Safety Data Sheet

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This Safety Data Sheet has been prepared in accordance with the REACH Regulation (EC) 1907/2006 and its modifications.

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

1.1. Product identifier

3M Steri-Gas Sterilisation Cartridges

REACH registration number	CASRN	EC Number	Ingredient Name
01-2119432402-53-0191	75-21-8	200-849-9	ethylene oxide
01-2119432402-53-0278	75-21-8	200-849-9	ethylene oxide
01-2119432402-53-0285	75-21-8	200-849-9	ethylene oxide
01-2119432402-53-0586	75-21-8	200-849-9	ethylene oxide

Product Identification Numbers

70-2007-8377-0 70-2007-8380-4 70-2007-8383-8

7100042033 7100042034 7100042035

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

Identified uses

Gas to sterilize in a 3M Steri-Vac(TM) Ethylene Oxide Sterilizer

1.3. Details of the supplier of the safety data sheet

Address: 3M Ireland Limited, The Iveagh Building, The Park, Carrickmines, Dublin 18.
Telephone: +353 1 280 3555
E Mail: tox.uk@mmm.com
Website: www.3M.com

1.4. Emergency telephone number

Emergency medical information: 8am-10pm (seven days) contact National Poisons Information Centre, Beaumont Hospital, Dublin 9 DOV2NO, Ireland. Telephone Number: +353 (0)1 809 2166

SECTION 2: Hazard identification

2.1. Classification of the substance or mixture

CLP REGULATION (EC) No 1272/2008

The health and environmental classifications of this material have been derived using the calculation method, except in cases where test data are available or the physical form impacts classification. Classification(s) based on test data or physical form are noted below, if applicable.

CLASSIFICATION:
Flammable Gases, Category 1A - Flam. Gas 1A; H220
Gas Under Pressure, Press. Gas (Liq.); H280
Acute Toxicity, Category 3 - Acute Tox. 3; H301
Acute Toxicity, Category 3 - Acute Tox. 3; H331
Skin Corrosion/Irritation, Category 1 - Skin Corr. 1; H314
Serious Eye Damage/Eye Irritation, Category 1 - Eye Dam. 1; H318
Germ Cell Mutagenicity, Category 1B - Muta. 1B; H340
Carcinogenicity, Category 1B - Carc. 1B; H350
Reproductive Toxicity, Category 1B - Repr. 1B; H360FD
Specific Target Organ Toxicity-Repeated Exposure, Category 1 - STOT RE 1; H372
Specific Target Organ Toxicity-Single Exposure, Category 3 - STOT SE 3; H336
Specific Target Organ Toxicity-Single Exposure, Category 3 - STOT SE 3; H335

For full text of H phrases, see Section 16.

2.2. Label elements
CLP REGULATION (EC) No 1272/2008

SIGNAL WORD
DANGER.

Symbols
GHS02 (Flame) |GHS04 (Gas cylinder) |GHS05 (Corrosion) |GHS06 (Skull and crossbones) |GHS08 (Health Hazard) |

Pictograms

Ingredients:

Ingredient	CAS Nbr	EC No.	% by Wt
ethylene oxide	75-21-8	200-849-9	<= 100

HAZARD STATEMENTS:

H220	Extremely flammable gas.
H280	Contains gas under pressure; may explode if heated.
H301 + H331	Toxic if swallowed or if inhaled.
H314	Causes severe skin burns and eye damage.
H340	May cause genetic defects.
H350	May cause cancer.
H360Fd	May damage fertility. Suspected of damaging the unborn child
H336	May cause drowsiness or dizziness.
H335	May cause respiratory irritation.
H372	Causes damage to organs through prolonged or repeated exposure: nervous system.

PRECAUTIONARY STATEMENTS

Prevention:

P201	Obtain special instructions before use.
P260C	Do not breathe gas.
P280J	Wear protective gloves, protective clothing, respiratory protection, and eye/face protection.

Response:

P301 + P330 + P331	IF SWALLOWED: Rinse mouth. Do NOT induce vomiting.
P303 + P361 + P353	IF ON SKIN (or hair): Take off immediately all contaminated clothing. Rinse skin with water or shower.
P305 + P351 + P338	IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.
P310	Immediately call a POISON CENTRE or doctor/physician.
P377	Leaking gas fire: Do not extinguish, unless leak can be stopped safely.

Storage:

P403 + P233	Store in a well-ventilated place. Keep container tightly closed.
P410	Protect from sunlight.

For containers not exceeding 125 ml the following Hazard and Precautionary statements may be used:

<=125 ml Hazard statements

H220	Extremely flammable gas.
H301 + H331	Toxic if swallowed or if inhaled.
H314	Causes severe skin burns and eye damage.
H340	May cause genetic defects.
H350	May cause cancer.
H360Fd	May damage fertility. Suspected of damaging the unborn child
H336	May cause drowsiness or dizziness.
H335	May cause respiratory irritation.
H372	Causes damage to organs through prolonged or repeated exposure: nervous system.

<=125 ml Precautionary statements

Prevention:

P201	Obtain special instructions before use.
P260C	Do not breathe gas.
P280J	Wear protective gloves, protective clothing, respiratory protection, and eye/face protection.

Response:

P301 + P330 + P331	IF SWALLOWED: Rinse mouth. Do NOT induce vomiting.
P303 + P361 + P353	IF ON SKIN (or hair): Take off immediately all contaminated clothing. Rinse skin with water or shower.
P305 + P351 + P338	IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.
P310	Immediately call a POISON CENTRE or doctor/physician.
P377	Leaking gas fire: Do not extinguish, unless leak can be stopped safely.

Storage:

P403 + P233	Store in a well-ventilated place. Keep container tightly closed.

SUPPLEMENTAL INFORMATION:

Supplemental Precautionary Statements:
Restricted to professional users.

2.3. Other hazards

May cause frostbite.
This material does not contain any substances that are assessed to be a PBT or vPvB

SECTION 3: Composition/information on ingredients

3.1. Substances

Ingredient	Identifier(s)	%	Classification according to Regulation (EC) No. 1272/2008 [CLP]
ethylene oxide	(CAS-No.) 75-21-8 (EC-No.) 200-849-9	<= 100	Flam. Gas 1A, H220 Liquified gas, H280 Acute Tox. 3, H331(LC50 = 700 ppm **ATE values per Annex VI**) Acute Tox. 3, H301(LD50 = 100 mg/kg **ATE values per Annex VI**) Skin Corr. 1, H314 Eye Dam. 1, H318 Muta. 1B, H340 Carc. 1B, H350 Repr. 1B, H360Fd STOT SE 3, H336 STOT SE 3, H335 STOT RE 1, H372 Nota U Chem. Unst. Gas A, H230

Please see section 16 for the full text of any H statements referred to in this section

For information on ingredient occupational exposure limits or PBT or vPvB status, see sections 8 and 12 of this SDS

3.2. Mixtures
Not applicable

SECTION 4: First aid measures

4.1. Description of first aid measures

Inhalation
Remove person to fresh air. Get medical attention.

Skin contact
Immediately flush with large amounts of water for at least 15 minutes. Remove contaminated clothing. Get immediate medical attention. Wash clothing before reuse.

Eye contact
Immediately flush with large amounts of water for at least 15 minutes. Remove contact lenses if easy to do. Continue rinsing. Immediately get medical attention.

If swallowed
Rinse mouth. Do not induce vomiting. Get immediate medical attention.

4.2. Most important symptoms and effects, both acute and delayed

The most important symptoms and effects based on the CLP classification include:
Toxic if inhaled. Irritating to the respiratory tract (coughing, sneezing, nasal discharge, headache, hoarseness, and nose and throat pain). Skin burns (localized redness, swelling, itching, intense pain, blistering, and tissue destruction). Serious damage to the eyes (corneal cloudiness, severe pain, tearing, ulcerations, and significantly impaired or loss of vision). Toxic if swallowed. Central nervous system depression (headache, dizziness, drowsiness, incoordination, nausea, slurred speech, giddiness, and unconsciousness). Target organ effects. See Section 11 for additional details.

4.3. Indication of any immediate medical attention and special treatment required
Not applicable

SECTION 5: Fire-fighting measures

5.1. Extinguishing media
In case of fire: Use a water spray or fog to extinguish, do not use straight streams. If water is not available use dry chemical, CO2, or foam to extinguish. Refer to other precautionary advice in SDS section 5. Use a fire fighting agent suitable for the surrounding fire.

5.2. Special hazards arising from the substance or mixture
Closed containers exposed to heat from fire may build pressure and explode.

Hazardous Decomposition or By-Products

Substance	Condition
Carbon monoxide	During combustion.
Carbon dioxide.	During combustion.

5.3. Advice for fire-fighters
Leaking gas fire: Do not extinguish, unless leak can be stopped safely. Eliminate all ignition sources if safe to do so. Wear full protective clothing, including helmet, self-contained, positive pressure or pressure demand breathing apparatus, bunker coat and pants, bands around arms, waist and legs, face mask, and protective covering for exposed areas of the head.

SECTION 6: Accidental release measures

6.1. Personal precautions, protective equipment and emergency procedures
Evacuate area. Eliminate all ignition sources if safe to do so. Keep away from heat/sparks/open flames/hot surfaces. - No smoking. Ventilate the area with fresh air. For large spill, or spills in confined spaces, provide mechanical ventilation to disperse or exhaust vapours, in accordance with good industrial hygiene practice. Refer to other sections of this SDS for information regarding physical and health hazards, respiratory protection, ventilation, and personal protective equipment.

6.2. Environmental precautions
Avoid release to the environment.

6.3. Methods and material for containment and cleaning up
If possible, seal leaking container. Place leaking containers in a well-ventilated area, preferably an operating exhaust hood, or if necessary outdoors on an impermeable surface until appropriate packaging for the leaking container or its contents is available. Close cylinder. Place in a metal container approved for transportation by appropriate authorities. Dispose of collected material as soon as possible.

6.4. Reference to other sections
Refer to Section 8 and Section 13 for more information

SECTION 7: Handling and storage

7.1. Precautions for safe handling
For industrial/occupational use only. Not for consumer sale or use. Do not use in a confined area with minimal air exchange. Do not handle until all safety precautions have been read and understood. Keep away from heat/sparks/open

flames/hot surfaces. - No smoking. Take precautionary measures against static discharge. Do not breathe dust/fume/gas/mist/vapours/spray. Do not get in eyes, on skin, or on clothing. Do not eat, drink or smoke when using this product. Wash thoroughly after handling. Avoid release to the environment. Wash contaminated clothing before reuse. Eliminate all ignition sources if safe to do so. Avoid contact with oxidising agents (eg. chlorine, chromic acid etc.) Use personal protective equipment (eg. gloves, respirators…) as required. Recommendations for storing Steri-Gas cartridges are stringent. Check your local fire protection codes for additional requirements. Keep all sources of ignition such as matches, lighted cigarettes, sparks and static discharge away from the sterilzer and cartridges. Store cartridges in an upright position. Keep only one day's requirement or a maximum of twelve(12) cartridges (one box) in the immediate sterilizer area. This area needs to have at least ten air changes per hour. Additional Steri-Gas cartridges should be stored in an approved flammable liquid storage cabinet vented to the outside atmosphere, or in an area suitable for storage of flammable liquids appropriately vented to the outside atmosphere, or into a non-recirculating, continuously operating, dedicated exhaust system.

7.2. Conditions for safe storage including any incompatibilities
Store in a well-ventilated place. Keep container tightly closed. Protect from sunlight. Store away from heat. Do not expose to temperatures exceeding 50 ºC/122ºF. Store away from acids. Store away from oxidising agents. Store away from areas where product may come into contact with food or pharmaceuticals.

7.3. Specific end use(s)
See information in Section 7.1 and 7.2 for handling and storage recommendations. See Section 8 for exposure controls and personal protection recommendations.

SECTION 8: Exposure controls/personal protection

8.1 Control parameters

Occupational exposure limits
If a component is disclosed in section 3 but does not appear in the table below, an occupational exposure limit is not available for the component.

Ingredient	CAS Nbr	Agency	Limit type	Additional comments
ethylene oxide	75-21-8	Ireland OELs	TWA(8 hours):1 ppm(1.8 mg/m3);TWA(8 hours):1.8 mg/m3(1 ppm)	SKIN

Ireland OELs : Ireland. OELs
TWA: Time-Weighted-Average
STEL: Short Term Exposure Limit
CEIL: Ceiling

Biological limit values
No biological limit values exist for any of the components listed in Section 3 of this safety data sheet.

Derived no effect level (DNEL)

Ingredient	Degradation Product	Population	Human exposure pattern	DNEL
ethylene oxide		Worker	Inhalation, Long-term exposure (8 hours), Systemic effects	2 mg/m³
ethylene oxide		Worker	Inhalation, Short-term exposure, Systemic effects	10 mg/m³

Predicted no effect concentrations (PNEC)

Ingredient	Degradation Product	Compartment	PNEC
ethylene oxide		Freshwater	0.084 mg/l
ethylene oxide		Freshwater sediments	0.178 mg/kg d.w.

ethylene oxide		Intermittent releases to water	0.84 mg/l
ethylene oxide		Marine water	0.0084 mg/l
ethylene oxide		Sewage Treatment Plant	13 mg/l
ethylene oxide		Soil (direct only)	0.0136 kg/d

Recommended monitoring procedures: Information on recommended monitoring procedures can be obtained from Indust. Inspect./Ministry (IE)

8.2. Exposure controls

In addition, refer to the annex for more information.

8.2.1. Engineering controls
Use general dilution ventilation and/or local exhaust ventilation to control airborne exposures to below relevant Exposure Limits and/or control dust/fume/gas/mist/vapours/spray. If ventilation is not adequate, use respiratory protection equipment.

8.2.2. Personal protective equipment (PPE)

Eye/face protection

Select and use eye/face protection to prevent contact based on the results of an exposure assessment. The following eye/face protection(s) are recommended:
Full face shield.
Indirect vented goggles.

Applicable Norms/Standards
Use eye/face protection conforming to EN 166

Skin/hand protection
Select and use gloves and/or protective clothing approved to relevant local standards to prevent skin contact based on the results of an exposure assessment. Selection should be based on use factors such as exposure levels, concentration of the substance or mixture, frequency and duration, physical challenges such as temperature extremes, and other use conditions. Consult with your glove and/or protective clothing manufacturer for selection of appropriate compatible gloves/protective clothing. Note: Nitrile gloves may be worn over polymer laminate gloves to improve dexterity.
Gloves made from the following material(s) are recommended:

Material	**Thickness (mm)**	**Breakthrough Time**
Polymer laminate - PE/EVAL/PE	No data available	> 8 hours
Polymer laminate	No data available	1-4 hours

The glove data presented are based on the substance driving dermal toxicity and the conditions present at the time of testing. Breakthrough time may be altered when the glove is subjected to use conditions that place additional stress on the glove.

Applicable Norms/Standards
Use gloves tested to EN 374

If this product is used in a manner that presents a higher potential for exposure (eg. spraying, high splash potential etc.), then use of protective coveralls may be necessary. Select and use body protection to prevent contact based on the results of an exposure assessment. The following protective clothing material(s) are recommended: Apron - polymer laminate

Respiratory protection

An exposure assessment may be needed to decide if a respirator is required. If a respirator is needed, use respirators as part of a full respiratory protection program. Based on the results of the exposure assessment, select from the following respirator type(s) to reduce inhalation exposure:

Half facepiece or full facepiece supplied-air respirator

For questions about suitability for a specific application, consult with your respirator manufacturer.

Applicable Norms/Standards
Use a respirator conforming to EN 140 or EN 136

Thermal hazards
Wear cold insulating gloves/face shield/eye protection.

8.2.3. Environmental exposure controls
Refer to Annex

SECTION 9: Physical and chemical properties

9.1. Information on basic physical and chemical properties

Physical state	Gas.
Specific Physical Form:	Compressed gas.
Colour	Colourless
Odor	Sweet Odor
Odour threshold	*No data available.*
Melting point/freezing point	*Not applicable.*
Boiling point/boiling range	10.6 ºC
Flammability (solid, gas)	Flammable gas: Category 1.
Flammable Limits(LEL)	3 % volume
Flammable Limits(UEL)	100 % volume
Flash point	-20 ºC [*Test Method:*Tagliabue closed cup]
Autoignition temperature	428.9 ºC [*Details:*CONDITIONS: Burns in the absence of air]
Decomposition temperature	*Not applicable.*
pH	7
Kinematic Viscosity	*Not applicable.*
Water solubility	Complete
Solubility- non-water	*No data available.*
Partition coefficient: n-octanol/water	*No data available.*
Vapour pressure	145,854.3 Pa [@ 20 ºC]
Density	*Not applicable.*
Relative density	0.87 [*Ref Std:*WATER=1] [*Details:*@ 20 °C]
Relative Vapour Density	1.49 [*Ref Std:*AIR=1]
Particle Characteristics	*Not applicable.*

9.2. Other information

9.2.1 Information with regard to physical hazard classes

Explosive properties Gas under pressure: Liquefied gas.

9.2.2 Other safety characteristics

EU Volatile Organic Compounds *No data available.*
Evaporation rate *Not applicable.*
Molecular weight *No data available.*
Percent volatile 100 %

SECTION 10: Stability and reactivity

10.1 Reactivity
This material is considered to be non reactive under normal use conditions

10.2 Chemical stability
Stable.

10.3 Possibility of hazardous reactions
Hazardous polymerisation may occur.

10.4 Conditions to avoid
Heat.

10.5 Incompatible materials
None known.

10.6 Hazardous decomposition products

Substance	Condition
None known.	

Refer to section 5.2 for hazardous decomposition products during combustion.

SECTION 11: Toxicological information

The information below may not agree with the EU material classification in Section 2 and/or the ingredient classifications in Section 3 if specific ingredient classifications are mandated by a competent authority. In addition, statements and data presented in Section 11 are based on UN GHS calculation rules and classifications derived from internal hazard assessments.

11.1. Information on hazard classes as defined in Regulation (EC) No 1272/2008

Signs and Symptoms of Exposure

Based on test data and/or information on the components, this material may produce the following health effects:

Inhalation
Toxic if inhaled.
Respiratory tract irritation: Signs/symptoms may include cough, sneezing, nasal discharge, headache, hoarseness, and nose and throat pain. May cause additional health effects (see below).

Skin contact
Frostbite: Signs/symptoms may include intense pain, discoloration of skin, and tissue destruction. Corrosive (skin burns): Signs/symptoms may include localised redness, swelling, itching, intense pain, blistering, ulceration, and tissue destruction.

Eye contact
Frostbite: Signs/symptoms may include intense pain, clouding of the cornea, redness, swelling, and blindness. Corrosive (eye burns): Signs/symptoms may include cloudy appearance of the cornea, chemical burns, severe pain, tearing, ulcerations, significantly impaired vision or complete loss of vision.

Ingestion
Toxic if swallowed.
Gastrointestinal corrosion: Signs/symptoms may include severe mouth, throat and abdominal pain, nausea, vomiting, and diarrhea; blood in the faeces and/or vomitus may also be seen.

Additional Health Effects:

Single exposure may cause target organ effects:
Central nervous system (CNS) depression: Signs/symptoms may include headache, dizziness, drowsiness, incoordination, nausea, slowed reaction time, slurred speech, giddiness, and unconsciousness. Respiratory effects: Signs/symptoms may include cough, shortness of breath, chest tightness, wheezing, increased heart rate, bluish coloured skin (cyanosis), sputum production, changes in lung function tests, and respiratory failure.

Prolonged or repeated exposure may cause target organ effects:
Ocular effects: Signs/symptoms may include blurred or significantly impaired vision. Peripheral neuropathy: Signs/symptoms may include tingling or numbness of the extremities, incoordination, weakness of the hands and feet, tremors and muscle atrophy. Kidney/Bladder effects: Signs/symptoms may include changes in urine production, abdominal or lower back pain, increased protein in urine, increased blood urea nitrogen (BUN), blood in urine, and painful urination.

Reproductive/Developmental Toxicity:
Contains a chemical or chemicals which can cause birth defects or other reproductive harm.

Genotoxicity:
Genotoxicity and Mutagenicity: May interact with genetic material and possibly alter gene expression.

Carcinogenicity:
Contains a chemical or chemicals which can cause cancer.

Toxicological Data
If a component is disclosed in section 3 but does not appear in a table below, either no data are available for that endpoint or the data are not sufficient for classification.

Acute Toxicity

Name	Route	Species	Value
ethylene oxide	Inhalation-Gas (4 hours)	official classification	LC50 700 ppm
ethylene oxide	Ingestion	official classification	LD50 100 mg/kg

ATE = acute toxicity estimate

Skin Corrosion/Irritation

Name	Species	Value
ethylene oxide	Human and animal	Corrosive

Serious Eye Damage/Irritation

Name	Species	Value
ethylene oxide	similar health hazards	Corrosive

Skin Sensitisation

Name	Species	Value
ethylene oxide	Human and animal	Not classified

Respiratory Sensitisation

Name	Species	Value

ethylene oxide	Human	Not classified

Germ Cell Mutagenicity

Name	Route	Value
ethylene oxide	In vivo	Mutagenic

Carcinogenicity

Name	Route	Species	Value
ethylene oxide	Inhalation	Multiple animal species	Carcinogenic.

Reproductive Toxicity

Reproductive and/or Developmental Effects

Name	Route	Value	Species	Test result	Exposure Duration
ethylene oxide	Inhalation	Toxic to development	Rat	NOAEL 33 ppm	during organogenesis
ethylene oxide	Inhalation	Toxic to female reproduction	Rat	NOAEL 33 ppm	1 generation
ethylene oxide	Inhalation	Toxic to male reproduction	Monkey	LOAEL 50 ppm	2 years

Target Organ(s)

Specific Target Organ Toxicity - single exposure

Name	Route	Target Organ(s)	Value	Species	Test result	Exposure Duration
ethylene oxide	Inhalation	respiratory system	Causes damage to organs	Human and animal	NOAEL Not available	
ethylene oxide	Inhalation	central nervous system depression	May cause drowsiness or dizziness	Human	NOAEL Not available	
ethylene oxide	Inhalation	respiratory irritation	May cause respiratory irritation		NOAEL Not available	

Specific Target Organ Toxicity - repeated exposure

Name	Route	Target Organ(s)	Value	Species	Test result	Exposure Duration
ethylene oxide	Inhalation	peripheral nervous system	Causes damage to organs through prolonged or repeated exposure	Human and animal	NOAEL Not available	
ethylene oxide	Inhalation	kidney and/or bladder	May cause damage to organs though prolonged or repeated exposure	Mouse	LOAEL 100 ppm	14 weeks
ethylene oxide	Inhalation	eyes	May cause damage to organs though prolonged or repeated exposure	Human and animal	NOAEL Not available	
ethylene oxide	Inhalation	respiratory system	Some positive data exist, but the data are not sufficient for classification	Mouse	LOAEL 200 ppm	14 weeks
ethylene oxide	Inhalation	endocrine system	Not classified	Rat	NOAEL 100 ppm	2 years
ethylene oxide	Inhalation	liver	Not classified	Multiple animal species	NOAEL 841 ppm	not available
ethylene oxide	Inhalation	hematopoietic system	Not classified	Mouse	NOAEL 250 ppm	10 weeks
ethylene oxide	Inhalation	immune system	Not classified	Mouse	LOAEL 200 ppm	14 weeks

ethylene oxide	Inhalation	heart	Not classified	Monkey	NOAEL 100 ppm	2 years

Aspiration Hazard
For the component/components, either no data is currently available or the data is not sufficient for classification.

Please contact the address or phone number listed on the first page of the SDS for additional toxicological information on this material and/or its components.

11.2. Information on other hazards

This material does not contain any substances that are assessed to be an endocrine disruptor for human health.

SECTION 12: Ecological information

The information below may not agree with the EU material classification in Section 2 and/or the ingredient classifications in Section 3 if specific ingredient classifications are mandated by a competent authority. In addition, statements and data presented in Section 12 are based on UN GHS calculation rules and classifications derived from 3M assessments.

12.1. Toxicity

Material	Organism	Type	Exposure	Test endpoint	Test result
3M Steri-Gas Sterilisation Cartridges	Water flea	Laboratory	48 hours	N/A	137 mg/l
3M Steri-Gas Sterilisation Cartridges	Fathead minnow	Laboratory	96 hours	N/A	84 mg/l
3M Steri-Gas Sterilisation Cartridges	Goldfish	Laboratory	24 hours	N/A	90 mg/l

12.2. Persistence and degradability

Material	CAS Nbr	Test type	Duration	Study Type	Test result	Protocol
ethylene oxide	75-21-8	Experimental Biodegradation	28 days	BOD	107 %BOD/ThOD	OECD 301C - MITI test (I)
ethylene oxide	75-21-8	Experimental Hydrolysis		Hydrolytic half-life (pH 7)	12.9 days (t 1/2)	

12.3 : Bioaccumulative potential

Material	Cas No.	Test type	Duration	Study Type	Test result	Protocol
ethylene oxide	75-21-8	Experimental Bioconcentration		Log Kow	-0.3	OECD 107 log Kow shke flsk mtd

12.4. Mobility in soil

Material	Cas No.	Test type	Study Type	Test result	Protocol
ethylene oxide	75-21-8	Modeled Mobility in Soil	Koc	3 l/kg	Episuite™

12.5. Results of the PBT and vPvB assessment

This material does not contain any substances that are assessed to be a PBT or vPvB

12.6. Endocrine disrupting properties

This material does not contain any substances that are assessed to be an endocrine disruptor for environmental effects

12.7. Other adverse effects
No information available.

SECTION 13: Disposal considerations

13.1 Waste treatment methods
Dispose of contents/ container in accordance with the local/regional/national/international regulations.

Incinerate in a permitted waste incineration facility. As a disposal alternative, utilize an acceptable permitted waste disposal facility. The facility should be equipped to handle gaseous waste. Empty drums/barrels/containers used for transporting and handling hazardous chemicals (chemical substances/mixtures/preparations classified as Hazardous as per applicable regulations) shall be considered, stored, treated & disposed of as hazardous wastes unless otherwise defined by applicable waste regulations. Consult with the respective regulating authorities to determine the available treatment and disposal facilities.

The coding of a waste stream is based on the application of the product by the consumer. Since this is out of the control of 3M, no waste code(s) for products after use will be provided. Please refer to the European Waste Code (EWC - 2000/532/EC and amendments) to assign the correct waste code to your waste stream. Ensure national and/or regional regulations are complied with and always use a licensed waste contractor.

EU waste code (product as sold)
16 05 04* Gases in pressure containers (including halons) containing dangerous substances

EU waste code (product container after use)
15 01 04 Metallic packaging

SECTION 14: Transportation information

	Ground Transport (ADR)	Air Transport (IATA)	Marine Transport (IMDG)
14.1 UN number or ID number	UN1040	UN1040	UN1040
14.2 UN proper shipping name	ETHYLENE OXIDE	ETHYLENE OXIDE	ETHYLENE OXIDE
14.3 Transport hazard class(es)	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	Not Environmentally Hazardous	Not applicable	Not a Marine Pollutant
14.6 Special precautions for user	Please refer to the other sections of the SDS for further information.	Please refer to the other sections of the SDS for further information.	Please refer to the other sections of the SDS for further information.
14.7 Marine Transport in bulk according to IMO instruments	No data available.	No data available.	No data available.

Control Temperature	No data available.	No data available.	No data available.
Emergency Temperature	No data available.	No data available.	No data available.
ADR Classification Code	2TF	Not applicable.	Not applicable.
IMDG Segregation Code	Not applicable.	Not applicable.	NONE

Please contact the address or phone number listed on the first page of the SDS for additional information on the transport/shipment of the material by rail (RID) or inland waterways (ADN).

SECTION 15: Regulatory information

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

Carcinogenicity

Ingredient	CAS Nbr	Classification	Regulation
ethylene oxide	75-21-8	Grp. 1: Carcinogenic to humans	International Agency for Research on Cancer
ethylene oxide	75-21-8	Carc. 1B	Regulation (EC) No. 1272/2008, Table 3.1

Global inventory status
Contact 3M for more information.

DIRECTIVE 2012/18/EU
Seveso hazard categories, Annex 1, Part 1

Hazard Categories	Qualifying quantity (tonnes) for the application of	
	Lower-tier requirements	Upper-tier requirements
H2 ACUTE TOXICITY	50	200
P2 FLAMMABLE GASES	10	50

Seveso named dangerous substances, Annex 1, Part 2

Dangerous Substances	Identifier(s)	Qualifying quantity (tonnes) for the application of	
		Lower-tier requirements	Upper-tier requirements
ethylene oxide	75-21-8	5	50

Regulation (EU) No 649/2012

Chemical	Identifier(s)	Annex I
ethylene oxide	75-21-8	Part 1 and Part 3

15.2. Chemical Safety Assessment

A chemical safety assessment has been carried out for this substance/mixture in accordance with Regulation (EC) No 1907/2006, as amended.

SECTION 16: Other information

List of relevant H 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.
H301 + H331	Toxic if swallowed or if inhaled.
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.
H350	May cause cancer.
H360Fd	May damage fertility. Suspected of damaging the unborn child
H372	Causes damage to organs through prolonged or repeated exposure.
H372	Causes damage to organs through prolonged or repeated exposure: nervous system.

Revision information:
Section 1: REACH registration number information was modified.
Section 8: glove data value information was added.
Section 8: glove data value information was modified.
Section 09: Particle Characteristics N/A information was added.
Section 15: Carcinogenicity information information was modified.

Annex

1. Title	
Substance identification	ethylene oxide; EC No. 200-849-9; CAS Nbr 75-21-8;
Exposure Scenario Name	Industrial Use of EO Cartridge as Auxiliary to Specific Medical Device
Lifecycle Stage	Use at industrial sites
Contributing activities	PROC 03 -Manufacture or formulation in the chemical industry in closed batch processes with occasional controlled exposure or processes with equivalent containment condition ERC 04 -Use of non-reactive processing aid at industrial site (no inclusion into or onto article)
Processes, tasks and activities covered	Ancillary tasks in sterilisation room Unloading sterilised material
2. Operational conditions and risk management measures	
Operating Conditions	**Physical state:**Gaseous **General operating conditions:** Air exchange rate:: >= 10 ; Indoor use with Local Exhaust Ventilation; Room size:: >= 28 m3; **Task: Routine - unloading and handling sterilised equipment**; Duration of exposure per day at workplace [for one worker]: <= 90 minute; **Task: Ancillary tasks in sterilisation room**;

	Duration of exposure per day at workplace [for one worker]: <= 180 minute;
Risk management measures	Under the operational conditions described above the following risk management measures apply: **General risk management measures:** **Human health:** None needed; **Environmental:** None needed; ; The following task-specific risk management measures apply in addition to those listed above: **Task: Development and validation - worker exposure concentrations not yet characterised**; **Human Health**; SCBA; **Task: Routine - unloading and handling sterilised equipment**; **Human Health**; Load must be transferred directly from steriliser after standard aeration cycle to aerator; Maximum of 6 chamber openings per worker per shift; Refer to operator's manual during development and validation for requirements on exposure controls;
Waste management measures	No use-specific waste management measures are required for this product. Refer to Section 13 of main SDS for disposal instructions:
3. Prediction of exposure	
Prediction of exposure	Human and environmental exposures are not expected to exceed the DNELs and PNECs when the identified risk management measures are adopted.

1. Title	
Substance identification	ethylene oxide; EC No. 200-849-9; CAS Nbr 75-21-8;
Exposure Scenario Name	Professional Use of EO Cartridge as Auxiliary to Specific Medical Device
Lifecycle Stage	Widespread use by professional workers
Contributing activities	PROC 03 -Manufacture or formulation in the chemical industry in closed batch processes with occasional controlled exposure or processes with equivalent containment condition ERC 08a -Widespread use of non-reactive processing aid (no inclusion into or onto article, indoor)
Processes, tasks and activities covered	Ancillary tasks in sterilisation room Unloading sterilised material
2. Operational conditions and risk management measures	
Operating Conditions	**Physical state:**Gaseous **General operating conditions:** 90 minute in-chamber standard cycle aeration followed by 10.5 hours additional cycle aeration; 90 minute in-chamber standard cycle aeration followed by immediate transfer to separate aeration chamber; Air exchange rate:: >= 10 ; Indoor use with Local Exhaust Ventilation; Room size:: >= 28 m3; **Task: Routine - unloading and handling sterilised equipment**; Duration of exposure per day at workplace [for one worker]: <= 90 minute; **Task: Ancillary tasks in sterilisation room**; Duration of exposure per day at workplace [for one worker]: <= 180 minute;
Risk management measures	Under the operational conditions described above the following risk management measures apply:

	General risk management measures: **Human health:** If in-chamber aeration is <2 hours,place spent cartridge with product load when transferring to seperate aerator for additional aeration cycle.; **Environmental:** None needed; ; The following task-specific risk management measures apply in addition to those listed above: **Task: Routine - unloading and handling sterilised equipment**; **Human Health**; Load must be transferred directly from steriliser after standard aeration cycle to aerator; Maximum of 6 chamber openings per worker per shift;
Waste management measures	No use-specific waste management measures are required for this product. Refer to Section 13 of main SDS for disposal instructions:
3. Prediction of exposure	
Prediction of exposure	Human and environmental exposures are not expected to exceed the DNELs and PNECs when the identified risk management measures are adopted.

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