

## **Annex XV dossier**

# **PROPOSAL FOR IDENTIFICATION OF A SUBSTANCE AS A CMR 1A OR 1B, PBT, vPvB OR A SUBSTANCE OF AN EQUIVALENT LEVEL OF CONCERN**

**Substance Name:** Methyloxirane [Propylene oxide]

**EC Number:** 200-879-2

**CAS Number:** 75-56-9

**Submitted by:** European Chemicals Agency at the request of the European Commission



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## **PROPOSAL FOR IDENTIFICATION OF A SUBSTANCE AS A CMR 1A OR 1B, PBT, VPVB OR A SUBSTANCE OF AN EQUIVALENT LEVEL OF CONCERN**

**Substance Name: Methyloxirane [Propylene oxide]**

**EC Number: 200-879-2**

**CAS number: 75-56-9**

The substance is proposed to be identified as substance meeting the criteria of Article 57 (a) and 57 (b) of Regulation (EC) 1907/2006 (REACH) owing to its classification as carcinogen 1B and mutagen category 1B<sup>1</sup> which corresponds to classification as carcinogen category 2 and mutagen category 2<sup>2</sup>.

### **Summary of how the substance meets the criteria set out in Article 57 (a) and 57 (b) of REACH (Carc. 1B and Muta. 1B).**

Methyloxirane [Propylene oxide] is covered by Index number 603-055-00-4 in Regulation (EC) No 1272/2008 and classified in Annex VI, part 3, Table 3.1 (list of harmonised classification and labelling of hazardous substances) as carcinogen, Carc. 1B (H350: "May cause cancer") and mutagenic Muta. 1B (H340: "May cause genetic defects"). The corresponding classification in Annex VI, part 3, Table 3.2 (the list of harmonised and classification and labelling of hazardous substances from Annex I to Directive 67/548/EEC) of Regulation (EC) No 1272/2008 is carcinogen, Carc. Cat. 2; R45 ("May cause cancer") and mutagen, Muta. Cat. 2; R46 ("May cause heritable genetic damage").

Therefore, this classification of the substance in Regulation (EC) No 1272/2008 shows that it meets the criteria for classification as carcinogenic and mutagenic in accordance with Article 57 (a) and 57 (b) of REACH.

### **Registration dossiers submitted for the substance? Yes**

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<sup>1</sup> Classification in accordance with Regulation (EC) No 1272/2008 Annex VI, part 3, Table 3.1 List of harmonised classification and labelling of hazardous substances.

<sup>2</sup> Classification in accordance with Regulation (EC) No 1272/2008, Annex VI, part 3, Table 3.2 List of harmonised classification and labelling of hazardous substances (from Annex I to Council Directive 67/548/EEC).

## **PART I**

### **JUSTIFICATION**

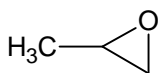
# 1 Identity of the substance and physical and chemical properties

## 1.1 Name and other identifiers of the substance

**Table 1: Substance identity**

<b>EC number:</b>	200-879-2
<b>EC name:</b>	methyloxirane
<b>CAS number (in the EC inventory):</b>	75-56-9
<b>CAS number:</b> <b>Deleted CAS numbers:</b>	75-56-9 16033-71-9
<b>CAS name:</b>	Oxirane, 2-methyl-
<b>IUPAC name:</b>	2-Methyloxirane
<b>Index number in Annex VI of the CLP Regulation</b>	603-055-00-4
<b>Molecular formula:</b>	C <sub>3</sub> H <sub>6</sub> O
<b>Molecular weight range:</b>	58.1 g/mol
<b>Synonyms:</b>	Oxirane, methyl- ; Oxypropylene; Propane, 1,2-epoxy- ; Propylene oxide; (±)-1,2-Epoxypropane; (±)-2-Methyloxirane; (±)-Epoxypropane; (±)-Methyloxirane; (±)-Propylene oxide; 1,2-Epoxypropane; 1,2-Propylene oxide; 2,3-Epoxypropane; 2-Methyloxirane; DL-1,2-Epoxypropane; Epihydrin; Epoxypropane; Methyloxacyclopropane; Methyloxirane; Propene oxide; Propozone; Propylene epoxide; dl-Propylene oxide

### Structural formula:



## 1.2 Composition of the substance

**Name:** Methyloxirane [Propylene oxide]

**Description:** ---

**Degree of purity:** 98 – 100 %

**Table 2: Constituents**

<b>Constituents</b>	<b>Typical concentration</b>	<b>Concentration range</b>	<b>Remarks</b>
Methyloxirane 200-879-2		98 – 100 %	Information according to the available registration dossiers.

## 2 Harmonised classification and labelling

Methyloxirane [Propylene oxide] is covered by Index number 603-055-00-4 in Annex VI, part 3 of Regulation (EC) No 1272/2008 as follows:

**Table 3: Classification according to part 3 of Annex VI, Table 3.1 ((list of harmonised classification and labelling of hazardous substances) of Regulation (EC) No 1272/2008**

Index No	International Chemical Identification	EC No	CAS No	Classification		Labelling			Spec. Conc. Limits, M-factors	Notes
				Hazard Class and Category Code(s)	Hazard statement code(s)	Pictogram, Signal Word Code(s)	Hazard statement code(s)	Suppl. Hazard statement code(s)		
603-055-00-4	propylene oxide; 1,2-epoxypropane; methyloxirane	200-879-2	75-56-9	Flam. Liq. 1 Carc. 1B Muta. 1B Acute Tox. 4 * Acute Tox. 4 * Acute Tox. 4 * Eye Irrit. 2 STOT SE 3 Skin Irrit. 2	H224 H350 H340 H332 H312 H302 H319 H335 H315	GHS02 GHS08 GHS07 Dgr	H224 H350 H340 H332 H312 H302 H319 H335 H315			



**Table 4: Classification according to part 3 of Annex VI, Table 3.2 (list of harmonized classification and labelling of hazardous substances from Annex I of Council Directive 67/548/EEC) of Regulation (EC) No 1272/2008**

<b>Index No</b>	<b>International Chemical Identification</b>	<b>EC No</b>	<b>CAS No</b>	<b>Classification</b>	<b>Labelling</b>	<b>Concentration Limits</b>	<b>Notes</b>
603-055-00-4	propylene oxide; 1,2-epoxypropane; methyloxirane	200-879-2	75-56-9	F+; R12 Carc. Cat. 2; R45 Muta. Cat. 2; R46 Xn; R20/21/22 Xi; R36/37/38	F+; T R: 45-46- 12-20/21/ 22- 36/37/38 S: 53-45		E

### **3 Environmental fate properties**

*Not relevant for the identification of the substance as SVHC in accordance with Article 57 (a) and (b).*

### **4 Human health hazard assessment**

*See section 2 on harmonised classification and labelling.*

### **5 Environmental hazard assessment**

*Not relevant for the identification of the substance as SVHC in accordance with Article 57(a) and (b).*

## **6 Conclusions on the SVHC Properties**

### **6.1 CMR assessment**

Methyloxirane [Propylene oxide] is covered by Index number 603-055-00-4 in Regulation (EC) No 1272/2008 and classified in Annex VI, part 3, Table 3.1 (list of harmonised classification and labelling of hazardous substances) as carcinogen, Carc. 1B (H350: "May cause cancer") and mutagenic Muta. 1B (H340: "May cause genetic defects"). The corresponding classification in Annex VI, part 3, Table 3.2 (the list of harmonised and classification and labelling of hazardous substances from Annex I to Directive 67/548/EEC) of Regulation (EC) No 1272/2008 is carcinogen, Carc. Cat. 2; R45 ("May cause cancer") and mutagen, Muta. Cat. 2; R46 ("May cause heritable genetic damage").

Therefore, this classification of the substance in Regulation (EC) No 1272/2008 shows that it meets the criteria for classification as carcinogenic and mutagenic in accordance with Article 57 (a) and 57 (b) of REACH.

## **PART II**

### **INFORMATION ON USE, EXPOSURE, ALTERNATIVES AND RISKS**

The available use and exposure information is provided in the registration dossiers (authorities with access rights only) or on ECHA's dissemination website<sup>3</sup>:

<http://echa.europa.eu/information-on-chemicals>

ECHA has not carried out further analysis of this information.

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<sup>3</sup> Information published by ECHA on the substance can be searched at this site (field "Search for Chemicals" at upper right) by EC number, CAS number or substance name.