WYTWÓRNIA Sterylgaz Spółka z o.o.

SAFETY DATA SHEET

Date of issue: 29.08.2019 Version: 1.0/EN

[In accordance with the criteria of Regulation No 1907/2006 (REACH) and 2015/830]

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

1.1 Product identifier

Trade name: **GAS „4-134"**
Chemical name: ethylene oxide
Index number: 603-023-00-X
Registration number: 01-2119432402-53-0021

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

Relevant identified uses: for sterilization of the medical equipment in hospital pressure sterilizers.

Uses advised against: not determinated.

1.3 Details of the supplier of the safety data sheet

Manufacturer: **Wytwórnia "Sterylgaz" Sp. z o.o.**

Address: ul. Długa 3, 09-402 Płock, Poland

Telephone/Fax number: +48 24 365 56 44, +48 24 264 03 94/+48 24 264 03 81

E-mail address for a competent person responsible for SDS: biuro@theta-doradztwo.pl

1.4 Emergency telephone number

112, +48 22 619 66 54 (Toxicological Office in Warsaw), +48 24 365 70 32, 24 365 70 33 (National Center for the Transport of Hazardous Materials-SPOT-24h)

Section 2: Hazards identification

2.1 Classification of the substance or mixture

Flam. Gas 1 H220, **Press. Gas** H280, **Carc. 1B** H350, **Muta. 1B** H340, **Acute Tox. 3** H331, **Eye Irrit. 2** H319, **Skin Irrit. 2** H315, **STOT SE 3** H335

Extremely flammable gas. Contains gas under pressure; may explode if heated. May cause cancer. May cause genetic defects. Toxic if inhaled. Causes serious eye irritation. Causes skin irritation. May cause respiratory irritation.

2.2 Label elements

Hazard symbols and signal words

DANGER

Hazard statements

H220	Extremely flammable gas.
H280	Contains gas under pressure; may explode if heated.
H315	Causes skin irritation.
H319	Causes serious eye irritation.
H331	Toxic if inhaled.
H335	May cause respiratory irritation.
H340	May cause genetic defects.
H350	May cause cancer.

Precautionary statements

P202	Do not handle until all safety precautions have been read and understood.
P210	Keep away from heat, hot surfaces, sparks, open flames and other ignition sources. No smoking.

P280	Wear protective gloves/protective clothing/eye protection.
P304+ P340	IF INHALED: Remove person to fresh air and keep comfortable for breathing.
P308+ P313	IF exposed or concerned: Get medical advice/attention.
P403	Store in a well-ventilated place.

Additional information

Biocide authorization number in Poland: 1130/04.

Active substance: ethylene oxide [100%, 100g/100g of product]

Restricted to professional users.

2.3 Other hazards

Ethylene oxide does not meet the PBT or vPvB criteria in accordance with the Annex XIII of the REACH Regulation. Ethylene oxide forms explosive mixtures with air. It is unstable and it can undergo a rapid polymerization accompanied by emission of large quantities of heat.

Section 3: Composition/information on ingredients

3.1 Substances

Chemical name:	ethylene oxide, oxirane
CAS number:	75-21-8
EINECS number:	200-849-9
Index number:	603-023-00-X

Section 4: First aid measures

4.1 Description of first aid measures

Skin contact: take off contaminated clothing. Wash out skin with plenty of water with soap. Use aseptic dressing. Do not use pastes or powders.

Eye contact: wash out with plenty of water with the eyelid hold wide open, for 10-15 min. Remove any contact lenses. Avoid powerful water stream – risk of cornea damage. Obtain medical attention immediately.

Ingestion: exposure by this route does not occur.

Inhalation: remove to fresh air, keep warm and calm. In case of breathing difficulties use oxygen. Consult a doctor, if symptoms occur.

4.2 Most import ant symptoms and effects, both acute and delayed

Ethylene oxide in liquid form erythema, blisters, severe skin damage.

4.3 Indication of any immediate medical attention and special treatment needed

Physician makes a decision regarding further medical treatment after thoroughly examination of the injured. A person rendering assistance in the endangered area should be equipped with respiratory protective equipment. In case of appearance of symptoms indicating pulmonary oedema, administer intravenously hydrocortisone, furosemide or dexamethasone to inhale.

Section 5: Firefighting measures

5.1 Extinguishing media

Suitable extinguishing media: extinguishing powder, carbon dioxide, water spray.

Small fire: in the open area, allow the product to burn, control the area and cool down cartridges with water. In closed areas, use extinguishing powder or foam extinguisher.

Large fire: extinguish with water spray.

Unsuitable extinguishing media: water jet – risk of the propagation of the flame.

5.2 Special hazards arising from the substance or mixture

May produce harmful fumes of carbon oxides and other unidentified decomposition products if burning. Do not inhale combustion products – it can be dangerous for health.

5.3 Advice for firefighters

Personal protection typical in case of fire. Do not stay in the fire zone without self-contained breathing apparatus and protective clothing resistant to chemicals. Extremely flammable gas, heavier than air, accumulates in lower parts of the rooms. There is a strong probability of forming explosive mixture with air – in case of such danger, an immediate evacuation must be ordered. Cool down containers with water to prevent bursting. Cartridges exposed to flame or high temperature can explode. Do not flush into surface water or ground water. Explosion group IIB. Temperature class T2.

Section 6: Accidental release measures

6.1 Personal precautions, protective equipment and emergency procedures

Limit the access for the outsiders into the breakdown area, until the suitable cleaning operations are completed. Ensure that only the trained personnel removes the effects of the accident. In case of release of large amounts of the product, it is necessary to take appropriate steps to prevent it from spreading into the environment. Wear adequate personal protective equipment. Avoid contact with skin and eyes. Ensure adequate ventilation. Do not enter enclosed / densely build-up areas without self-contained breathing apparatus. Avoid direct contact with releasing gas. Eliminate the source of the fire - do not smoke, remove any open flames, do not use sparkling tools.

6.2 Environmental precautions

In case of release of large amounts of the product, it is necessary to take appropriate steps to prevent it from spreading into the environment. Notify relevant emergency services.

6.3 Methods and material for containment and cleaning up

Small spillage: allow to evaporate, ventilate the area.

Large spillage: disperse the releasing gas with the use of e.g., water curtains or water fog stream, ventilate the area.

6.4 Reference to other sections

Appropriate conduct with waste product – section 13. Appropriate personal protective equipment – section 8.

Section 7: Handling and storage

7.1 Precautions for safe handling

Handle in accordance with good occupational hygiene and safety practices. Avoid skin and eyes contamination. Before break and after work wash hands carefully. Ensure adequate ventilation. Vapours can form with air exposure mixture. Do not inhale gas. Do not allow gas to accumulate in the air or create concentrations ranged within the explosive properties' limits or exceeding the highest permissible concentration. Provide general and / or local ventilation that guarantees at least 10 air changes per hour. Eliminate the source of the ignition - do not smoke, do not use open flame, do not use sparkling equipment; protect containers against heating; use electrical anti-explosive equipment.

7.2 Conditions for safe storage, including any incompatibilities

Keep only in certified, correctly labeled containers, in well-ventilated places designed for flammable gases, with safe electrical and ventilation instalation. Keep away from food, beverages or feed for animals. Avoid direct expose to sunlight. Protect against flame sources and heat. Do not smoke, use open flame or sparking equipment. Recommended storage temperature: below 30°C.

7.3 Specific end use(s)

This substance is used for sterilization of the medical equipment in hospital pressure sterilizers.

Section 8: Exposure controls/personal protection

8.1 Control parameters

Product does not contain any components with occupational exposure limit values at working place in Community.

Please check any national occupational exposure limit values in your country.
Legal Basis: Commission Directive 2006/15/EC, 2000/39/EC, 2009/161/EC, 2017/164/EC.

PNEC value

Freshwater	0,084 mg/l
Marine water	0,0084 mg/l

8.2 Exposure controls

Use the product in accordance with good occupational hygiene and safety practices. When handling, do not eat, drink or smoke. Before break and after work wash hands carefully. Avoid skin and eyes contamination. In the workplace, general and / or local ventilation should be provided in order to keep the harmful factor in the air below the permissible concentration limits.

Hand and body protection

Wear the protective gloves. The recommend material for glover: neoprene, butyl rubber. Wear antistatic protective clothing.

The material that the gloves are made of must be impenetrable and resistant to the product's effects. The selection of material must be performed with consideration of breakthrough time, penetration speed and degradation. Moreover, the selection of proper gloves depends not only on the material, but also on other quality features and changes depending on the manufacturer. The producer should provide detailed information regarding the exact breakthrough time. This information should be followed.

Eye/face protection

Wear tightly-fitting gogles.

Respiratory protection

In case of exceeding the highest permissible concentration values, in emergency situations it is advised to use AX type absorption equipment (class 1/protection against gases of volume concentration in air the below 0.1%; class 2/ protection against gases of concentration in the air below 0.5%; class 3/ protection against gases of volume concentration in the air up to 1%). If the oxygen concentration is ≤ 19% and/or max gas concentration in the air is ≥ 1.0 % of total volume, self-contained breathing apparatus must be used.

Applied personal protective equipment must comply with the requirements of the Regulation 2016/425/EU. The employer is obliged to provide protective equipment relevant to performed activities and in accordance with all quality requirements, including its maintenance and cleaning.

Environmental exposure controls

Do not allow the large quantity of mixture to contaminate surface water/ground water.

Section 9: Physical and chemical properties

9.1 Information on basic physical and chemical properties

physical state:	gas
colour:	colorless
odour:	characteristic, ethereal
odour threshold:	not determined
pH:	not applicable
melting point/freezing point:	-111°C
initial boiling point and boiling range:	10,73°C
flash point:	-18°C
evaporation rate:	not determined
flammability (solid, gas):	extremely flammable gas
upper/lower flammability or explosive limits:	2,6%/100% vol.

vapour pressure (25°C):	1752 hPa
relative vapour density (relative to air):	1,52
vapour density (10,7°C):	1,9 g/dm^3
liquid density (6°C):	0,89 g/dm^3
solubility(ies):	soluble in water, acetone, benzene, methanol, ethyl ether
partition coefficient: n-octanol/water:	-0,3
auto-ignition temperature:	430°C
decomposition temperature:	not determined
explosive properties:	explosive
oxidising properties:	not display
dynamic viscosity:	not determined
kinematic viscosity:	not determined

9.2 Other information

heat of evaporation (10,7°C):	579,9 J/g
heat of combustion:	-29,7 kJ/g
critical temperature:	195,8°C

Section 10: Stability and reactivity

10.1 Reactivity

Product is highly reactive. See subsection: 10.2-10.5.

10.2 Chemical stability

The product is not stable. Undergoes a deflagration in gas and liquid phase. Undergoes a violent decomposition.

10.3 Possibility of hazardous reactions

In case of heating, exposure to sunlight or under the influence of catalysts, this substance undergoes a rapid, exothermic polymerization reaction. Uncontrolled polymerization in closed container may cause explosions. In case of contact with metals such as: copper, silver, mercury, magnesium and their alloys – a rapid, exothermic decomposition takes place. Sodium hydroxide, slaked lime, ammonia, amines, alcohols, mercaptans – dangerous reaction course (with ignition or explosion). Forms explosive mixtures with air. Causes softening of some plastics.

10.4 Conditions to avoid

Avoid direct sunlight, electrostatic discharge and heat sources.

10.5 Incompatible materials

Strong oxidizing agents, strong bases, metals, metal alloys, acids, metal oxides.

10.6 Hazardous decomposition products

Ethylene, acethylene, hydrogen.

Section 11: Toxicological information

11.1 Information on toxicological effects

Acute toxicity

LD_{50} (oral, rat)	72 g/kg
LD_{50} (skin, rabbit)	1 090 g/kg
LC_{50} (inhalation, rat)	1,44 mg/l/4h
LC_{50} (inhalation, mouse)	836 ppm/4h

Toxic if inhaled.

Skin corrosion/irritation

Causes skin irritation.

Serious eye damage/irritation

Causes serious eye irritation.

Respiratory or skin sensitisation

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

Germ cell mutagenicity

May cause genetic defects (Muta. 1B).

Carcinogenicity

May cause cancer (Carc. 1B).

Reproductive toxicity

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

STOT-single exposure

May cause respiratory irritation.

STOT-repeated exposure

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

Aspiration hazard

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

Exposure effects

Eye contact: gas causes tearing and burning sensation, redness of conjunctiva, irritation. Liquid ethylene oxide and/or concentrate solution of ethylene oxide cause redness, pain and cornea damage.

Skin contact: irritation, dermatitis, liquid ethylene oxide causes erythema, blisters and large skin damage. The results of burns: skin discoloration. The result of skin burns is its discoloration.

Inhalation: irritation of respiratory tract, weakness, headache and dizziness, nausea, cough, drowsiness, narcosis. High concentration can cause emphysema, cardiac rhythm disturbance.

Effect of chronic exposure: long-term exposure to low concentration of gas can cause disturbance of smell, depression of central nervous system, kidneys and liver damage.

Section 12: Ecological information

12.1 Toxicity

Toxicity for fish: LC_{50} 84 mg/l/96h/ Pimephales promelas

Toxicity for daphnia: EC_{50} 137 mg/l/48h/ Daphnia magna

Product is not classified as dangerous for environment.

12.2 Persistence and degradability

Abiotic degradation

After vaporisation or exposure to atmospheric air, the ethylene oxide is half-photodegradable, as a result of the reaction with OH radicals, within 57 days (Epiwin, AOP v1.92) [BASF AG, 2007]. In 25°C and at pH 7,4, due to the hydrolysis, the ethylene oxide underwent the half-decomposition within 12 days [Conway & al., 1993].

Biotic degradation

It is rapidly biodegradable. Assessment of biodegradability based on the closed bottle test gave the result of 69% degradation of ethylene oxide after 20 days [Dow Chemical., 1978].

12.3 Bioaccumulative potential

Bioaccumulation is not expected.

12.4 Mobility in soil

Product is soluble in water. It disperses in air rapidly.

12.5 Results of PBT and vPvB assessment

From the point of view of the available data on biotic and abiotic degradation, bioaccumulation and toxicity, it can be stated that ethylene oxide does not meet the PBT and vPvB criteria.

12.6 Other adverse effects

This product has no influence on the ozone layer depletion.

Section 13: Disposal considerations

13.1 Waste treatment methods

Disposal methods for the product: cartridges that are not empty, and therefore they are not suitable to be reused, should be transferred to the producer to disposal.

Disposal methods for used packing: emptied containers must be aerated. Aerated containers are considered as non-dangerous wastes. Empty containers should be reused/recycled/eliminated in accordance with the local legislation. Waste code: 15 01 04 (metallic packaging).

Legal basis: Directive 2008/98/EC as amended, 94/62/EC as amended.

Section 14: Transport information

	Transport type	ADR/RID	IMO/IMDG	IATA-DGR
14.1	UN number	UN 2037	UN 2037	UN 2037
		LQ=120 ml	F-D, S-U	
14.2	UN proper shipping name	RECEPTACLES, SMALL, CONTAINING GAS (GAS CARTRIDGES)		
14.3	Transport hazard class(es)	2	2	2
	Classification code	5 TF code	-	-
	Label	2.3+2.1	2.3+2.1	2.3+2.1
14.4	Packing group	not applicable	not applicable	not applicable
14.5	Environmental hazards	no	no	no

14.6 Special precautions for user

Use appropriate personal protective equipment according to section 8. Avoid heating and flame sources.

14.7 Transport in bulk according to Annex II of Marpol and the IBC Code

Not applicable.

Section 15: Regulatory information

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

Regulation (EC) No 1907/2006 of the European Parliament and of the Council of 18 December 2006 concerning the Registration, Evaluation, Authorization and Restriction of Chemicals (REACH), establishing a European Chemicals Agency, amending Directive 1999/45/EC and repealing Council Regulation (EEC) No 793/93 and Commission Regulation (EC) No 1488/94 as well as Council Directive 76/769/EEC and Commission Directives 91/155/EEC, 93/67/EEC, 93/105/EC and 2000/21/EC as amended.

Regulation (EC) No 1272/2008 of the European Parliament and of the Council of 16 December 2008 on classification, labelling and packaging of substances and mixtures, amending and repealing Directives 67/548/EEC and 1999/45/EC, and amending Regulation (EC) No 1907/2006 (Text with EEA relevance) as amended.

Commission Regulation (EU) No 2015/830 of 28 May 2015 amending Regulation (EC) No 1907/2006 of the European Parliament and of the Council on the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH) (Text with EEA relevance).

Directive 2008/98/EC of the European Parliament and of the Council of 19 November 2008 on waste and repealing certain Directives as amended.

European Parliament and Council Directive 94/62/EC of 20 December 1994 on packaging and packaging waste as amended.

Commission Directive 2000/39/EC of 8 June 2000 establishing a first list of indicative occupational exposure limit values in implementation of Council Directive 98/24/EC on the protection of the health and safety of workers from the risks related to chemical agents at work.

Commission Directive 2006/15/EC of 7 February 2006 establishing a second list of indicative occupational exposure limit values in implementation of Council Directive 98/24/EC and amending Directives 91/322/EEC and 2000/39/EC.
Commission Directive 2009/161/EU of 17 December 2009 establishing a third list of indicative occupational exposure limit values in implementation of Council Directive 98/24/EC and amending Commission Directive 2000/39/EC.
Commission Directive 2017/164/EU of 31 January 2017 establishing a fourth list of indicative occupational exposure limit values pursuant to Council Directive 98/24/EC, and amending Commission Directives 91/322/EEC, 2000/39/EC and 2009/161/EU.
Regulation (EU) No 2016/425 of the European Parliament and of the Council of 9 March 2016 on personal protective equipment and repealing Council Directive 89/686/EEC.

Restrictions and prohibitions (Annex XVII, REACH)

Ethylene oxide is a CMR substance - restricted to professional users.

15.2 Chemical safety assessment

Chemical safety assessment was carried out for ethylene oxide.

Section 16: Other information

Full text of indicated H phrases mentioned in section 2

H220	Extremely flammable gas.
H280	Contains gas under pressure; may explode if heated.
H315	Causes skin irritation.
H319	Causes serious eye irritation.
H331	Toxic if inhaled.
H335	May cause respiratory irritation.
H340	May cause genetic defects.
H350	May cause cancer.

Clarification of aberrations and acronyms

Acute Tox. 3	Acute toxicity, cat. 3
Flam. Gas 1	Flammable gas category 1
Press. Gas	Pressure gas
Skin Irrit. 2	Skin irritation category 2
Eye Irrit. 2	Eye Irritation category 2
STOT SE 3	Specific Target Organ Toxicity-single exposure category 3
Carc. 1B	Carcinogenic category 1B
Muta. 1B	Mutagenic category 1B

Trainings

Before commencing working with the product, the user should learn the Health & Safety regulations, regarding handling chemicals, and in particular, undergo a proper workplace training. People associated with transport of hazardous materials in accordance with ADR should be adequately trained for their job responsibilities (general training, bench and safety).

Key literature references and sources of data

This SDS was prepared on the basis of the documents provided by the manufacturer, literature data, online databases (eg. ECHA, TOXNET, COSING) as well as our knowledge and experience, taking into account current legislation.

Other data

Date of update:	29.08.2019
Version:	1.0/EN
Composed by:	mgr Tetiana Tracz (on the basis of producer's data)
Safety Data Sheet made by:	**„THETA"** Doradztwo Techniczne

The information above is based on a current available data concerning the product, but also on the experience and knowledge in this field of the producer. They are neither a quality description of the product nor a guarantee of particular features. They are to be treated as aid to safety in transport, storage and usage of the product. That does not free the user from the responsibility of improper usage of the information above and also of improper compliance with the law norms in the field.