

Ethylenoxid

Print date 21.12.2022
Revision date 21.12.2022
Version 21.0 (en)
replaces version of 02.08.2021 (20.0)

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

1.1 Product identifier

Trade name/designation Ethylene oxide
Art-Nr(n). 1400-1402, 70140
Substance name ethylene oxide
INDEX No. 603-023-00-X
EC No. 200-849-9
REACH No. 01-2119432402-53
CAS No. 75-21-8

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

Sector of uses [SU]

SU3 Industrial uses
SU8 Manufacture of bulk, large scale chemicals (including petroleum products)
SU9 Manufacture of fine chemicals
SU22 Professional uses: Public domain (administration, education, entertainment, services, craftsmen)

Process categories [PROC]

PROC1 Chemical production or refinery in closed process without likelihood of exposure or processes with equivalent containment conditions.
PROC2 Chemical production or refinery in closed continuous process with occasional controlled exposure or processes with equivalent containment conditions
PROC3 Manufacture or formulation in the chemical industry in closed batch processes with occasional controlled exposure or processes with equivalent containment condition
PROC8b Transfer of substance or mixture (charging and discharging) at dedicated facilities
PROC9 Transfer of substance or mixture into small containers (dedicated filling line, including weighing)
PROC15 Use as laboratory reagent

Environmental release categories [ERC]

ERC1 Manufacture of the substance
ERC6a Use of intermediate
ERC6c Use of monomer in polymerisation processes at industrial site (inclusion or not into/onto article)

* **Use of the substance/mixture**

Biocidal product.

1.3 Details of the supplier of the safety data sheet

Supplier

GHC Gerling, Holz & Co. Handels GmbH
Ruhrstraße 113
D-22761 Hamburg
Telephone +49 40 853 123 0
E-mail hamburg@ghc.de
Website www.ghc.com

Department responsible for information:
GHC Gerling, Holz & Co. Handels GmbH
Telephone +49 40 853 123 0

E-mail (competent person):
msds@ghc.de

* **1.4 Emergency telephone number**

EN: Poison Information Center Mainz +49 6131 19240

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*** SECTION 2: Hazards identification***** 2.1 Classification of the substance or mixture**

Classification according to Regulation (EC) No 1272/2008 [CLP]	Classification procedure
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Chem. Unst. Gas A, H220

Chem. Unst. Gas A, H230

Press. Gas (Liq.), H280

Acute Tox. 3, H301

Acute Tox. 3, H331

Skin Corr. 1, H314

Eye Dam. 1, H318

Muta. 1B, H340

Carc. 1B, H350i

Repr. 1B, H360Fd

STOT SE 3, H335

STOT SE 3, H336

STOT RE 1, H372

Hazard statements for physical hazards

H220 Extremely flammable gas.

H230 May react explosively even in the absence of air.

H280 Contains gas under pressure; may explode if heated.

Hazard statements for health hazards

H301 Toxic if swallowed.

H314 Causes severe skin burns and eye damage.

H318 Causes serious eye damage.

H331 Toxic if inhaled.

H335 May cause respiratory irritation.

H336 May cause drowsiness or dizziness.

H340 May cause genetic defects.

H350i May cause cancer by inhalation.

H360Fd May damage fertility. Suspected of damaging the unborn child.

H372 Causes damage to the nervous system and to blood forming organs through prolonged or repeated exposure by inhalation.

Additional information

List substance (Regulation (EC) No. 1272/2008, Annex VI, part 3)

*** 2.2 Label elements***** Labelling according to Regulation (EC) No. 1272/2008 [CLP]****Hazard pictograms**

GHS02



GHS05



GHS06



GHS08

Signal word

Danger

Hazard statements

H220 Extremely flammable gas.

H230 May react explosively even in the absence of air.

H280 Contains gas under pressure; may explode if heated.

H301 Toxic if swallowed.

H314 Causes severe skin burns and eye damage.

H331 Toxic if inhaled.

H335 May cause respiratory irritation.

H336 May cause drowsiness or dizziness.

H340 May cause genetic defects.

H350i May cause cancer by inhalation.

H360Fd May damage fertility. Suspected of damaging the unborn child.

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H372 Causes damage to the nervous system and to blood forming organs through prolonged or repeated exposure by inhalation.

- * **Precautionary statements**
 P210 Keep away from heat, hot surfaces, sparks, open flames and other ignition sources. No smoking.
 P260 Do not inhale gas/vapours.
 P301 + P310 IF SWALLOWED: Immediately call a POISON CENTER/doctor.
 P303 + P361 + P353 IF ON SKIN (or hair): Take off immediately all contaminated clothing. Rinse skin with water [or shower].
 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.
 P403 + P233 Store in a well-ventilated place. Keep container tightly closed.
 P405 Store locked up.
- * **Supplemental hazard information**
 EIGA0803 Restricted to professional users.
 Please return container with residual pressure.
 Withdrawal out of the liquid phase only.
- * **2.3 Other hazards**
- * **Adverse human health effects and symptoms**
 The product is skin resorptive.
 May form explosive mixtures with air.
 Gas/vapour heavier than air. May accumulate in confined spaces, particularly at or below ground level.
 Receptacle under pressure.
- * **Other adverse effects**
 The substance/mixture does not contain components considered to have endocrine disrupting properties according to REACH Article 57(f) or Commission Delegated regulation (EU) 2017/2100 or Commission Regulation (EU) 2018/605 at levels of 0.1% or higher.
- * **Results of PBT and vPvB assessment**
 This substance does not meet the PBT/vPvB criteria of REACH, Annex XIII.

SECTION 3: Composition / information on ingredients**3.1 Substances**

Substance name	ethylene oxide
INDEX No.	603-023-00-X
EC No.	200-849-9
REACH No.	01-2119432402-53
CAS No.	75-21-8
Specific concentration limit (SCL)	Acute Tox. 3;H301: ATE = 100 mg/kg Acute Tox. 3;H331: ATE = 700 ppm

Additional information
 Content: >= 99,9 %

3.2 Mixtures

not applicable

* **SECTION 4: First aid measures*** **4.1 Description of first aid measures**

- * **General information**
 Remove contaminated, saturated clothing immediately.
 First aider: Pay attention to self-protection!
 Call a physician immediately.
 Symptoms may develop several hours following exposure; medical observation therefore necessary for at least 48 hours.

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- * **Following inhalation**
Remove casualty to fresh air and keep warm and at rest.
In the event of pulmonary irritation treat initially with corticoid spray, e.g. Ventolair- or Pulmicort- metered-dose aerosol (Ventolair and Pulmicort are registered trademarks).
In case of respiratory standstill give artificial respiration by respiratory bag (Ambu bag) or respirator. Obtain medical assistance.
- * **Following skin contact**
In case of skin contact rinse with warm water.
In case of frostbite rinse with lukewarm (not hot) water for at least 15 minutes. Do not remove clothing frozen to the skin. Thaw with lukewarm water. Apply a sterile dressing. Obtain medical assistance.
- After eye contact**
Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing. Obtain medical assistance.
- Following ingestion**
Do NOT induce vomiting.
Rinse mouth immediately and drink plenty of water.
- * **4.2 Most important symptoms and effects, both acute and delayed**
- * **Symptoms**
Dyspnoea
Depression of central nervous system
Vomiting
Redness / blebs on the skin.
- Effects**
Risk of bullous dermatitis on exposure to vapors.
Pulmonary oedema
- 4.3 Indication of any immediate medical attention and special treatment needed**
- Notes for the doctor**
Treat symptomatically.
Pulmonary oedema prophylaxis.
- * **SECTION 5: Firefighting measures**
- * **5.1 Extinguishing media**
- * **Suitable extinguishing media**
Extinguishing powder
alcohol resistant foam
Water spray jet
- Unsuitable extinguishing media**
Full water jet
Carbon dioxide (CO₂)
- * **5.2 Special hazards arising from the substance or mixture**
- * **Hazardous combustion products**
In case of fire formation of dangerous gases possible.
Carbon monoxide
Carbon dioxide (CO₂)
- * **5.3 Advice for firefighters**
- * **Special protective equipment for firefighters**
Wear a self-contained breathing apparatus and chemical protective clothing.
- * **Additional information**
If possible, shut off gas valves and move containers to a safe location.
Use water spray jet to protect personnel and to cool endangered containers.
Exposure to fire may cause rupture / explosion of the containers.
Do not extinguish a leaking gas flame unless absolutely necessary. Spontaneous/explosive re-ignition may occur. Extinguish any other fire.
Fire residues and contaminated firefighting water must be disposed of in accordance with the local regulations.

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* **SECTION 6: Accidental release measures**

* **6.1 Personal precautions, protective equipment and emergency procedures**

- * **For non-emergency personnel**
Use personal protection equipment.
Leave the danger area.
Keep people away and stay on the upwind side.

- * **For emergency responders**
Personal protection by wearing close-fitting protective clothing and breathing apparatus.
Pay attention to extension of gas especially at ground (heavier than air) and in direction of the wind.
Eliminate all ignition sources if safe to do so.
Remove persons to safety.

* **6.2 Environmental precautions**

If possible, stop flow of product.
Do not allow to enter into soil/subsoil.
Do not allow to enter into surface water or drains.

* **6.3 Methods and material for containment and cleaning up**

- * **For containment**
If necessary, secure leaky pressure receptacles using a salvage container.
Prevent the liquid from spreading over a wide area (set up barriers, cover sewage systems).
Limit expansion of the gas (water spray jet).

- * **For cleaning up**
Leave to vapourize.
Provide adequate ventilation.

6.4 Reference to other sections

Disposal: see section 13
Personal protection equipment: see section 8

* **SECTION 7: Handling and storage**

* **7.1 Precautions for safe handling**

- * **Protective measures**
Use only in well-ventilated areas.
Transfer and handle product only in closed systems.
Usual measures for fire prevention.
Containers' temperature should not be increased above 50 °C.
The working pressure in the receptacle must not exceed the saturation vapour pressure of the pure product resulting at a temperature of 50 °C.
Prevent cylinders from falling over.
Take precautionary measures against static discharges. Ground barrels and installations. Use only antistatically equipped (spark-free) tools.
Use explosion-proof machinery, apparatus, ventilation facilities, tools etc.
Ensure valve protection device is correctly fitted.
Ensure valve outlet cap nut or plug (where provided) is correctly fitted.
Open valve slowly to avoid pressure shock.
Do not allow backflow into the container.
Entering of water into the container must be prevented.
No water to valves, flanges and other fittings.
Purging of pipes and valves with inert gases - to avoid: water, solvents.

Advices on general occupational hygiene

When using do not eat, drink, smoke, sniff.
Wash hands before breaks and after work.
Remove contaminated clothing and protective equipment before entering eating areas.

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* **7.2 Conditions for safe storage, including any incompatibilities**

- * **Requirements for storage rooms and vessels**
 All regulations and local requirements for the storage of containers have to be respected.
 Keep container tightly closed and in a well-ventilated place.
 Containers' temperature should not be increased above 50 °C.
 Prevent cylinders from falling over.
 Only use containers specifically approved for the substance/product.
 Information on suitable materials for receptacles and valves see ISO 11114.

Storage class

2A Gases (except aerosol dispensers and lighters)

- * **Materials to avoid**
 Do not store together with explosives.
 Do not store together with flammable liquids.
 Do not store together with flammable solids.
 Do not store together with pyrophoric and self-heating substances.
 Do not store together with oxidizing liquids or oxidizing solids.
 Do not store together with toxic liquids or toxic solids.
 Do not store together with infectious substances.
 Do not store together with radioactive material.
 Do not store together with food or feed.

- * **Further information on storage conditions**
 Recommended storage temperature: =< 10 °C.
 Store product under (gas):
 Nitrogen

* **7.3 Specific end use(s)**

- * **Recommendation**
 Exposure scenarios (ES) see annex to this safety data sheet.
 Use as a biocidal product: Used for disinfection of surfaces, materials, equipment and furniture which are not used for direct contact with food or feeding stuffs. Read attached instructions before use. PCS No. 100681.

* **SECTION 8: Exposure controls/personal protection*** **8.1 Control parameters*** **Occupational exposure limit values**

CAS No.	EC No.	Substance name	occupational exposure limit value
75-21-8	200-849-9	Ethylene oxide	1 [ml/m ³ (ppm)] 1,8 [mg/m ³] (IE)

* **DNEL worker**

CAS No.	Substance name	DNEL value	DNEL type	Remark
75-21-8	ethylene oxide	1.8 mg/m ³	long-term inhalative (local)	, Carcinogenicity.
75-21-8	ethylene oxide	1.8 mg/m ³	long-term inhalative (systemic)	, Carcinogenicity.
75-21-8	ethylene oxide	10 mg/m ³	acute inhalative (systemic)	Assessment factor 10, Neurotoxizität.

* **PNEC**

CAS No.	Substance name	PNEC Value	PNEC type	Remark
75-21-8	ethylene oxide	0.008 mg/L	aquatic, marine water	Assessment factor 10000, assessment factor.
75-21-8	ethylene oxide	0.017 mg/kg	soil	
75-21-8	ethylene oxide	0.033 mg/kg	sediment, marine water	
75-21-8	ethylene oxide	0.084 mg/L	aquatic, freshwater	Assessment factor 1000, assessment factor.
75-21-8	ethylene oxide	0.329 mg/kg	sediment, freshwater	
75-21-8	ethylene oxide	0.84 mg/kg	aquatic, intermittent release	Assessment factor 100, assessment factor.

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CAS No.	Substance name	PNEC Value	PNEC type	Remark
75-21-8	ethylene oxide	13 mg/L	sewage treatment plant (STP)	Assessment factor 10, assessment factor.

*** 8.2 Exposure controls****Appropriate engineering controls****Technical measures to prevent exposure**

Transfer and handle only in enclosed systems.

Personal protection equipment**Eye/face protection**

Protective goggles according to EN 166, in case of increased risk add protective face shield.

Hand protection

Safety gloves according to EN 374:

Glove material specification [make/type, thickness, permeation time/life]: IIR, >= 0,7 mm, > 30 min

Body protection:

Safety shoes with steel toecap.

Body covering work clothing or chemical resistant suit at increased risk.

Respiratory protection

Keep self contained breathing apparatus readily available for emergency use.

Respiratory protection necessary at:

high concentrations

Suitable respiratory protection apparatus:

Short term: filter apparatus, filter AX

Respiratory protection complying with EN 137.

In case of rescue and maintenance activities in storage containers use environment-independent breathing apparatus because of risk of suffocation due to displacement of oxygen.

*** Environmental exposure controls***** Remark**

Prevent release to the environment.

*** SECTION 9: Physical and chemical properties***** 9.1 Information on basic physical and chemical properties****Physical state**

Gaseous / liquefied under pressure.

Colour

colourless

Odour

like:

Ether

Safety relevant basis data

	Value	Method	Source, Remark
Odour threshold:	260 ppm		
Melting point/freezing point			not applicable
Boiling point or initial boiling point and boiling range	10.4 °C pressure 1013 hPa		
flammability			flammable
Lower and upper explosion limit	Upper explosion limit 100 Vol-%		
Lower and upper explosion limit	Lower explosion limit 2.6 Vol-%		
Flash point			not applicable
Auto-ignition temperature	435 °C		

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	Value	Method	Source, Remark
Decomposition temperature	approx. 570 °C		
pH			not applicable
Viscosity			not applicable
Solubility(ies)	Water solubility		easily soluble
Partition coefficient n-octanol/water (log value)	-0.3 (25°C)		
Vapour pressure	1451 hPa (20°C)		
Density and/or relative density			not applicable
Relative vapour density	1.56		air = 1
particle characteristics			not applicable

*** 9.2 Other information***** Information with regard to physical hazard classes***** Gases under pressure****Safety characteristics**

	Value	Method, Result	Source, Remark
Critical temperature	195.8 °C		

*** Other information**

Vapours are heavier than air.

*** SECTION 10: Stability and reactivity****10.1 Reactivity**

See section "Possibility of hazardous reactions".

*** 10.2 Chemical stability**

Hydrolyses

*** 10.3 Possibility of hazardous reactions**

Risk of polymerisation.
 Reactions with numerous chemical compounds.
 Reactions with light metals.
 Reactions with alkali metals.
 Reactions with amines.

*** 10.4 Conditions to avoid**

Light
 Heat sources / heat - risk of bursting.
 Water / moisture.
 Ignition sources, open flames, glowing metal surfaces, etc.

*** 10.5 Incompatible materials**

Air
 Oxygen
 Oxidising agent
 Alcohols
 Chlorine

*** 10.6 Hazardous decomposition products**

When handled and stored appropriately, no dangerous decomposition products are known.

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*** SECTION 11: Toxicological information****11.1 Information on hazard classes as defined in Regulation (EC) No 1272/2008***** Acute toxicity***** Animal data**

	Effective dose	Method, Evaluation	Source, Remark
Acute oral toxicity	LD50: 330 mg/kg Species Rat	OECD 401	
Acute dermal toxicity			Study scientifically not necessary.
Acute inhalation toxicity	LC50: 660 ppm Species Mouse	OECD 403	

*** Assessment/classification**
 Toxic by inhalation and if swallowed.

*** Skin corrosion/irritation****Animal data**

Result / Evaluation	Method	Source, Remark
corrosive Species Rabbit		

*** Assessment/classification**
 Causes severe burns.

*** Serious eye damage/irritation****Animal data**

Result / Evaluation	Method	Source, Remark
corrosive Species Rabbit		

*** Assessment/classification**
 Causes serious eye damage.

*** Sensitisation to the respiratory tract**

*** Other information**
 No data available

*** Skin sensitisation****Animal data**

Result / Evaluation	Dose / Concentration	Method	Source, Remark
not sensitising.	Species Guinea pig		

*** Assessment/classification**
 Based on available data, the classification criteria are not met.

*** Repeated dose toxicity (subacute, subchronic, chronic)**

	Effective dose	Method	Specific effects:	Organs affected:	Source, Remark
Subchronic inhalation toxicity	NOAEC < 50 ppm Species Rat	OECD 413			
Chronic inhalation toxicity	NOAEC 10 ppm Species Rat	OECD 453			

*** Germ cell mutagenicity**

	Value	Method	Result / Evaluation	Remark
In vitro mutagenicity/genotoxicity			positive	

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	Value	Method	Result / Evaluation	Remark
In vivo mutagenicity/genotoxicity			positive	

- * **Assessment/classification**
 May cause genetic defects.

* **Carcinogenicity****Animal data**

	Value	Method	Result / Evaluation	Remark
Carcinogenicity	NOAEC < 10 ppm Species Rat Exposure duration 2 a	OECD 453		

- * **Assessment/classification**
 May cause cancer by inhalation.

* **Reproductive toxicity****Animal data**

	Value	Method	Result / Evaluation	Remark
Reproductive toxicity	NOAEC 33 ppm	OECD 415		

- * **Assessment/classification**
 May damage fertility. Suspected of damaging the unborn child.

* **STOT-single exposure*** **STOT SE 3*** **Irritation to respiratory tract**

- * **Assessment/classification**
 May cause respiratory irritation.

* **Narcotic effects**

- * **Assessment/classification**
 May cause drowsiness or dizziness.

* **STOT-repeated exposure*** **Animal data**

	Effective dose	Method	Specific effects:	Organs affected:	Source, Remark
Inhalative specific target organ toxicity (repeated exposure)	450 ppm Species Rat	OECD 413		haematopoietic system	
Inhalative specific target organ toxicity (repeated exposure)	450 ppm Species Rat	OECD 413		central nervous system	

- * **Assessment/classification**
 Causes damage to the nervous system and to blood forming organs through prolonged or repeated exposure by inhalation.

* **Aspiration hazard**

- * **Assessment/classification**
 Study technically not feasible.

11.2 Information on other hazards* **Other information**

May be absorbed through the skin.
 Risk of strong health injuries in case of long-term exposition.

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*** SECTION 12: Ecological information***** 12.1 Toxicity***** Aquatic toxicity**

	Effective dose	Method, Evaluation	Source, Remark
Acute (short-term) fish toxicity	LC50: 84 mg/L Species Pimephales promelas (fathead minnow) Test duration 96 h	EPA 660/3-75/009	
Chronic (long-term) fish toxicity	not determined		
Acute (short-term) toxicity to crustacea	LC50 212 mg/L Species Daphnia magna (Big water flea) Test duration 48 h	EPA 660/3-75/009	
Chronic (long-term) toxicity to aquatic invertebrate	not determined		
Acute (short-term) toxicity to algae and cyanobacteria	EC50 240 mg/L Species Pseudokirchneriella subcapitata Test duration 96 h	EPA 660/3-75/009	Analogous to a similar product.
Chronic (long-term) toxicity to aquatic algae and cyanobacteria	not determined		
Toxicity to other aquatic plants/organisms	not determined		
Toxicity to microorganisms	EC10 130 mg/L Species activated sludge Test duration 3 h	OECD 209	

*** 12.2 Persistence and degradability**

	Value	Method	Source, Remark
Biodegradation	Degradation rate > 95 % Test duration 28 d	OECD 301C/ ISO 9408/ EEC 92/69/V, C.4-F	CAS No.75-21-8 ethylene oxide

*** Assessment/classification**
 Readily biodegradable (according to OECD criteria).

*** 12.3 Bioaccumulative potential**

*** Assessment/classification**
 Based on the n-octanol/water partition coefficient accumulation in organisms is not expected.

*** 12.4 Mobility in soil**

	Value	Distribution	Transport type	Method	Remark
Half-life time in soil	CAS No.75-21-8 ethylene oxide 0.51- 0.67			log Koc	Calculated

*** 12.5 Results of PBT and vPvB assessment**

This substance does not meet the PBT/vPvB criteria of REACH, Annex XIII.

*** 12.6 Endocrine disrupting properties**

	Effective dose	Method, Evaluation	Source, Remark
Endocrine disrupting properties			See section 2.3

12.7 Other adverse effects

No data available

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*** SECTION 13: Disposal considerations***** 13.1 Waste treatment methods****Waste codes/waste designations according to EWC/AVV**

Waste code product	Waste name
160504 *	gases in pressure containers (including halons) containing hazardous substances

*** Appropriate disposal / Product**
 Waste disposal according to directive 2008/98/EC, covering waste and dangerous waste.
 Prevent release to the environment. No disposal via the sewage.

Appropriate disposal / Package

Transportable pressure equipment (empty, residual pressure): Return to supplier / manufacturer.

*** SECTION 14: Transport information**

	Land transport (ADR/RID)	Sea transport (IMDG)	Air transport (ICAO-TI / IATA-DGR)
14.1 UN number or ID number	UN 1040	UN 1040	UN 1040
14.2 UN proper shipping name	ETHYLENE OXIDE WITH NITROGEN	ETHYLENE OXIDE WITH NITROGEN	Ethylene oxide
14.3 Transport hazard class(es)	2.3 (2.1)	2.3 (2.1)	2.3 (2.1)
14.4 Packing group	-	-	-
14.5 Environmental hazards	No	No	No

14.6 Special precautions for user

The protective measures listed in Sections 6, 7 and 8 of the Safety Data Sheet have to be considered.

14.7 Maritime transport in bulk according to IMO instruments

No carriage in bulk.

Land transport (ADR/RID)

UN number or ID number	UN 1040
UN proper shipping name	ETHYLENE OXIDE WITH NITROGEN
Transport hazard class(es)	2.3 (2.1)
Hazard label(s)	2.3+2.1
Classification code	2TF
Packing group	-
Environmental hazards	No
Limited quantity (LQ)	0
Special provisions	342
Tunnel restriction code	B/D

*** Sea transport (IMDG)**

UN number or ID number	UN 1040
UN proper shipping name	ETHYLENE OXIDE WITH NITROGEN
Transport hazard class(es)	2.3 (2.1)
Packing group	-
Environmental hazards	No
Limited quantity (LQ)	0
Marine pollutant	No
EmS	F-D, S-U

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Air transport (ICAO-TI / IATA-DGR)

UN number or ID number UN 1040
 UN proper shipping name Ethylene oxide
 Transport hazard class(es) 2.3 (2.1)
 Packing group -
 Environmental hazards No

Remark
 FORBIDDEN

*** SECTION 15: Regulatory information***** 15.1 Safety, health and environmental regulations/legislation specific for the substance or mixture***** EU legislation***** Restrictions of occupation**

Observe employment restrictions under the Maternity Protection Directive (92/85/EEC) for expectant or nursing mothers.
 Observe restrictions to employment for juvenils according to the 'juvenile work protection guideline' (94/33/EC).

*** Other regulations (EU)***** To follow:**

Regulation (EC) No 1907/2006 concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH), Annex XVII No 28 - 30.

Regulation (EC) No 1907/2006 concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH), Annex XVII No 40.

Regulation (EU) No 528/2012 concerning the making available on the market and use of biocidal products.

Regulation (EU) No 649/2012 concerning the export and import of dangerous chemicals.

Directive 2012/18/EU on the control of major-accident hazards involving dangerous substances.

*** Directive 2010/75/EU on industrial emissions [Industrial Emissions Directive] VOC**

VOC-value $\geq 99.9\%$

15.2 Chemical Safety Assessment*** National regulations**

For this substance a chemical safety assessment has been carried out.

*** SECTION 16: Other information****Key literature references and sources for data**

Information from our suppliers and data from the "GESTIS Substances Database" and the "Registered Substances" database of the European Chemicals Agency (ECHA) were used to create this safety data sheet.

*** Additional information**

The information contained herein is based on the state of our knowledge. It characterizes the product with regard to the appropriate safety precautions. It does not represent a guarantee of the properties of the product.

Relevant H- and EUH-phrases (Number and full text)

H220 H230 Extremely flammable gas.
 H280 Contains gas under pressure; may explode if heated.
 H301 Toxic if swallowed.
 H314 Causes severe skin burns and eye damage.
 H318 Causes serious eye damage.
 H331 Toxic if inhaled.
 H335 May cause respiratory irritation.
 H336 May cause drowsiness or dizziness.
 H340 May cause genetic defects.
 H350i May cause cancer by inhalation.

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H360FD May damage fertility. May damage the unborn child.
H360Fd May damage fertility. Suspected of damaging the unborn child.
H372 Causes damage to organs through prolonged or repeated exposure.

Indication of changes

* Data changed compared with the previous version

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9.1. Manufacture and distribution of the substance

9.1.1. Exposure Scenario

Table 2. Description of the ES

9.1.1.1. Title		
Reference number	1	
Free short title	Manufacture and distribution of the substance	
Systematic title based on use descriptor	SU 8, 9 and 3; PROC 1, 2,3 and 8b; ERC 1	
Processes, tasks, activities covered	Use of the substance in a closed process, in closed continuous processes with occasional controlled exposure or in closed batch processes including the transfer of the substance from/to vessels/large containers at dedicated facilities.	
Environment characteristic covered	-	
9.1.1.2. Operational conditions and risk management measures		
The technical conditions and risk management measures in EO producing and handling facilities need to be always sufficiently efficient to prevent inhalation exposure of workers in concentrations above the DMEL long term- systemic effects for workers (2.0 mg/m ³). The intention should be to seek the lowest exposure at any time.		
9.1.1.2.2.1 Control of workers exposure for PROC 1		
Title information related to contributing scenario		
Workers related free short title	Use in closed process, no likelihood of exposure	
Use descriptor covered	PROC 1	
Processes, tasks, activities covered	Use of the substance in high integrity contained system where little potential exists for exposures, e.g. any sampling via closed loop systems	
Assessment values	measured values*	
Product characteristic		
Physical state	gaseous	
Concentration of substance	100%	
Amounts used		
Not relevant		
Frequency and duration of use/exposure		
Duration of exposure	> 4 hours	hours/day
Frequency of exposure	≤ 240	days/year
Human factors not influenced by risk management		
Not relevant		
Other given operational conditions affecting workers exposure		
Location	Inside or Outside	

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Annex: Exposure scenarios

Domain	Industrial	
Technical conditions and measures at process level (source) to prevent release		
Processes take place in a high integrity contained and monitored system.		
Technical conditions and measures to control dispersion from source towards the worker		
Sampling takes place in a closed loop system. Samples are taken in steel drums, loaded in a closed process and sent to the laboratory. Each facility is fully equipped with gas sensor heads to detect gas leakage. In case of leakage this system is connected to a water sprinkler system to avoid volatilization of the gaseous phase.		
Organisational measures to prevent /limit releases, dispersion and exposure		
Workers are located in isolated measuring stations with light high pressure conditions to avoid any diffusion of ethylene oxide. They are located outside of the isolated measuring station for short monitoring tours and sampling only. Each of these processes takes no longer than than 2 hours and never exceeds a total of 6 hours per day. The industrial facility has a thorough training program for employees to practice the appropriate work process and monitoring.		
Conditions and measures related to personal protection, hygiene and health evaluation		
When workers are located outside of the isolated measuring station during monitoring, they wear overalls, helmets, goggles and safety shoes. During sampling, they wear overalls, helmets, face shields, ethylene oxide resistant and impermeable gloves (e.g. butyl rubber), safety shoes.		
9.1.1.2.2.2 Control of workers exposure for PROC 2 and PROC 3		
Title information related to contributing scenario		
Workers related free short title	Use in closed, continuous process with occasional controlled exposure (e.g. sampling) or use in closed batch process	
Use descriptor covered	PROC 2 and PROC 3	
Processes, tasks, activities covered	Continuous process but where the design philosophy is not specifically aimed at minimizing emissions. Occasional exposure will arise e.g. through maintenance or sampling; Batch manufacture of a chemical or formulation where the predominant handling is in a contained manner, but where some opportunity for contact with chemicals occurs (e.g. through sampling)	
Assessment values	measured values *	
Product characteristic		
Physical state	gaseous	
Concentration of substance	100%	
Amounts used		
Not relevant		
Frequency and duration of use/exposure		
Duration of exposure	< =2 hours	per day
Frequency of exposure	≤ 240	days/year
Human factors not influenced by risk management		
Not relevant		
Other given operational conditions affecting workers exposure		
Location	Inside or Outside	

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Annex: Exposure scenarios

Domain	Industrial	
Technical conditions and measures at process level (source) to prevent release		
Processes take place in a high integrity contained and monitored system.		
Technical conditions and measures to control dispersion from source towards the worker		
Each facility is fully equipped with gas sensor heads to detect gas leakage. In case of leakage this system is connected to a water sprinkler system to avoid volatilization of the gaseous phase.		
Organisational measures to prevent /limit releases, dispersion and exposure		
Workers are located outside of the isolated measuring station for short monitoring and maintenance tours only. Pumps and equipment are regularly checked for monitoring purpose on first indication of potential leakages. Each of these processes takes no longer than 5-10 minutes and never exceeds a total of 2 hours per day. The industrial facility has a thorough training program for employees to practice the appropriate work process and monitoring.		
Conditions and measures related to personal protection, hygiene and health evaluation		
When workers are located outside of the isolated measuring station during monitoring, they wear overalls, helmets, goggles and safety shoes. During maintenance, leakages and minor accidents workers use suitable respiratory protection (breathing air, full face piece), ethylene oxide resistant and impermeable gloves (e.g. butyl rubber), ethylene oxide resistant and impermeable boots (e.g. nitrile rubber) and ethylene oxide impermeable, special chemical resistant overalls (e.g. Microchem 4000 model 151).		
9.1.1.2.2.3 Control of workers exposure for PROC 8b		
Title information related to contributing scenario		
Workers related free short title	Transfer of substance or preparation from/to vessels/large containers at dedicated facilities	
Use descriptor covered	PROC 8b	
Processes, tasks, activities covered	Sampling, loading, filling, transfer in dedicated facilities. Exposure to the substance and cleaning of equipment to be expected; Filling lines specifically designed to for both, capturing vapour and aerosol emissions and minimise spillage	
Assessment values	measured values *	
Product characteristic		
Physical state	gaseous	
Concentration of substance	100%	
Amounts used		
Not relevant		
Frequency and duration of use/exposure		
Duration of exposure	15 mins – 1 hours	per day
Frequency of exposure	≤ 240	days/year
Human factors not influenced by risk management		
Not relevant		
Other given operational conditions affecting workers exposure		
Location	Inside or Outside	

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Annex: Exposure scenarios

Domain	Industrial
Technical conditions and measures at process level (source) to prevent release	
Processes take place in a high integrity contained and monitored system.	
Technical conditions and measures to control dispersion from source towards the worker	
Transfer to dedicated on-site facilities takes place via pipelines in a highly contained system without workers leaving the isolated measuring stations. Each facility is fully equipped with gas sensor heads to detect gas leakage. In case of leakage this system is connected to a water sprinkler system to avoid volatilization of the gaseous phase. Filling, loading and unloading of special containments (according to the pressure vessel regulation of the respective country) for transfer to destinations outside of the manufacturing facility is carried out under strictly controlled conditions following the strict regulations for the transport of ethylene oxide in pressure vessels of the respective country in Europe. The transport of ethylene oxide in bulk is subject to strict regulations within Europe. In addition, the international movement of ethylene oxide by road, rail or sea is subject to international agreements which lay down specific requirements concerning transport which are observed by all parties involved.	
Organisational measures to prevent /limit releases, dispersion and exposure	
Workers are located outside of the isolated measuring station for short loading and filling processes only. Each of these processes takes no longer than 5-10 minutes and never exceeds a total of 1 hour per day. The industrial facility has a special and thorough training program for employees to practice the appropriate work processes.	
Conditions and measures related to personal protection, hygiene and health evaluation	
When workers are located outside of the isolated measuring station for e.g. cleaning of equipment, they use suitable respiratory protection (breathing air, full face piece), chemical resistant gloves (e.g. butyl rubber), chemical resistant boots (e.g. nitrile rubber) and ethylene oxide impermeable, special chemical resistant overalls (e.g. Microchem 4000 model 151).	

* collected during regular external audits of the facilities conducted by an independent accredited measuring body for dangerous substances.

9.1.2. Exposure Estimation for workers / PROC 1, 2, 3, 8b, 9

Exposure assessment for systemic (inhalation) exposure was done using actual measured values from regular external audits of the facilities, conducted by an independent accredited measuring body for dangerous substances. Therefore, no exposure calculation was performed via an exposure assessment tool. The peak value of the last 10 years measurements was taken to reflect the worst case exposure of workers: 0.621 mg/m³ (for more information see Appendix).

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Annex: Exposure scenarios**9.2. Polymer production****9.2.1. Exposure Scenario****Table 3. Description of the ES**

9.2.1.1. Title	
Reference number	2
Free short title	Polymer production
Systematic title based on use descriptor	SU 8, 9 and 3; PROC 1, 2, 3, 8b and 9; ERC 6c
Processes, tasks, activities covered	Use of the substance in a closed process, in closed continuous processes with occasional controlled exposure or in closed batch processes including the transfer of the substance from/to vessels/large containers at dedicated facilities or to small containers (including weighing)
Environment characteristic covered	-
9.2.1.2. Operational conditions and risk management measures	
The technical conditions and risk management measures in EO producing and handling facilities need to be always sufficiently efficient to prevent inhalation exposure of workers in concentrations above the DMEL long term- systemic effects for workers (2.0 mg/m ³). The intention should be to seek the lowest exposure at any time.	
9.2.1.2.2.1 Control of workers exposure for PROC 1	
Title information related to contributing scenario	
Workers related free short title	Use in closed process, no likelihood of exposure
Use descriptor covered	PROC 1
Processes, tasks, activities covered	Use of the substance in high integrity contained system where little potential exists for exposures, e.g. any sampling via closed loop systems
Assessment values	measured values *
Product characteristic	
Physical state	gaseous
Concentration of substance	100%
Amounts used	
Not relevant	
Frequency and duration of use/exposure	
Duration of exposure	< =2 hours hours/day
Frequency of exposure	≤ 240 days/year
Human factors not influenced by risk management	
Not relevant	
Other given operational conditions affecting workers exposure	

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Annex: Exposure scenarios

Location	Inside or Outside	
Domain	Industrial	
Technical conditions and measures at process level (source) to prevent release		
Processes take place in a high integrity contained and monitored system.		
Technical conditions and measures to control dispersion from source towards the worker		
Sampling takes place in a closed loop system. Samples are taken in steel drums, loaded in a closed process and directly sent to the laboratory. Each facility is fully equipped with gas sensor heads to detect gas leakage. In case of leakage this system is connected to a water sprinkler system to avoid volatilization of the gaseous phase.		
Organisational measures to prevent /limit releases, dispersion and exposure		
Workers are located in isolated measuring stations with light high pressure conditions to avoid any diffusion of ethylene oxide. They are located outside of the isolated measuring station for short monitoring tours and sampling only. Each of these processes takes no longer than 5-10 minutes and never exceeds a total of 2 hours per day. The industrial facility has a thorough training program for employees to practice the appropriate work process and monitoring.		
Conditions and measures related to personal protection, hygiene and health evaluation		
When workers are located outside of the isolated measuring station during monitoring, they wear overalls, helmets, goggles and safety shoes. During sampling, they wear overalls, helmets, face shields, ethylene oxide resistant and impermeable gloves (e.g. butyl rubber) and safety shoes.		
9.2.1.2.2.2 Control of workers exposure for PROC 2 and PROC 3		
Title information related to contributing scenario		
Workers related free short title	Use in closed, continuous process with occasional controlled exposure (e.g. sampling) or use in closed batch process	
Use descriptor covered	PROC 2 and PROC 3	
Processes, tasks, activities covered	Continuous process but where the design philosophy is not specifically aimed at minimizing emissions. Occasional exposure will arise e.g. through maintenance or sampling; Batch manufacture of a chemical or formulation where the predominant handling is in a contained manner, but where some opportunity for contact with chemicals occurs (e.g. through sampling)	
Assessment values	measured values *	
Product characteristic		
Physical state	gaseous	
Concentration of substance	100%	
Amounts used		
Not relevant		
Frequency and duration of use/exposure		
Duration of exposure	< =2 hours	per day
Frequency of exposure	≤ 240	days/year
Human factors not influenced by risk management		
Not relevant		

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Annex: Exposure scenarios

Other given operational conditions affecting workers exposure		
Location	Inside or Outside	
Domain	Industrial	
Technical conditions and measures at process level (source) to prevent release		
Processes take place in a high integrity contained and monitored system.		
Technical conditions and measures to control dispersion from source towards the worker		
Each facility is fully equipped with gas sensor heads to detect gas leakage. In case of leakage this system is connected to a water sprinkler system to avoid volatilization of the gaseous phase.		
Organisational measures to prevent /limit releases, dispersion and exposure		
Workers are located outside of the isolated measuring station for short monitoring and maintenance tours only. Pumps and equipment are regularly checked for monitoring purpose on first indication of potential leakages. Each of these processes takes no longer than 5-10 minutes and never exceeds a total of 2 hours per day. The industrial facility has a thorough training program for employees to practice the appropriate work process and monitoring.		
Conditions and measures related to personal protection, hygiene and health evaluation		
When workers are located outside of the isolated measuring station during monitoring, they wear overalls, helmets, goggles and safety shoes. During maintenance, leakages and minor accidents workers use suitable respiratory protection (breathing air, full face piece), ethylene oxide resistant and impermeable gloves (e.g. butyl rubber), ethylene oxide resistant and impermeable boots (e.g. nitrile rubber) and ethylene oxide impermeable, special chemical resistant overalls (e.g. Microchem 4000 model 151) and portable gas sensors.		
9.2.1.2.2.3 Control of workers exposure for PROC 8b and PROC 9		
Title information related to contributing scenario		
Workers related free short title	Transfer of substance or preparation from/to vessels/large containers at dedicated facilities and transfer into small containers at dedicated facilities (including weighing)	
Use descriptor covered	PROC 8b and PROC 9	
Processes, tasks, activities covered	Sampling, loading, filling, transfer in dedicated facilities. Exposure to the substance and cleaning of equipment to be expected; Filling lines specifically designed to for both, capturing vapour and aerosol emissions and minimise spillage	
Assessment values	measured values *	
Product characteristic		
Physical state	gaseous	
Concentration of substance	100%	
Amounts used		
Not relevant		
Frequency and duration of use/exposure		
Duration of exposure	15 mins – 1 hours	per day
Frequency of exposure	≤ 240	days/year
Human factors not influenced by risk management		
Not relevant		

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Annex: Exposure scenarios

Other given operational conditions affecting workers exposure		
Location	Inside or Outside	
Domain	Industrial	
Technical conditions and measures at process level (source) to prevent release		
Processes take place in a high integrity contained and monitored system.		
Technical conditions and measures to control dispersion from source towards the worker		
<p>Transfer to dedicated on-site facilities takes place via pipelines in a highly contained system without workers leaving the isolated measuring stations. Each facility is fully equipped with gas sensor heads to detect gas leakage. In case of leakage this system is connected to a water sprinkler system to avoid volatilization of the gaseous phase.</p> <p>Filling, loading and unloading of special containments (according to the pressure vessel regulation of the respective country) for transfer to destinations outside of the manufacturing facility is carried out under strictly controlled conditions following the strict regulations for the transport of ethylene oxide in pressure vessels of the respective country in Europe. The transport of ethylene oxide in bulk is subject to strict regulations within Europe. In addition, the international movement of ethylene oxide by road, rail or sea is subject to international agreements which lay down specific requirements concerning transport which are observed by all parties involved.</p>		
Organisational measures to prevent /limit releases, dispersion and exposure		
Workers are located outside of the isolated measuring station for short loading and filling processes only. Each of these processes takes no longer than 5-10 minutes and never exceeds a total of 1 hour per day. The industrial facility has a special and thorough training program for employees to practice the appropriate work processes.		
Conditions and measures related to personal protection, hygiene and health evaluation		
When workers are located outside of the isolated measuring station for e.g. cleaning of equipment, they use suitable respiratory protection (breathing air, full face piece), chemical resistant gloves (e.g. butyl rubber), chemical resistant boots (e.g. nitrile rubber) and ethylene oxide impermeable, special chemical resistant overalls (e.g. Microchem 4000 model 151).		

* collected during regular external audits of the facilities conducted by an independent accredited measuring body for dangerous substances.

9.2.2. Exposure Estimation

Exposure assessment for systemic (inhalation) exposure was done using actual measured values from regular external audits of the facilities, conducted by an independent accredited measuring body for dangerous substances. Therefore, no exposure calculation was performed via an exposure assessment tool. The peak value of the last 10 years measurements was taken to reflect the worst case exposure of workers: 0.621 mg/m³ (for more information see Appendix).

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Annex: Exposure scenarios**9.3. Use as an intermediate****9.3.1. Exposure Scenario****Table 4. Description of the ES**

9.3.1.1. Title	
Reference number	3
Free short title	Use as an intermediate
Systematic title based on use descriptor	SU 8, 9 and 3; PROC 1, 2, 3, 8b and 9; ERC 6a
Processes, tasks, activities covered	Use of the substance in a closed process, in closed continuous processes with occasional controlled exposure or in closed batch processes including the transfer of the substance from/to vessels/large containers at dedicated facilities or to small containers (including weighing)
Environment characteristic covered	-
9.3.1.2. Operational conditions and risk management measures	
The technical conditions and risk management measures in EO producing and handling facilities need to be always sufficiently efficient to prevent inhalation exposure of workers in concentrations above the DMEL long term- systemic effects for workers (2.0 mg/m ³). The intention should be to seek the lowest exposure at any time.	
9.3.1.2.2.1 Control of workers exposure for PROC 1	
Title information related to contributing scenario	
Workers related free short title	Use in closed process, no likelihood of exposure
Use descriptor covered	PROC 1
Processes, tasks, activities covered	Use of the substance in high integrity contained system where little potential exists for exposures, e.g. any sampling via closed loop systems
Assessment values	measured values *
Product characteristic	
Physical state	gaseous
Concentration of substance	100%
Amounts used	
Not relevant	
Frequency and duration of use/exposure	
Duration of exposure	< =2 hours hours/day
Frequency of exposure	≤ 240 days/year
Human factors not influenced by risk management	
Not relevant	
Other given operational conditions affecting workers exposure	

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Annex: Exposure scenarios

Location	Inside or Outside	
Domain	Industrial	
Technical conditions and measures at process level (source) to prevent release		
Processes take place in a high integrity contained and monitored system.		
Technical conditions and measures to control dispersion from source towards the worker		
Sampling takes place in a closed loop system. Samples are taken in steel drums, loaded in a closed process and directly sent to the laboratory. Each facility is fully equipped with gas sensor heads to detect gas leakage. In case of leakage this system is connected to a water sprinkler system to avoid volatilization of the gaseous phase.		
Organisational measures to prevent /limit releases, dispersion and exposure		
Workers are located in isolated measuring stations with light high pressure conditions to avoid any diffusion of ethylene oxide. They are located outside of the isolated measuring station for short monitoring tours and sampling only. Each of these processes takes no longer than 5-10 minutes and never exceeds a total of 2 hours per day. The industrial facility has a thorough training program for employees to practice the appropriate work process and monitoring.		
Conditions and measures related to personal protection, hygiene and health evaluation		
When workers are located outside of the isolated measuring station during monitoring, they wear overalls, helmets, goggles and safety shoes. During sampling, they wear overalls, helmets, face shields, ethylene oxide resistant and impermeable gloves (e.g. butyl rubber) and safety shoes.		
9.3.1.2.2.2 Control of workers exposure for PROC 2 and PROC 3		
Title information related to contributing scenario		
Workers related free short title	Use in closed, continuous process with occasional controlled exposure (e.g. sampling) or use in closed batch process	
Use descriptor covered	PROC 2 and PROC 3	
Processes, tasks, activities covered	Continuous process but where the design philosophy is not specifically aimed at minimizing emissions. Occasional exposure will arise e.g. through maintenance or sampling; Batch manufacture of a chemical or formulation where the predominant handling is in a contained manner, but where some opportunity for contact with chemicals occurs (e.g. through sampling)	
Assessment values	measured values *	
Product characteristic		
Physical state	gaseous	
Concentration of substance	100%	
Amounts used		
Not relevant		
Frequency and duration of use/exposure		
Duration of exposure	< =2 hours	per day
Frequency of exposure	≤ 240	days/year
Human factors not influenced by risk management		
Not relevant		

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Annex: Exposure scenarios

Other given operational conditions affecting workers exposure		
Location	Inside or Outside	
Domain	Industrial	
Technical conditions and measures at process level (source) to prevent release		
Processes take place in a high integrity contained and monitored system.		
Technical conditions and measures to control dispersion from source towards the worker		
Each facility is fully equipped with gas sensor heads to detect gas leakage. In case of leakage this system is connected to a water sprinkler system to avoid volatilization of the gaseous phase.		
Organisational measures to prevent /limit releases, dispersion and exposure		
Workers are located outside of the isolated measuring station for short monitoring and maintenance tours only. Pumps and equipment are regularly checked for monitoring purpose and samples are taken from the circumfluent water film of the pumps on first indication of potential leakages. Each of these processes takes no longer than 5-10 minutes and never exceeds a total of 2 hours per day. The industrial facility has a thorough training program for employees to practice the appropriate work process and monitoring.		
Conditions and measures related to personal protection, hygiene and health evaluation		
When workers are located outside of the isolated measuring station during monitoring, they wear overalls, helmets, goggles and safety shoes. During maintenance, leakages and minor accidents workers use suitable respiratory protection (breathing air, full face piece), ethylene oxide resistant and impermeable gloves (e.g. butyl rubber), ethylene oxide resistant and impermeable boots (e.g. nitrile rubber) and ethylene oxide impermeable, special chemical resistant overalls (e.g. Microchem 4000 model 151) and portable gas sensors.		
9.3.1.2.2.3 Control of workers exposure for PROC 8b and PROC 9		
Title information related to contributing scenario		
Workers related free short title	Transfer of substance or preparation from/to vessels/large containers at dedicated facilities and transfer into small containers at dedicated facilities (including weighing)	
Use descriptor covered	PROC 8b and PROC 9	
Processes, tasks, activities covered	Sampling, loading, filling, transfer in dedicated facilities. Exposure to the substance and cleaning of equipment to be expected; Filling lines specifically designed to for both, capturing vapour and aerosol emissions and minimise spillage	
Assessment values	measured values *	
Product characteristic		
Physical state	gaseous	
Concentration of substance	100%	
Amounts used		
Not relevant		
Frequency and duration of use/exposure		
Duration of exposure	15 mins – 1 hours	per day
Frequency of exposure	≤ 240	days/year
Human factors not influenced by risk management		
Not relevant		

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Annex: Exposure scenarios

Other given operational conditions affecting workers exposure		
Location	Inside or Outside	
Domain	Industrial	
Technical conditions and measures at process level (source) to prevent release		
Processes take place in a high integrity contained and monitored system.		
Technical conditions and measures to control dispersion from source towards the worker		
<p>Transfer to dedicated on-site facilities takes place via pipelines in a highly contained system without workers leaving the isolated measuring stations. Each facility is fully equipped with gas sensor heads to detect gas leakage. In case of leakage this system is connected to a water sprinkler system to avoid volatilization of the gaseous phase.</p> <p>Filling, loading and unloading of special containments (according to the pressure vessel regulation of the respective country) for transfer to destinations outside of the manufacturing facility is carried out under strictly controlled conditions following the strict regulations for the transport of ethylene oxide in pressure vessels of the respective country in Europe. The transport of ethylene oxide in bulk is subject to strict regulations within Europe. In addition, the international movement of ethylene oxide by road, rail or sea is subject to international agreements which lay down specific requirements concerning transport which are observed by all parties involved.</p>		
Organisational measures to prevent /limit releases, dispersion and exposure		
Workers are located outside of the isolated measuring station for short loading and filling processes only. Each of these processes takes no longer than 5-10 minutes and never exceeds a total of 1 hour per day. The industrial facility has a special and thorough training program for employees to practice the appropriate work processes.		
Conditions and measures related to personal protection, hygiene and health evaluation		
When workers are located outside of the isolated measuring station for e.g. cleaning of equipment, they use suitable respiratory protection (breathing air, full face piece), chemical resistant gloves (e.g. butyl rubber), chemical resistant boots (e.g. nitrile rubber) and ethylene oxide impermeable, special chemical resistant overalls (e.g. Microchem 4000 model 151).		

* collected during regular external audits of the facilities conducted by an independent accredited measuring body for dangerous substances.

9.3.2. Exposure Estimation

Exposure assessment for systemic (inhalation) exposure was done using actual measured values from regular external audits of the facilities, conducted by an independent accredited measuring body for dangerous substances. Therefore, no exposure calculation was performed via an exposure assessment tool. The peak value of the last 10 years measurements was taken to reflect the worst case exposure of workers: 0.621 mg/m³ (for more information see Appendix).

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Annex: Exposure scenarios**9.4. Use as laboratory reagent****9.4.1. Exposure Scenario****Table 5. Description of the ES**

9.4.1.1. Title		
Reference number	4	
Free short title	Use as a laboratory reagent	
Systematic title based on use descriptor	SU 3 and 22; PROC 15; ERC 1	
Processes, tasks, activities covered	Use of substances at small scale laboratory (< 1 l or 1 kg present at workplace).	
Environment characteristic covered	-	
9.4.1.2. Operational conditions and risk management measures		
9.4.1.2.2.1 Control of workers exposure for PROC 15		
Title information related to contributing scenario		
Workers related free short title	Use as a laboratory reagent	
Use descriptor covered	PROC 15	
Processes, tasks, activities covered	Use of substances at small scale laboratory (< 1 l or 1 kg present at workplace).	
Assessment Method	ECETOC TRA Worker v2.0 with modifications ¹	
Product characteristic		
Physical state	gaseous	
Concentration of substance	100%	
Amounts used		
Not relevant		
Frequency and duration of use/exposure		
Duration of exposure	15min - 1h	Per day
Frequency of exposure	≤ 240	days/year
Human factors not influenced by risk management		
Not relevant		
Other given operational conditions affecting workers exposure		
Location	Inside	
Domain	Industrial and Professional	
Technical conditions and measures at process level (source) to prevent release		
Ethylene oxide is stored in highly contained vessels at any time.		
Technical conditions and measures to control dispersion from source towards the worker		
Appropriate local exhaust ventilation: Effectiveness: 99%		
Organisational measures to prevent /limit releases, dispersion and exposure		
Laboratories have a thorough training program for employees for the appropriate handling of ethylene oxide.		
Conditions and measures related to personal protection, hygiene and health evaluation		
Use of suitable respiratory protection: Effectiveness: 97.5% (full face shield)		

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Annex: Exposure scenarios

Use of ethylene oxide impermeable gloves (e.g. butyl rubber)

Respiratory protection: another effectiveness value was applied

9.4.2. Exposure Estimation

Table 6. Estimated exposure for workers / PROC 15

Route of exposure	Concentrations		Justification
	Value	Unit	
Long-term exposure, systemic, inhalative	0.05	mg/m ³	
Short-term exposure, systemic, inhalative	0.91	mg/m ³	

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Annex: Exposure scenarios

10. RISK CHARACTERISATION

General remarks

The technical conditions and risk management measures in EO producing and handling facilities should always be sufficiently efficient to prevent exposure of the workers in concentrations above the DMEL. The intention should be to seek the lowest exposure at any time. Therefore, it can be assumed that a qualitative description of the exposure scenarios is sufficient to ensure that exposure concentrations are at least below the DMEL and the RCR will never be > 1.

Human Health – Worker

Risk characterization for local inhalative effects:

As discussed in the hazard assessment, ethylene oxide does not exert local irritation at concentrations below exerting systemic toxicity including carcinogenicity. The proposed DNEL is therefore a systemic DNEL, however considered to be protective also from local toxicity. Thus the exposure scenarios described by actual measured values (resulting in a RCR < 1: measured values vs. systemic DNELs) also cover local effects.

Human health – Worker and Consumer

The risk characterization covers the life cycle of the substance (monomer) until the polymerization reaction. The unreacted residual monomer in a polymer is to be regarded as impurity that need not be critically addressed in the exposure assessment. Also covered is the life cycle of the substance as an intermediate until the respective chemical reaction and finally distillation of the product.

Environment

In the chemical safety assessment performed according to Article 14(3) in connection with Annex I section 3 (Environmental Hazard Assessment) and section 4 (PBT/ vPvB Assessment) no hazard was identified. Therefore according to REACH Annex I (5.0) an exposure estimation and risk characterization is not necessary. Consequently all identified uses of the substance are assessed as safe for the environment.

Ethylene oxide is only used as an intermediate or as a monomer in polymer production. Both uses are performed in closed systems and under strictly controlled conditions. Unintended releases into the environment are hence not to be expected. Additionally, regular external audits of the facilities, conducted by an independent accredited measuring body for dangerous substances, ensure that the measured values of air around the highly contained facilities do not exceed the legally permitted thresholds. Therefore, environmental exposure is negligible.