

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: Diethyl sulphate

EC Number: 200-589-6

CAS Number: 64-67-5

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

CONTENTS

CONTENTS	3
TABLES	3
PROPOSAL FOR IDENTIFICATION OF A SUBSTANCE AS A CMR 1A OR 1B, PBT, VPVB OR A SUBSTANCE OF AN EQUIVALENT LEVEL OF CONCERN	4
PART I	5
JUSTIFICATION	5
1 IDENTITY OF THE SUBSTANCE AND PHYSICAL AND CHEMICAL PROPERTIES	5
1.1 Name and other identifiers of the substance	5
1.2 Composition of the substance	6
2 HARMONISED CLASSIFICATION AND LABELLING	7
3 ENVIRONMENTAL FATE PROPERTIES	9
4 HUMAN HEALTH HAZARD ASSESSMENT	9
5 ENVIRONMENTAL HAZARD ASSESSMENT	9
6 CONCLUSIONS ON THE SVHC PROPERTIES	9
6.1 CMR assessment	9
PART II	10
INFORMATION ON USE, EXPOSURE, ALTERNATIVES AND RISKS	10

TABLES

Tables

Table 1: Substance identity	5
Table 2: Constituents	6
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	7
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	8

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- 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 1B¹ which corresponds to classification as carcinogen category 2 and mutagen category 2².

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

Diethyl sulphate is listed as Index number 016-027-00-6 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 mutagen, Muta. 1B (H340: "May cause genetic defects."). 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.") and mutagen, Muta. Cat.2; R46 ("May cause heritable genetic damage.").

Therefore, this classification of diethyl sulphate in Regulation (EC) No 1272/2008 shows that the substance 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

¹ 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.

² 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

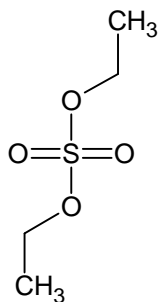
1 Identity of the substance and physical and chemical properties

1.1 Name and other identifiers of the substance

Table 1: Substance identity

EC number:	200-589-6
EC name:	diethyl sulphate
CAS number (in the EC inventory):	64-67-5
CAS number: Deleted CAS numbers:	64-67-5 98503-29-8, 182115-04-4
CAS name:	Sulfuric acid, diethyl ester
IUPAC name:	Diethyl sulfate
Index number in Annex VI of the CLP Regulation	016-027-00-6
Molecular formula:	C ₄ H ₁₀ O ₄ S
Molecular weight range:	154.2 g/mol
Synonyms:	Ethyl sulfate (Et ₂ SO ₄) DES Ethyl sulfate

Structural formula:



1.2 Composition of the substance

Name: Diethyl sulphate

Description: ---

Degree of purity: 99.5 – 100 %

Table 2: Constituents

Constituents	Typical concentration	Concentration range	Remarks
Diethyl sulphate 200-589-6		99.5 – 100 %	Information according to the available registration dossiers.

2 Harmonised classification and labelling

Diethyl sulphate is listed as Index number 016-027-00-6 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)		
016-027-00-6	diethyl sulphate	200-589-6	64-67-5	Carc. 1B	H350	GHS05	H350			
				Muta. 1B	H340	GHS08	H340			
				Acute Tox. 4 *	H332	GHS07	H332			
				Acute Tox. 4 *	H312	Dgr	H312			
				Acute Tox. 4 *	H302		H302			
				Skin Corr. 1B	H314		H314			

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
016-027-00-6	diethyl sulphate	200-589-6	64-67-5	Carc. Cat. 2; R45 Muta. Cat. 2; R46 Xn; R20/21/ 22 C; R34	T R: 45-46- 20/21/22- 34 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 57(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 57(b).

6 Conclusions on the SVHC Properties

6.1 CMR assessment

Diethyl sulphate is listed as Index number 016-027-00-6 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 mutagen, Muta. 1B (H340: "May cause genetic defects."). 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.") and mutagen, Muta. Cat.2; R46 ("May cause heritable genetic damage").

Therefore, this classification of diethyl sulphate in Regulation (EC) No 1272/2008 shows that the substance 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 website³:

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

ECHA has not carried out further analysis of this information.

³ 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.