

Justification for the selection of a substance for CoRAP inclusion

Substance Name (Public Name): dimethyl disulphide

Chemical Group:

EC Number: 210-871-0

CAS Number: 624-92-0

Submitted by: Germany

Published: 26/03/2014

Note

This document has been prepared by the evaluating Member State given in the CoRAP update.

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1 IDENTITY OF THE SUBSTANCE

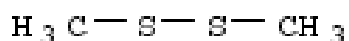
1.1 Other identifiers of the substance

Table 1: Substance identity

EC name:	dimethyl disulphide
IUPAC name:	Dimethyldisulfid
Index number in Annex VI of the CLP Regulation	-
Molecular formula:	C ₂ H ₆ S ₂
Molecular weight or molecular weight range:	94.19 g/mol
Synonyms/Trade names:	Methyl disulfide (8CI); (Methyldithio)methane; 2,3-Dithiabutane; DMDS; Dimethyl disulfide; Dimethyl disulphide; Dithioether; NSC 9370; Sulfa-Hitech

Type of substance Mono-constituent Multi-constituent UVCB

Structural formula:



1.2 Similar substances/grouping possibilities

None identified.

2 CLASSIFICATION AND LABELLING

2.1 Harmonised Classification in Annex VI of the CLP

There is no harmonized classification of dimethyl disulphide according to Annex VI of Regulation (EC) No 1272/2008.

2.2 Self classification

- In the registration

Classification		Labelling		Specific Concentration limits, M-Factors
Hazard Class and Category Code(s)	Hazard Statement Code(s)	Hazard Statement Code(s)	Supplementary Hazard Statement Code(s)	
Acute Tox. 4	H302	H302		M (acute)=1 M(chronic)=10
Flam. Liq 2	H225	H225		
Skin Sens. 1	H317	H317		
Eye Irrit. 2	H319	H319		
Acute Tox. 3	H331	H331		
STOT SE 3	H335	H335		
Aquatic Acute1	H400			
Aquatic Chronic 1	H410	H410		

Signal Words:

Danger

Pictograms:

GHS02

GHS06

GHS09

- The following hazard classes are in addition notified among the aggregated self classifications in the C&L Inventory:

Classification		Labelling		Specific Concentration limits, M-Factors
Hazard Class and Category Code(s)	Hazard Statement Code(s)	Hazard Statement Code(s)	Supplementary Hazard Statement Code(s)	
Flam. Liq. 1	H224	H224		
Flam. Liq. 3	H226	H226		
Skin Irrit. 2	H315	H315		
Acute Tox. 1	H330	H330		

Acute Tox. 2	H300	H300	
Acute Tox. 2	H310	H310	
Acute Tox. 2	H330	H330	
Acute Tox. 3	H301	H301	
Acute Tox. 3	H331	H331	
Acute Tox. 4	H312	H312	
Acute Tox. 4	H332	H332	
Repr. 2	H361	H361	
Aquatic Chronic 2	H411	H411	
Not Classified			

Signal Words:

Pictograms:

GHS07

GHS08

2.3 Proposal for Harmonised Classification in Annex VI of the CLP

None

3 INFORMATION ON AGGREGATED TONNAGE AND USES

From ECHA dissemination site			
<input type="checkbox"/> 1 – 10 tpa	<input type="checkbox"/> 10 – 100 tpa	<input type="checkbox"/> 100 – 1000 tpa	
<input type="checkbox"/> 1000 – 10,000 tpa	<input checked="" type="checkbox"/> 10,000 – 100,000 tpa	<input type="checkbox"/> 100,000 – 1,000,000 tpa	
<input type="checkbox"/> 1,000,000 – 10,000,000 tpa	<input type="checkbox"/> 10,000,000 – 100,000,000 tpa	<input type="checkbox"/> > 100,000,000 tpa	
<input type="checkbox"/> <1 >+ tpa (e.g. 10+ ; 100+ ; 10,000+ tpa)		<input checked="" type="checkbox"/> Confidential	
Besides the existing full registration the substance is also registered as intermediate, for which the tonnages are confidential.			
<input checked="" type="checkbox"/> Industrial use	<input type="checkbox"/> Professional use	<input type="checkbox"/> Consumer use	<input type="checkbox"/> Closed System
<p>Dimethyl disulphide is a high production volume chemical. The substance is used at industrial sites in refineries as hydrotreating catalyst activator, in petrochemical sites as anti-coking agent, as laboratory agent and as intermediate in chemical synthesis.</p>			

4 JUSTIFICATION FOR THE SELECTION OF THE CANDIDATE CoRAP SUBSTANCE

4.1 Legal basis for the proposal

- Article 44(2) (refined prioritisation criteria for substance evaluation)
- Article 45(5) (Member State priority)

4.2 Selection criteria met (why the substance qualifies for being in CoRAP)

- Fulfils criteria as CMR/ Suspected CMR
- Fulfils criteria as Sensitiser/ Suspected sensitiser
- Fulfils criteria as potential endocrine disrupter
- Fulfils criteria as PBT/vPvB / Suspected PBT/vPvB
- Fulfils criteria high (aggregated) tonnage (*tpa* > 1000)
- Fulfils exposure criteria
- Fulfils MS's (national) priorities

4.3 Initial grounds for concern to be clarified under Substance Evaluation

Hazard based concerns		
CMR <input type="checkbox"/> C <input type="checkbox"/> M <input type="checkbox"/> R	Suspected CMR ¹ <input type="checkbox"/> C <input type="checkbox"/> M <input type="checkbox"/> R	<input type="checkbox"/> Potential endocrine disruptor
<input type="checkbox"/> Sensitiser	<input type="checkbox"/> Suspected Sensitiser ¹	
<input type="checkbox"/> PBT/vPvB	<input type="checkbox"/> Suspected PBT/vPvB ¹	<input type="checkbox"/> Other (please specify below)
Exposure/risk based concerns		
<input type="checkbox"/> Wide dispersive use	<input type="checkbox"/> Consumer use	<input type="checkbox"/> Exposure of sensitive populations
<input checked="" type="checkbox"/> Exposure of environment	<input type="checkbox"/> Exposure of workers	<input type="checkbox"/> Cumulative exposure
<input type="checkbox"/> High RCR	<input checked="" type="checkbox"/> High (aggregated) tonnage	<input checked="" type="checkbox"/> Other (please specify below)

¹ CMR/Sensitiser: known carcinogenic and/or mutagenic and/or reprotoxic properties/known sensitising properties (according to CLP harmonized or registrant self-classification or CLP Inventory)

Suspected CMR/Suspected sensitiser: suspected carcinogenic and/or mutagenic and/or reprotoxic properties/suspected sensitising properties (not classified according to CLP harmonized or registrant self-classification)

Suspected PBT: Potentially Persistent, Bioaccumulative and Toxic

Dimethyl disulphide has been determined in an internal pre-screening for (hazardous) substances based on criteria developed for environmental exposure assessment. Aim of the pre-screening was to identify substances not solely on the basis of their intrinsic properties but also to consider aspects of environmental exposure. The focus was on determining possible risks resulting from a high PEC/PNEC ratio. Following criteria were considered among others: high production volume, physical-chemical properties, low PNEC, and environmental classification (not only according to GHS). If released to the environment dimethyl disulphide may cause risks because it is not readily biodegradable (potentially persistent) and shows toxicity in aquatic organisms. Besides the concerns specified above, environmental exposure scenarios in a chemical safety report for dimethyl disulphide indicate a deviation from standard emission factors provided in ECHA Guidance Document R.16 (here: use of A and B tables from EU Technical Guidance Document on Risk Assessment, 2003) without further justification. Moreover, life cycle steps have been aggregated without indication whether the resulting environmental releases represent the summed up ones or only the worst case. In result there are doubts that the emission estimation in the CSR reflects a realistic worst case and therefore the environmental RCRs might be higher than estimated by the registrant.

Substance Evaluation is proposed in order to examine the plausibility of emission factors and traceability of emission estimations together with clarification whether risks exist. The Substance evaluation will also include a cursory evaluation of the relevant environmental endpoints.

4.4 Other completed/ongoing regulatory processes that may affect suitability for substance evaluation

<input type="checkbox"/> Compliance check, Final decision	<input type="checkbox"/> Dangerous substances Directive 67/548/EEC
<input type="checkbox"/> Testing proposal	<input type="checkbox"/> Existing Substances Regulation 793/93/EEC
<input type="checkbox"/> Annex VI (CLP)	<input type="checkbox"/> Plant Protection Products Regulation 91/414/EEC
<input type="checkbox"/> Annex XV (SVHC)	<input type="checkbox"/> Biocidal Products Directive 98/8/EEC ; Biocidal Product Regulation (Regulation (EU) 528/2012)
<input type="checkbox"/> Annex XIV (Authorisation)	<input type="checkbox"/> Other (provide further details below)
<input type="checkbox"/> Annex XVII (Restriction)	
<i>Please provide further details when relevant.</i>	

4.5 Preliminary indication of information that may need to be requested to clarify the concern

<input type="checkbox"/> Information on toxicological properties	<input type="checkbox"/> Information on physico-chemical properties
<input type="checkbox"/> Information on fate and behaviour	<input checked="" type="checkbox"/> Information on exposure
<input type="checkbox"/> Information on ecotoxicological properties	<input checked="" type="checkbox"/> Information on uses
<input type="checkbox"/> Information ED potential	<input type="checkbox"/> Other (provide further details below)

By means of Substance Evaluation, we expect to obtain further information on exposure and uses of dimethyl disulphide as well as a comprehensible exposure assessment of the substance in order to get a clearer picture of possible risks. Moreover, depending on the outcome of the SEv appropriate information might be requested.

4.6 Potential follow-up and link to risk management

<input type="checkbox"/> Harmonised C&L	<input type="checkbox"/> Restriction	<input type="checkbox"/> Authorisation	<input checked="" type="checkbox"/> Other (provide further details)
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Depending on outcome of the SEv.