

Ethylene Oxide

For use as a gaseous sterilant (PT2)

Document IIIA

Section 9





**Proposals including justification for the
classification and labelling of the active substance**

September 2019

9. CLASSIFICATION AND LABELLING

Classification and labelling

Current classification and labelling:






Hazard symbol(s):				
Indications of danger:	Flam. Gas 1	Press. Gas	Acute Tox 3 by inhalation Eye Irrit. 2 Skin Irrit. 2	Carc 1B Muta. 1B STOT SE 3
Hazard statements:	H220	Extremely flammable gas		
	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, sparks, open flames or hot surfaces		
	P260	Do not breath gas		
	P280	Wear protective gloves/protective clothing/ eye protection/face protection		
	P302 + P352	If on skin: Wash with plenty of soap and water		
	P304 + P340+ P315	IF INHALED: Remove victim to fresh air and keep at rest in a position comfortable for breathing. Get immediate medical advice/attention		
	P305 + P351 + P338+315	If in eyes: Rinse cautiously with warm water for several minutes. Remove contact lenses, if present and easy to do so. Get immediate medical advice/attention		
	P308 +P313	If exposed or concerned: Get medical advice/attention		
	P332+ P313	If skin irritation occurs: Get medical advice/attention		
	P377	Leaking gas fire: Do not extinguish, unless leak can be stopped safely		
	P381	Eliminate all ignition sources if safe to do so		

	P403	Store in well ventilated place
	P405	Store locked up

Justifications for the proposal

Chemistry classification criteria	
Explosive properties	Ethylene oxide is explosive at concentrations of greater than 3% vol in air.
Oxidising properties	None
Flammability	Extremely flammable. Flammable limits of 3-100% in ambient air.
Health classification criteria	
Acute oral toxicity	The LD ₅₀ was 330 mg/kg bw in the rat (95% CI 290-360 mg/kg bw) and 270 mg/kg bw (95% CI 190-380 mg/kg bw) in the guinea pig.
Acute dermal toxicity	No reports of the dermal toxicity of ethylene oxide were found
Acute inhalation toxicity	The 4 hour LD ₅₀ in rats is 1.4 mg/L
Skin irritation	No information was found on skin irritation
Eye irritation	Ethylene oxide has been shown to be an irritant to the eye of the rabbit.
Skin sensitisation	No information was found on skin sensitisation
Environmental classification criteria	
96 hour LC ₅₀ , fish	The LD ₅₀ value for Fathead minnow was 84 mg/L
48 hours EC ₅₀ , <i>Daphnia magna</i>	The 48 hour EC ₅₀ values for <i>Daphnia magna</i> were between 137 and 300 mg/L
96 hour EC ₅₀ , algae	No information was reported on the toxicity of ethylene oxide to algae
48 hour LD ₅₀ , honey bee	No information was reported on the toxicity of ethylene oxide to honey bees
Ready biodegradability	Ethylene oxide is not classified as readily biodegradable
Log P _{ow}	-0.30
Bioconcentration factor (BCF)	Ethylene oxide is not expected to bioaccumulate

Proposed classification and labelling in accordance with the revised harmonised classification for Ethylene Oxide, due to be published in the 14th ATP in January 2020:

Hazard symbol(s):					
Indications of danger:	Flam. Gas 1	Press. Gas	Skin Corr. 1 Eye Dam. 1	Acute Tox 3 by inhalation Acute Tox 3 if swallowed	Carc 1B Muta. 1B Repr. 1B STOT SE 3 STOT RE 1
Hazard statements:	H220		Extremely flammable gas		
	H280		Contains gas under pressure; may explode if heated		
	H350		May cause cancer		
	H340		May cause genetic defects		
	H360Fd		May damage fertility and the unborn child		
	H301		Toxic if swallowed		
	H331		Toxic if inhaled		
	H335		May cause respiratory irritation		
	H336		May cause drowsiness or dizziness		
	H372		Causes damage to organs (nervous system) through prolonged or repeated exposure		
	H314		Causes severe skin burns and eye damage		
	H318		Causes serious eye damage		
Precautionary statements:	P202		Do not handle until all safety precautions have been read and understood		
	P210		Keep away from heat, sparks, open flames or hot surfaces		
	P260		Do not breathe gas		
	P377		Leaking gas fire: Do not extinguish, unless leak can be stopped safely		
	P280		Wear protective gloves/protective clothing/ eye protection/face protection		
	P308 + P313		If exposed or concerned: Get medical advice/attention		
	P301 + P330 + P331		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
	P304 + P340 + P310		IF INHALED: Remove person to fresh air and keep comfortable for breathing. Immediately call a POISON CENTER/doctor
	P305 + P351 + P338		If in eyes: Rinse cautiously with warm water for several minutes. Remove contact lenses, if present and easy to do so.
	P403 + P233		Store in a well-ventilated place. Keep container tightly closed
	P405		Store locked up

Evaluation by Competent Authorities	
	Evaluation by Rapporteur Member State
Date	02 March 2020
Materials and Methods	Not applicable.
Results and discussion	<p>Comments to justification for the proposal:</p> <p><u>General comment:</u> Regarding the justifications for the harmonised classification of ethylene oxide, the eCA refers to the CLH report and has not evaluated the justifications given by the applicant in this document.</p> <p><u>Environmental classification criteria:</u> Read-across data for algal toxicity are available, but they are above environmental classification criteria ($EC_{50} = 240$ mg/L and no reasons to believe that the value for ethylene oxide would be significantly lower). The eCA considers that the available data does not warrant a discussion on environmental classification of ethylene oxide in the context of this risk assessment.</p> <p>Comment to the classification listed with reference to the 14th ATP to CLP:</p> <p>The hazard statement code H280 is not part of the harmonised classification. However, this hazard statement code seems appropriate for the product D495 SS.</p>
Conclusion	The harmonised classification of ethylene oxide as given in Regulation (EC) No. 1272/2008, amended by the 14 th ATP to CLP, applies.
Reliability	Not applicable.
Acceptability	Not applicable.
Remarks	According to the applicant commercial products are provided in containers made from suitable material such as aluminium canisters or stainless steel drums.