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.

#### Respiratory or skin sensitisation

### >58% Ethylene oxide ≤87% / Carbon dioxide

No (test)data on the mixture available

Judgement is based on the relevant ingredients

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

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#### 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 Not classified as sensitizing for inhalation

#### Specific target organ toxicity

#### >58% Ethylene oxide ≤87% / Carbon dioxide

No (test)data on the mixture available

Classification is based on the relevant ingredients

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

ethylene oxide

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

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)

#### >58% Ethylene oxide ≤87% / Carbon dioxide

No (test)data on the mixture available

ethylene oxide

Result	Method	Test substrate	Effect	Value determination
Positive without metabolic	Equivalent to OECD 471	Bacteria (S.typhimurium)		Experimental value
activation				
Positive without metabolic	Equivalent to OECD 476	Chinese hamster lung		Experimental value
activation		fibroblasts (V79)		

### Mutagenicity (in vivo)

### >58% Ethylene oxide ≤87% / Carbon dioxide

No (test)data on the mixture available

Classification is based on the relevant ingredients

ethylene oxide

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

### Conclusion

May cause genetic defects.

#### Carcinogenicity

## >58% Ethylene oxide ≤87% / Carbon dioxide

No (test)data on the mixture available

Classification is based on the relevant ingredients

ethylene oxide

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

### Conclusion

May cause cancer.

#### Reproductive toxicity

### >58% Ethylene oxide ≤87% / Carbon dioxide

No (test)data on the mixture available

Judgement is based on the relevant ingredients

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#### ethylene oxide

	Parameter	Method	Value	Exposure time	Species	Effect	- 0.	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

Toxicity to reproduction is unlikely to be significant

#### **Toxicity other effects**

>58% Ethylene oxide ≤87% / Carbon dioxide

No (test)data on the mixture available

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

>58% Ethylene oxide ≤87% / Carbon dioxide

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

>58% Ethylene oxide ≤87% / Carbon dioxide

No (test)data on the mixture available

Judgement of the mixture is based on the relevant ingredients

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	EC50	Equivalent to OECD 201	240 mg/l	96 h	Pseudokirchneri ella 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

carbon dioxide

	Parameter	Method	Value	Duration	Species		Fresh/salt water	Value determination
Acute toxicity fishes	LC50		35 mg/l	96 h	Salmo gairdneri			Literature study; Lethal

#### Conclusion

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

## 12.2. Persistence and degradability

>58% Ethylene oxide ≤87% / Carbon dioxide

Half-life soil (t1/2 soil)

Method	Value	Primary degradation/mineralisation	Value determination
			Not applicable (gas)

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#### 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		Primary degradation/mineralisation	Value determination
	Not applicable		

#### carbon dioxide

Half-life soil (t1/2 soil)

Method		Primary degradation/mineralisation	Value determination
	Not applicable (gas)		

#### Conclusion

Does not contain any not readily biodegradable component(s)

## 12.3. Bioaccumulative potential

>58% Ethylene oxide ≤87% / Carbon dioxide

#### Log Kow

Method	Remark	Value	Temperature	Value determination
	Not applicable (mixture)			

#### ethylene oxide

#### Log Kow

_	0						
	Method	Remark	Value	Temperature	Value determination		
			-0.3	25 °C			

#### carbon dioxide

#### Log Kow

Method	Remark	Value	Temperature	Value determination
		0.83		Experimental value

## Conclusion

Does not contain bioaccumulative component(s)

### 12.4. Mobility in soil

ethylene oxide

#### (log) Koc

1 - 6/					
	Parameter	Method	Value	Value determination	
	log Koc	SRC PCKOCWIN v1.66	0.157	OSAR	

## Volatility (Henry's Law constant H)

Value	Method	Temperature	Remark	Value determination
12.159 Pa.m³/mol		25 °C		QSAR

#### Percent distribution

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

## carbon dioxide

## Volatility (Henry's Law constant H)

Value	Method	Temperature	Remark	Value determination
0.0152 atm m³/mol		25 °C		Estimated value

### Conclusion

Not applicable (gas)

### 12.5. Results of PBT and vPvB assessment

Does not contain component(s) that meet(s) the criteria of PBT and/or vPvB as listed in Annex XIII of Regulation (EC) No 1907/2006.

### 12.6. Other adverse effects

>58% Ethylene oxide ≤87% / Carbon dioxide

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

Contains component(s) included in the list of substances which may contribute to the greenhouse effect (IPCC)

None of the known components is 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)

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#### carbon dioxide

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

Included in the list of substances which may contribute to the greenhouse effect (IPCC)

## <u>SECTION 13: Disposal considerations</u>

The information in this section is based upon the risk analysis of the mixture. If applicable and available, SUMI's (Safe Use Mixture Information) are attached in annex. Always use the relevant SUMI that corresponds 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 and Regulation (EU) No 2017/997.

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**

Revision number: 0400

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	1041
14.2. UN proper shipping name	
Proper shipping name	Ethylene oxide and carbon dioxide mixture
14.3. Transport hazard class(es)	
Hazard identification number	239
Class	2
Classification code	2F
14.4. Packing group	
Packing group	
Labels	2.1
14.5. Environmental hazards	
Environmentally hazardous substance mark	no
14.6. Special precautions for user	
Special provisions	662
Limited quantities	none.
ail (RID)	
14.1. UN number	
UN number	1041
14.2. UN proper shipping name	
Proper shipping name	Ethylene oxide and carbon dioxide mixture
14.3. Transport hazard class(es)	,
Hazard identification number	239
Class	2
Classification code	2F
14.4. Packing group	-
Packing group	
Labels	2.1 (+13)
14.5. Environmental hazards	
Environmentally hazardous substance mark	no
14.6. Special precautions for user	
Special provisions	662
Limited quantities	none.
nland waterways (ADN)	<u> </u>
14.1. UN number	
UN number	1041
14.2. UN proper shipping name	11041
Proper shipping name	Ethylene oxide and carbon dioxide mixture
14.3. Transport hazard class(es)	Entryiene onide and carbon dionide miniture
Class	2
Ciuss	

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Classification code	2F	
14.4. Packing group		
Packing group		
Labels	2.1	
14.5. Environmental hazards	-	
Environmentally hazardous substance mark	no	
14.6. Special precautions for user	·	
Special provisions	662	
Limited quantities	none	
Sea (IMDG/IMSBC)		
14.1. UN number		
UN number	1041	
14.2. UN proper shipping name		
Proper shipping name	ethylene oxide and carbon dioxide mixture	
14.3. Transport hazard class(es)		
Class	2.1	
14.4. Packing group		
Packing group		
Labels	2.1	
14. <u>5</u> . Environmental hazards		
Marine pollutant	-	
Environmentally hazardous substance mark	no	
14.6. Special precautions for user		
Special provisions		
Limited quantities	none.	
14.7. Transport in bulk according to Annex II of Marpol and th	e IBC Code	
Annex II of MARPOL 73/78	Not applicable	
Air (ICAO-TI/IATA-DGR)		
14.1. UN number		
UN number	1041	
14.2. UN proper shipping name	<del> </del>	
Proper shipping name	Ethylene oxide and carbon dioxide mixture	
14.3. Transport hazard class(es)		
Class	2.1	
14.4. Packing group	<del> </del>	
Packing group		
Labels	2.1	

## SECTION 15: Regulatory information

Environmentally hazardous substance mark

Limited quantities: maximum net quantity per packaging

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

VOC content Directive 2010/75/EU

Labels

14.<u>5. Environmental hazards</u>

14.<u>6. Special precautions for user</u> Special provisions

Passenger and cargo transport

VOC content	Remark
58 % - 87 %	

no

Α1

Indicative occupational exposure limit values (Directive 98/24/EC, 2000/39/EC and 2009/161/EU)

Product name	Skin resorption
Ethylene oxide	Skin

## **REACH Annex XVII - Restriction**

Revision number: 0400

Contains component(s) 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	Regulation (EC) No 1272/2008 and are listed in Appendix 1 or Appendix 2, respectively.	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,  — 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

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International CEO Not 1272/2008. or			
mutagen category 14 or 18 in Part 3 of Annex I 10 to Regulation (EC) to 1277/2008 and are listed in Appendix 3 or Appendix 4, respectively.  I shall not be placed on the market, or used, as 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, ethe relevant ageneric concentration limit specified in Part 3 of Annex VI to Regulation (EC) No 1272/2008, or, ethe relevant ageneric concentration limit specified in Part 3 of Annex VI to Regulation (EC) No 1272/2008, or, ethe relevant ageneric concentration limit specified in Part 3 of Annex VI to Regulation (EC) No 1272/2008, or, ethe relevant ageneric concentration limit specified in Part 3 of Annex VI to Regulation (EC) No 1272/2008, or, ethe relevant ageneric concentration limit specified in Part 3 of Annex VI to Regulation (EC) No 1272/2008, or, ethe relevant ageneric concentration limit specified in Part 3 of Annex VI to Regulation (EC) No 1272/2008, or, ether relevant ageneric concentration limit specified in Part 3 of Annex VI to Regulation (EC) No 1272/2008, or, ether relevant ageneric concentration limit specified in Part 3 of Annex VI to Regulation (EC) No 1272/2008, or, ether relevant ageneric concentration limit specified in Part 3 of Annex VI to Regulation (EC) No 1272/2008, or, ether relevant ageneric concentration limit specified in Part 3 of Annex VI to (a) medicinal or veterinary products as defined by Directive 98/70/EC, or, ether of the pack agenery of the products the defined by Directive 98/70/EC, ether of the pack agenery and indelibly as follows: "Restricted to products the pack give state of the products and indelibly as follows: "Restricted to products the pack agenery and products the pack agenery and products therefore as few products as defined by Directive 98/70/EC, or, ether sold of the products therefore as the pack of the	· ethylene oxide	Substances which are classified as germ cell	— the relevant generic concentration limit specified in Part 3 of Annex I of 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 way of 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 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 Regulation (EC) No 1272/2008; (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.
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 or pyrophoric solids category 1, regardless of whether they appear in Part 3 of Annex VI to that Regulation or not.  - 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 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:  "For professional users only".		mutagen category 1A or 1B in Part 3 of Annex VI to Regulation (EC) No 1272/2008 and are listed in Appendix 3 or Appendix 4,	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 generic concentration limit specified in Part 3 of Annex I of 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 way of 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 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 Regulation (EC) No 1272/2008; (e) the substances listed in Appendix 11, column 1, for the applications or uses listed in Appendix 11, column 2 of Appendix 11, the
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.	· 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	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 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: "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

Additional classification
Oxyde d'éthylène; 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 et reprotoxiques au travail.

## **National legislation The Netherlands**

>58% Ethylene oxide ≤87% / Carbon dioxide

	- (a)  -
lWaterbezwaarliikheid	IZ (2): Algemene Beoordelingsmethodiek (ABM)
	IZ (2): Algemene Beoordelingsmethodiek (ABM)
[vvater bezwaarrijkrieru	2 (2), Algeriane beoordelingsmethodick (Abivi)

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#### ethylene oxide

SZW - Lijst van	Ethyleenoxide; Listed in SZW-list of carcinogenic substances
kankerverwekkende stoffen	
SZW - Lijst van mutagene	Ethyleenoxide; Listed in SZW-list of mutagenic substances
stoffen	
SZW - Lijst van voor de	Ethyleenoxide; 1B; May damage fertility.
voortplanting giftige stoffen	
(vruchtbaarheid)	

#### **National legislation France**

>58% Ethylene oxide ≤87% / Carbon dioxide

No data available

ethylene oxide

Catégorie cancérogène	Oxyde d'éthylène; C1B
Catégorie mutagène	Oxyde d'éthylène; M1B

## National legislation Germany >58% Ethylene oxide ≤87% / Carbon dioxide

WGK	3; Verordnung über Anlagen zum Umgang mit wassergefährdenden Stoffen (AwSV) - 18. April 2017		
ethylene oxide			
TA-Luft	5.2.7.1.1/		

## **National legislation United Kingdom**

>58% Ethylene oxide ≤87% / Carbon dioxide

No data available ethylene oxide

Ethylene oxide; Carc Carcinogen

Other relevant data ≥58% Ethylene oxide ≤87% / Carbon dioxide

No data available

ethylene oxide

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

#### 15.2. Chemical safety assessment

No chemical safety assessment has been conducted for the mixture.

ethylene oxide

A chemical safety assessment has been performed.

## SECTION 16: Other information

## Full text of any H-statements referred to under heading 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 organs (central nervous system) through prolonged or repeated exposure.

(\*) INTERNAL CLASSIFICATION BY BIG

ADI Acceptable daily intake

AOEL Acceptable operator exposure level

CLP (EU-GHS) Classification, labelling and packaging (Globally Harmonised System in Europe)

DMEL **Derived Minimal Effect Level** DNEL Derived No Effect Level EC50 Effect Concentration 50 %

ErC50 EC50 in terms of reduction of growth rate

LC50 Lethal Concentration 50 %

LD50 Lethal Dose 50 %

NOAEL No Observed Adverse Effect Level No Observed Effect Concentration NOEC

OECD Organisation for Economic Co-operation and Development

PBT Persistent, Bioaccumulative & Toxic PNFC Predicted No Effect Concentration STP **Sludge Treatment Process** 

very Persistent & very Bioaccumulative

#### Specific concentration limits CLP

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

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. 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.

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