

## **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:** Dimethyl sulphate

**EC Number:** 201-058-1

**CAS Number:** 77-78-1

**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: Dimethyl sulphate**

**EC Number: 201-058-1**

**CAS number: 77-78-1**

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

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

Dimethyl sulphate is listed as Index number 016-023-00-4 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."). The corresponding classification in Annex VI, part 3, Table 3.2 (the list of harmonised 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.").

Therefore, this classification of dimethyl sulphate in Regulation (EC) No 1272/2008 shows that the substance meets the criteria for classification as carcinogenic in accordance with Article 57 (a) 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

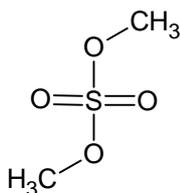
#### 1 Identity of the substance and physical and chemical properties

##### 1.1 Name and other identifiers of the substance

Table 1: Substance identity

<b>EC number:</b>	201-058-1
<b>EC name:</b>	dimethyl sulphate
<b>CAS number (in the EC inventory):</b>	77-78-1
<b>CAS number:</b> <b>Deleted CAS numbers:</b>	77-78-1 62086-97-9, 98478-67-2, 139443-72-4
<b>CAS name:</b>	Sulfuric acid, dimethyl ester
<b>IUPAC name:</b>	Dimethyl sulfate
<b>Index number in Annex VI of the CLP Regulation</b>	016-023-00-4
<b>Molecular formula:</b>	C <sub>2</sub> H <sub>6</sub> O <sub>4</sub> S
<b>Molecular weight range:</b>	126.1 g/mol
<b>Synonyms:</b>	

**Structural formula:**



## 1.2 Composition of the substance

**Name:** Dimethyl sulphate

**Description:** ---

**Degree of purity:** 98 – 100 %

**Table 2: Constituents**

<b>Constituents</b>	<b>Typical concentration</b>	<b>Concentration range</b>	<b>Remarks</b>
Dimethyl sulphate 201-058-1		98 – 100 %	Information according to the available registration dossiers.

## 2 Harmonised classification and labelling

Dimethyl sulphate is listed by Index number 016-023-00-4 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)		
016-023-00-4	dimethyl sulphate	201-058-1	77-78-1	Carc. 1B Muta. 2 Acute Tox. 2 * Acute Tox. 3 * Skin Corr. 1B Skin Sens. 1	H350 H341 H330 H301 H314 H317	GHS06 GHS08 GHS05 Dgr	H350 H341 H330 H301 H314 H317		Carc. 1B; H350: C ≥ 0,01 % Muta. 2; H341: C ≥ 0,01 % STOT SE 3; H335: C ≥ 5 %	

**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**

Index No	International Chemical Identification	EC No	CAS No	Classification	Labelling	Concentration Limits	Notes
016-023-00-4	dimethyl sulphate	201-058-1	77-78-1	Carc. Cat. 2; R45 Muta. Cat. 3; R68 T+; R26 T; R25 C; R34 R43	T+ R: 45-25- 26-34-43- 68 S: 53-45	Car. Cat. 2; R45: C ≥ 0,01 % Muta. Cat. 3, R68: C ≥ 0,01 % C; R34: C ≥ 10 % Xi; R36/37/38: 5 % ≤ C < 10 %	E

### **3 Environmental fate properties**

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

### **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).*

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

### **6.1 CMR assessment**

Dimethyl sulphate is listed as Index number 016-023-00-4 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."). The corresponding classification in Annex VI, part 3, Table 3.2 (the list of harmonised 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.").

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