

# Ethylene Oxide

For use as a gaseous sterilant (PT2)

**Document IIIA**

**Section 8**

**Measures necessary to protect man, animals and the  
environment**

February 2020

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<p>Please refer to “Technical Notes for Guidance on Dossier Preparation including preparation and evaluation of study summaries under Directive 98/8 EC Concerning the Placing of Biocidal Products on the Market (Appendix 7.1 and 7.2)” for a list of the Standard Terms and Abbreviations used in this document.</p>
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<b>Section A8</b>	<b>Measures necessary to protect man, animals and the environment</b>	
		<b>Official use only</b>

## 8.1 Recommended methods and precautions concerning handling, use, storage, transport or fire

<b>8.1.0 Methods and precautions concerning placing on the market</b>	<p>Engineering controls are required equipment must be compliant with ATEX (<i>Appareils destinés à être utilisés en ATmosphères Explosibles</i>) Directives. Equipment location must be in compliance with national guidance if appropriate.</p> <p>Protection measures should be implemented following a proper risk assessment carried out to meet specific local conditions.</p>	
<b>8.1.1 Methods and precautions concerning production, handling and use of the active substance and its formulations</b>	<p><b>Handling –</b>          Use spark/explosion proof appliances and lighting systems.          Use antistatic tools.          Use earthed equipment.          Keep away from naked flames/heat.          Keep away from ignition sources/sparks.          Treatment should only take place in suitable rooms and systems.          Observe very strict hygiene – avoid contact.          Remove contaminated clothing immediately.          Use only in thoroughly ventilated areas.          Transfer and handle only in enclosed systems.          Ensure that barrels and installations are thoroughly earthed (grounded).          Measure the concentration in air regularly.</p> <p><b>Engineering controls –</b>          Prevent cylinders from falling over.          Ensure valve protection device is correctly fitted.          Ensure that valve outlet cap nut or plug (where provided) is properly fitted.          Open valve slowly to avoid pressure shock.          Do not allow backfeed into the container.          Work under local exhaust/ventilation.          Exhaust gas must be neutralised.          Gas chromatograph based leak detection systems should be in use in process plants and laboratories where EtO may be present.</p> <p><b>Exposure limits</b>          Belgium – 1ppm – Time-weighted average exposure limit 8h.          Netherlands – 0.46ppm, 0.84mg/m<sup>3</sup> – Time-weighted average exposure limit 8h (public occupational exposure limit value).          France – 1ppm – Time-weighted average exposure limit 8h (Valeur non réglementaire indicative). 5ppm – Short time value Valeur non réglementaire indicative).          UK – 5ppm, 9.2mg/m<sup>3</sup> – Time-weighted average exposure limit 8h (Workplace exposure limit (EH40/2005))</p> <p><b>Personal protection (also applicable for accidental release)</b>  <b>Respiratory -</b></p>	<b>X</b>

	<p>Gas mask with filter type AX. Self-contained breathing apparatus if conc. In air &gt;5ppm. Keep self-contained breathing apparatus readily available for emergency use. In case of rescue and maintenance activities in storage containers use environment-independent breathing apparatus because of risk of suffocation by edging out of oxygen from the air.</p> <p><b>Hand -</b> Insulated gloves. Materials: Good resistance – butyl rubber Less resistance – neoprene, natural rubber Poor resistance – polyethylene, PVC, nitrile rubber, leather</p> <p><b>Eye -</b> Safety goggles, in case of increased risk add protective face shield</p> <p><b>Skin and body -</b> Protective clothing. Head/neck protection.</p> <p><b>Other information -</b> Do not inhale gases/vapours/aerosols At work do not eat, drink or smoke.</p>	
<p><b>8.1.2 Methods and precautions concerning storage of the active substance and its formulations</b></p>	<p><b>Warehouse storage –</b> Ethylene oxide should be stored in a cool, dark, well-labelled, well – ventilated, fire proof area and provide automatic sprinkler system preferably away from other chemicals, outdoors, or in a detached building or shelter. Unauthorised persons should not be admitted. Provide a tub to collect spills. Sources of heat and ignition should be kept away Gas/vapour heavier than air at 20°C - Provide good room ventilation, even at ground level. May be stored under inert gas. Suitable packaging material – stainless steel, carbon steel, polypropylene. Non-suitable packaging material – aluminium, iron, copper, tin Ethylene oxide should be kept in closed original container. Suitable materials for the valve are brass, copper alloys, carbon steels, aluminium alloys or stainless steel.</p> <p><b>User level storage –</b> Do not store with animal feedstuffs. Do not store together with food. Do not store together with oxidising agents. Keep away from heat sources, ignition sources, combustible materials, oxidising agents, (strong) acids, (strong) bases, highly flammable materials, metals, halogens, alcohols, amines, water/moisture. Provide the tank with earthing. Keep container tightly closed and store in a cool and ventilated place. Prevent cylinders from falling over. Protect from heat Storage temperature must not exceed 50°C and it is recommended to keep the temperature below 10°C</p>	
<p><b>8.1.3 Methods and precautions concerning transport of the active substance and its formulations</b></p>	<p><b>Land transport</b> ADR/RID UN 1040. Classification code 2TF Avoid transport on vehicles where the load space is not separated from the driver's compartment.</p>	

	<p>Ensure vehicle driver is aware of the potential hazards of the load and knows what to do in the event of an accident or an emergency.</p> <p>Before transporting product containers :</p> <ul style="list-style-type: none"> <li>- Ensure that containers are firmly secured.</li> <li>- Ensure cylinder valve is closed and not leaking.</li> <li>- Ensure valve outlet cap nut or plug (where provided) is correctly fitted.</li> <li>- Ensure valve protection device (where provided) is correctly fitted.</li> <li>- Ensure there is adequate ventilation.</li> </ul> <p><b>Sea transport</b> IMDG UN 1040 Ethylene Oxide Classes 2.3 (toxic substance) and 2.1 flammable gas</p> <p><b>Air transport:</b> ICAO/IATA-DGA Forbidden</p>	
<p><b>8.1.4 Methods and precautions concerning fire of the active substance and its formulations</b></p>	<p><b>Extinguish media</b></p> <p>Suitable extinguishing media Small fire – Quick-acting ABC powder extinguisher, Quick-acting BC powder extinguisher.</p> <p>Unsuitable extinguishing media Small fire – Quick-acting CO2 extinguisher, water (water can be used to control jet flame), foam Major fire – Water (water can be used to control jet flame), foam</p> <p><b>Special exposure hazards</b> – In case of fire, formation of dangerous gasses is possible. Formation of explosive mixtures in air is possible. In the event of a fire carbon monoxide and carbon dioxide are formed.</p> <p>On heating, explosive decomposition. Polymerises on exposure to temperature rise, on exposure to impurities, on exposure to light, on exposure to (some) metals and on exposure to acids/bases with heat release resulting in increased fire or explosion risk. Reacts slowly on exposure to water/moisture: heat release resulting in increased fire or explosion risk.</p> <p><b>Protective equipment</b> – Use breathing apparatus with an independent air supply. Wear full protective clothing, insulating gloves, head/neck protection.</p> <p>Advice for firefighters – If no hazards for/from the surroundings: controlled burning. If hazardous substances are nearby: consider extinguishment. Extinguish only if gas supply/leak can be shut afterwards. Physical explosion risk: extinguish/cool from behind cover. Do not move the load if exposed to heat. Take account of toxic fire-fighting water: use water moderately and if possible collect or contain it.</p> <p><b>Other information</b> – Cool tanks/drums/endangered containers with water spray jet or remove to safety. Exposure to fire may cause containers to rupture/explode. Do not extinguish a leaking gas flame unless absolutely necessary. Spontaneous /explosive re-ignition may occur. Extinguish any other fire.</p>	

## 8.2 In case of fire, nature of reaction products, combustion gases, etc.

<b>Hazardous decomposition/combustion products –</b>	Carbon monoxide, carbon dioxide.	
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## 8.3 Emergency measures in case of an accident

<b>8.3.1 Specific treatment in case of an accident, e.g. first-aid measures, antidotes, medical treatment if available</b>	<p><b>Symptoms and effects –</b></p> <p><b>First aid</b></p> <p><b>General</b> – Check vital functions. Unconscious: maintain adequate airway and respiration. Respiratory arrest: artificial respiration or oxygen. Cardiac arrest: perform resuscitation. Victim conscious with laboured breathing: half-seated. Victim in shock: on his back with legs slightly raised. Vomiting: prevent asphyxia/aspiration pneumonia. Prevent cooling by covering the victim (no warming up). Keep watching the victim. Give psychological aid. Keep the victim calm, avoid physical strain. Depending on the victim’s condition: doctor/hospital. Never give alcohol.</p> <p><b>Inhalation</b> – Remove the victim into fresh air. Immediately consult a doctor/medical service. Do not apply mouth-to-mouth resuscitation.</p> <p><b>Skin contact</b> – Wash immediately with plenty of water. Soap may be used. Do not apply (chemical) neutralizing agents. Take victim to a doctor if irritation persists. In case of frostbite: wash immediately with plenty of water (15 minutes)/shower. Do not remove clothing if it sticks to the skin. Cover wounds with sterile bandage. Consult a doctor/medical service.</p> <p><b>Eye contact</b> – Rinse immediately with plenty of water for 15 minutes. Do not apply neutralising agents. Remove contact lenses, if present and easy to do. Continue rinsing. Take victim to an ophthalmologist.</p> <p><b>Ingestion</b> – Immediately after ingestion: give plenty of water to drink. Do not induce vomiting. Consult a doctor/medical service if you feel unwell.</p> <p><b>Advice to physicians</b>  <b>Symptoms of acute poisoning</b>  <b>Eyes:</b> Irritation of the eye tissue. Frostbites.  <b>Skin:</b> Frostbites. Tingling/irritation of the skin. Following symptoms may appear later: swelling of the skin. Red skin. Blisters. May stain the skin. After contact with water: caustic burns/corrosion of the skin.</p> <p><b>Inhalation:</b> Dry/sore throat. Irritation of the respiratory tract. Irritation of the nasal mucous membranes. Central nervous system depression. Nausea. Vomiting. Headache. Dizziness. Disturbances of consciousness. Exposure to high concentrations: disturbances of heart rate. Respiratory difficulties. Following symptoms may appear later: cramps/uncontrolled muscular contractions. Risk of lung oedema.</p> <p><b>Ingestion:</b> Not applicable</p>	
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	Delayed symptoms: no effects known.	
<b>8.3.2 Emergency measures to protect the environment</b>	<p><b>Personal precautions, protective equipment and emergency procedures:</b> Keep upwind. Seal off low-lying areas. Close doors and windows or adjacent premises. Stop engines and no smoking. No naked flames or sparks. Use spark and explosion proof appliances and lighting equipment. Protect substance from light. Avoid ingress of water into containers. Wear insulating gloves, head/neck protection, protective clothing.</p> <p><b>Environmental precautions:</b> Contain released product, pump into suitable containers. Plug the leak, cut off the supply. Dam up the liquid spill. Tip the container on one side to stop the leak. Try to reduce evaporation. Take account of toxic/corrosive precipitation water. Prevent soil and water pollution. Prevent spreading in sewers.</p> <p><b>Methods and materials for containment and clean up:</b> Damaged/cooled tanks must be emptied. Do not use compressed air for pumping over spills. Prevent evaporation in covering with: foam. Take collected spill to manufacturer/competent authority. Wash clothing and equipment after handling.</p>	

#### 8.4 Possibility of destruction or decontamination following release in or on the following:

<b>8.4.1 Possibility of destruction or decontamination following release in the air</b>	Any ethylene oxide exhausted to the atmosphere is expected to be rapidly dispersed and diluted and will subsequently be degraded to concentrations equivalent to or below naturally occurring background levels.	<b>X</b>
<b>8.4.2 Possibility of destruction or decontamination following release in water, including drinking water</b>	If exposed to water ethylene oxide is expected to undergo hydrolysis and biological degradation and the duration of any potential exposure will therefore be short-lived. The rapid volatilisation rate in water (volatilisation half-life in water ~1 hour), will also limit the environmental exposure to ethylene oxide.	
<b>8.4.3 Possibility of destruction or decontamination following release in or on soil</b>	If exposed to soil ethylene oxide is expected to undergo hydrolysis and biological degradation and the duration of any potential exposure will therefore be short-lived.	

#### 8.5 Procedures for waste management of the active substance for industry or professional users e.g. possibility of re-use or recycling, neutralisation, conditions for controlled discharge, and incineration

<b>8.5.1 Possibility of re-use or recycling</b>	<p><b>Disposal of product contaminated packaging</b> – Transportable pressure equipment (empty, residual pressure) should be returned to the supplier/manufacturer. Waste material code packaging (Directive 2008/98/EC): 15 01 10*(packaging containing residues or contaminated by dangerous substances).</p> <p><b>Provisions relating to waste:</b></p>	<b>X</b>
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	<p>Waste material code (Directive 2008/98/EC): 16 05 04*(gases in pressure containers and discarded chemicals: gases in pressure containers (including halons) containing hazardous substances). Depending on branch of industry and production process, also other waste codes may apply.</p> <p><b>Disposal methods:</b> Refer to manufacturer/supplier for information on recovery/recycling. Remove waste in accordance with local and/or national regulations. Hazardous waste shall not be mixed together with other waste. Different types of hazardous waste shall not be mixed together if this may entail a risk of pollution or create problems for the further management of the waste. Hazardous waste shall be managed responsibly. All entities that store, transport or handle hazardous waste shall take the necessary measures to prevent risks of pollution or damage to people or animals.</p>	
<b>8.5.2 Possibility of neutralisation of effects</b>	On completion of the process, ethylene oxide from the chamber is exhausted to the atmosphere via a catalytic converter which converts the gas to carbon dioxide and water, typically with efficiency greater than 99.9%. The sterilisation chamber is then repeatedly flushed with nitrogen and / or air to remove the remaining ethylene oxide from the chamber and the sterilised products are subjected to high rates of air exchange to remove any residual ethylene oxide from the product and packaging.	
<b>8.5.3 Conditions for controlled discharge including leachate qualities on disposal</b>	Do not discharge into drains or the environment.	
<b>8.5.4 Conditions for controlled incineration</b>	Not applicable	

### 8.6 Observations on undesirable or unintended side-effects, for example, on beneficial and other non-target organisms

	No undesirable or unintended side-effects have been observed. Direct exposure to soil and the natural terrestrial environment will not occur following use of ethylene oxide as proposed and any indirect exposure is expected to be extremely low. It will also undergo hydrolysis and biological degradation in soil and water and so there will be no chronic exposure. In these circumstances the risk to non-target organisms will be negligible	<b>X</b>
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### 8.7 Identification of any substances falling within the scope of List I or List II of the Annex to Directive 80/68/EEC on the protection of ground water against pollution caused by certain dangerous substances

	Ethylene oxide does not fall within the scope of List I. List II of the directive covers all biocidal products.	
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	<b>Evaluation by Competent Authorities</b>	
	<b>Evaluation by Rapporteur Member State</b>	
<b>Date</b>	02 March 2020	
<b>Sections 8.1-8.7</b>	<p><b>Comment (8.1.1.)</b> Occupational exposure limits for Ethylene oxide is currently defined in directive (EU) 2017/2398 <i>on the protection of workers from the risks related to exposure to carcinogens or mutagens at work</i>, which entered into force 17 January 2020. Directive (EU) 2017/2398 defines a maximum OEL for EtO of 1.8 mg/m<sup>3</sup>, equivalent to 1 ppm, but more stringent binding OELs can be set nationally by individual Member States.</p> <p>The DMEL derived for professionals in the biocide evaluation is significantly lower than the OEL given in Directive (EU) 2017/2398: 3 ppb versus 1 ppm.</p> <p><b>Comment (8.4.1):</b> Reference should be made to the CAR, chapter A.4. Ethylene oxide is relatively persistent in air, and the residence time in air upon release therefore depends on other conditions in the air, such as wind and convection.</p> <p><b>Comment (8.5.1):</b> According to the applicant, any potential liquid waste (e.g. from acid scrubbers) containing ethylene oxide is not released to STPs and subsequently to surface waters, but handled specifically as toxic waste and disposed of without emissions to the environment. Therefore, no risk assessment has been done covering the release to STPs. It is important that this release pathway to the environment is avoided.</p> <p><b>Comment (8.6):</b> Reference should be made to the CAR, chapter A.4.</p>	
<b>Reliability</b>	0 (not applicable)	
<b>Acceptability</b>	These measures must be re-evaluated prior to the product authorisation phase in order to ensure that they comply with the hazards of the active substance and the risk assessment of the product.	
<b>Remarks</b>	-	