

SAFETY DATA SHEET

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

>9% Ethylene oxide ≤58% / Carbon dioxide

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

1.1. Product identifier

Product name : >9% Ethylene oxide ≤58% / Carbon dioxide

Synonyms : carbon dioxide/ethylene oxide, mixtures, 9%<conc ethylene oxide≤58%; ethylene oxide/carbon dioxide, mixtures, 9%

<conc ethylene oxide≤58%

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

+32 2 252 17 51

info.grimbergen@balchem.com

Manufacturer of the product

BALCHEM NV

Westvaartdijk 85

B-1850 Grimbergen Belgium

1 +32 2 251 60 87

(iii) +32 2 252 17 51

info.grimbergen@balchem.com

1.4. Emergency telephone number

 ${\it 24h/24h} \ (Telephone \ advice: English, French, German, \ Dutch):$

+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	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.
STOT RE	category 1	H372: Causes damage to organs (central nervous system) through prolonged or repeated exposure.
Acute Tox.	category 4	H332: Harmful if inhaled.
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.
STOT SE	category 3	H335: May cause respiratory irritation.

2.2. Label elements







 $\label{lem:continuous} \textbf{Created by: Brandweerinformatiecentrum voor gevaarlijke stoffen vzw (BIG)}$

Technische Schoolstraat 43 A, B-2440 Geel

http://www.big.be

Revision number: 0000

© BIG vzw

Publication date: 2019-03-14

Reference number: 5120-5121-5123-5125-5130-5135-

519

Product number: 61509 1 / 15



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.

May cause cancer. H350

H340 May cause genetic defects.

Causes damage to organs through prolonged or repeated exposure. H372

H302 + H332 Harmful if swallowed or if inhaled.

Causes skin irritation. H315 Causes serious eye irritation. H319 May cause respiratory irritation. H335

P-statements

Keep away from heat, hot surfaces, sparks, open flames and other ignition sources. No smoking. P210

P280 Wear protective gloves, protective clothing and eye protection/face protection.

Do not breathe gas. P260

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.

IF exposed or concerned: Get medical advice/attention. P308 + P313

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	42% <c≤91%< td=""><td>Press. Gas - Liquefied gas; H280</td><td>(1)(2)(I)</td><td>Constituent</td></c≤91%<>	Press. Gas - Liquefied gas; H280	(1)(2)(I)	Constituent

⁽¹⁾ For H-statements in full: see heading 16

Publication date: 2019-03-14

Reference number: 5120-5121-5123-5125-5130-5135-

Revision number: 0000 Product number: 61509 2/15

⁽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

⁽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. Respiratory problems: 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

Publication date: 2019-03-14

Reference number: 5120-5121-5123-5125-5130-5135-

5195

Product number: 61509 3 / 15

Revision number: 0000 Product number: 61509

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. 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.

EU

Carbon dioxide	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
Ethylene oxide	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	30000 ppm (A)
	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

The Hetherlands	
Ethyleenoxide	Time-weighted average exposure limit 8 h (Public occupational exposure 0.46 ppm
	limit value)
	Time-weighted average exposure limit 8 h (Public occupational exposure 0.84 mg/m³
	limit value)
Kooldioxide	Time-weighted average exposure limit 8 h (Public occupational exposure 4919 ppm
	limit value)
	Time-weighted average exposure limit 8 h (Public occupational exposure 9000 mg/m³
	limit value)

Publication date: 2019-03-14

Reference number: 5120-5121-5123-5125-5130-5135-

5195

Revision number: 0000 Product number: 61509 4 / 15

France

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 ³

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 ³
	Short time value (Workplace exposure limit (EH40/2005))	15000 ppm
	Short time value (Workplace exposure limit (EH40/2005))	27400 mg/m ³
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 ³

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

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

$\bf 8.1.3$ 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

<u>DNEL/DMEL - Workers</u> ethylene oxide

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

PNEC

Publication date: 2019-03-14

Reference number: 5120-5121-5123-5125-5130-5135-

Revision number: 0000 Product number: 61509 5 / 15

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

Revision number: 0000

Critical tomporature	I-10 °C - 70 °C	!
icilical terriperature	[-10 C-70 C	

Publication date: 2019-03-14

Reference number: 5120-5121-5123-5125-5130-5135-

5195

Product number: 61509 6 / 15

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

>9% Ethylene oxide ≤58% / 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

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

Harmful if swallowed.

Harmful if inhaled.

Not classified as acute toxic in contact with skin

Corrosion/irritation

>9% Ethylene oxide ≤58% / 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	Species	Value	Remark
						determination	
Eye	Irritating	Equivalent to		24; 48 hours	Rabbit	Experimental	Aqueous solution
		OECD 405				value	
Skin	Irritating		1 minutes - 60		Rabbit	Experimental	Aqueous solution
			minutes			value	
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

>9% Ethylene oxide ≤58% / Carbon dioxide

No (test)data on the mixture available

Judgement is based on the relevant ingredients

Publication date: 2019-03-14

Reference number: 5120-5121-5123-5125-5130-5135-

Product number: 61509 7 / 15

Revision number: 0000

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

>9% Ethylene oxide ≤58% / 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 exposure	Parameter	Method	Value	Organ	Effect	Exposure time		Value determination
Dermal								Data waiving
Inhalation (vapours)	NOAEC	Equivalent to OECD 453	10 ppm	Central nervous system		104 weeks (6h / day, 5 days / week)	Rat (male / female)	Experimental value
Inhalation (vapours)	NOAEC	Subchronic toxicity test	10 ppm			10 weeks (6h / day, 5 days / week) - 11 weeks (6h / day, 5 days / week)	Mouse (male / female)	Experimental value

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)

>9% Ethylene oxide ≤58% / 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)

>9% Ethylene oxide ≤58% / 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

>9% Ethylene oxide ≤58% / 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

>9% Ethylene oxide ≤58% / Carbon dioxide

No (test)data on the mixture available

Judgement is based on the relevant ingredients

Publication date: 2019-03-14

Reference number: 5120-5121-5123-5125-5130-5135-

5195

Product number: 61509 8 / 15

Revision number: 0000 Product nur

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

>9% Ethylene oxide ≤58% / Carbon dioxide

No (test)data on the mixture available

Chronic effects from short and long-term exposure

>9% Ethylene oxide ≤58% / 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

>9% Ethylene oxide ≤58% / 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

>9% Ethylene oxide ≤58% / Carbon dioxide

Half-life soil (t1/2 soil)

Revision number: 0000

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

Publication date: 2019-03-14

Reference number: 5120-5121-5123-5125-5130-5135-

5195

Product number: 61509 9 / 15

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 ³	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

>9% Ethylene oxide ≤58% / 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

•	- 0,			
	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

>9% Ethylene oxide ≤58% / 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)

Publication date: 2019-03-14

 $Reference\ number:\ 5120-5121-5123-5125-5130-5135-$

5195

Product number: 61509 10 / 15

Revision number: 0000

carbon dioxide

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

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

SECTION 13: Disposal considerations

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: 0000

Waste material code packaging (Directive 2008/98/EC).

15 01 10* (packaging containing residues of or contaminated by dangerous substances).

SECTION 14: Transport information

4.1. UN number	
UN number	1041
4.2. UN proper shipping name	·
Proper shipping name	Ethylene oxide and carbon dioxide mixture
4.3. Transport hazard class(es)	. ,
Hazard identification number	239
Class	2
Classification code	2F
4.4. Packing group	
Packing group	
Labels	2.1
4. <u>5. Environmental hazards</u>	
Environmentally hazardous substance mark	no
4.6. Special precautions for user	
Special provisions	662
Limited quantities	none.
4.1. UN number UN number	1041
4.2. UN proper shipping name	
Proper shipping name	Ethylene oxide and carbon dioxide mixture
4.3. Transport hazard class(es)	
Hazard identification number	239
Class	2
Classification code	2F
4.4. Packing group	
Packing group	
Labels	2.1 (+13)
4.5. Environmental hazards	
Environmentally hazardous substance mark	no
4.6. Special precautions for user	lcc2
Special provisions	662
Limited quantities	none.
nd waterways (ADN)	
4.1. UN number	1044
UN number	1041
4.2. UN proper shipping name	
Proper shipping name	Ethylene oxide and carbon dioxide mixture

Publication date: 2019-03-14

Reference number: 5120-5121-5123-5125-5130-5135-

5195

Product number: 61509 11 / 15

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
9 % - 58 %	

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

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	category 1A or 1B in Part 3 of Annex VI to 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

Publication date: 2019-03-14

Reference number: 5120-5121-5123-5125-5130-5135-

5195

Product number: 61509 12 / 15

Revision number: 0000

· ethylene oxide	Substances which are classified as germ cell 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, respectively.	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 mixture 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. 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 Regulation (EC) No 1272/2008, or, — the relevant specific concentration limit specified 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 labellin
· 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.	derogation 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 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 market unless they conform to the requirements indicated.
National legislation Belgium >9% Ethylene oxide ≤58% / Carb No data available	on dioxide	· · · · · · · · · · · · · · · · · · ·
ethylene oxide		
Additional classification	1 · · · · · · · · · · · · · · · · · · ·	gnifie que l'agent en question relève du champ d'application de l'arrêté royal du 2 on des travailleurs contre les risques liés à l'exposition à des agents cancérigènes et

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

>9% Ethylene oxide ≤58% / Carbon dioxide

Waterbezwaarlijkheid Z (2); Algemene Beoordelingsmethodiek (ABM)

Publication date: 2019-03-14

Reference number: 5120-5121-5123-5125-5130-5135-

5195

Product number: 61509 13 / 15

ethylene oxide

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

National legislation France

>9% Ethylene oxide ≤58% / Carbon dioxide

No data available

ethylene oxide

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

National legislation Germany >9% Ethylene oxide ≤58% / 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

>9% Ethylene oxide ≤58% / Carbon dioxide

No data available

ethylene oxide

Carcinogen	Ethylene oxide; Carc	
------------	----------------------	--

Other relevant data

>9% Ethylene oxide ≤58% / 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.

H332 Harmful if inhaled.

H335 May cause respiratory irritation.

H340 May cause genetic defects.

H350 May cause cancer.

Revision number: 0000

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 %

FrC50 EC50 in terms of reduction of growth rate

LC50 Lethal Concentration 50 %

LD50 Lethal Dose 50 %

NOAEL No Observed Adverse Effect Level NOEC No Observed Effect Concentration

OECD Organisation for Economic Co-operation and Development

PRT Persistent, Bioaccumulative & Toxic **PNEC** Predicted No Effect Concentration STP **Sludge Treatment Process**

vPvB very Persistent & very Bioaccumulative

Publication date: 2019-03-14

Reference number: 5120-5121-5123-5125-5130-5135-

Product number: 61509 14 / 15

Specific concentration limits CLP						
-	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.

Publication date: 2019-03-14

Reference number: 5120-5121-5123-5125-5130-5135-

5195

Revision number: 0000

Product number: 61509 15 / 15