

## Justification for the selection of a substance for CoRAP inclusion

**Substance Name (Public Name):** disodium disulphite

**Chemical Group:**

**EC Number:** 231-673-0

**CAS Number:** 7681-57-4

**Submitted by:** National Institute of Chemical Safety,  
Hungary

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### 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

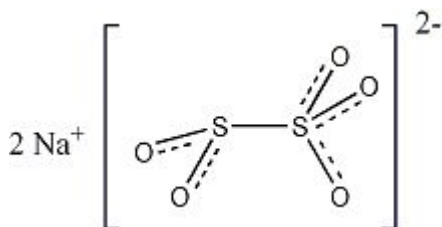
### 1.1 Other identifiers of the substance

Table 1: Substance identity

<b>EC name:</b>	disodium disulphite
<b>IUPAC name:</b>	disodium disulphite
<b>Index number in Annex VI of the CLP Regulation</b>	016-063-00-2
<b>Molecular formula:</b>	H <sub>2</sub> O <sub>5</sub> S <sub>2</sub> .2Na
<b>Molecular weight or molecular weight range:</b>	190.1
<b>Synonyms/Trade names:</b>	<i>sodium metabisulphite</i> <i>NatriumDisulfit</i> <i>Sodium Pyrosulfite</i> <i>Disulfurous acid, disodium salt (9CI)</i>

**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

Index No.: 016-063-00-2

Classification		Labelling			Specific 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)		
Acute tox. 4*	H302	GHS07	H302	EUH031		
Eye Dam. 1	H318	GHS05 Dgr	H318			

### 2.2 Self classification

- In the registration: Follows the harmonized classification.
  - Acute tox. 4; H302: Harmful if swallowed.
  - Eye Damage 1; H318: Causes serious eye damage.
  
- The following hazard classes are in addition notified among the aggregated self classifications in the C&L Inventory:
  - Aquatic Chronic 3; H412: Harmful to aquatic life with long lasting effects.
  - Acute Tox. 3; H301: Toxic if swallowed.
  - Skin Sens. 1; H317: May cause an allergic skin reaction.
  - Resp. Sens. 1; H334: May cause allergy or asthmatic symptoms or breathing difficulties if inhaled.
  - STOT SE 3; H335: May cause respiratory irritation.
  - STOT RE 1; H372: Causes damage to organs.
  - Not classified

### 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 type="checkbox"/> 10,000 – 100,000 tpa	<input checked="" 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 type="checkbox"/> Confidential	
<i>Please provide further details if appropriate</i>			
<input checked="" type="checkbox"/> Industrial use	<input checked="" type="checkbox"/> Professional use	<input checked="" type="checkbox"/> Consumer use	<input type="checkbox"/> Closed System
Use: <ul style="list-style-type: none"> <li>- in textile/leather industry</li> <li>- in manufacture of food products</li> <li>- in plastic/rubber industry</li> <li>- in water treatment/mining/offshore/metal industry</li> <li>- in paper/pulp industry/bleaching</li> <li>- in fibre industry</li> <li>- in photographic industry/photographic applications</li> <li>- manufacture and industrial use of sodium metabisulfite</li> <li>- as in agriculture/fertilizer</li> </ul>			

### 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

<b>Hazard based concerns</b>		
CMR <input type="checkbox"/> C <input type="checkbox"/> M <input type="checkbox"/> R	Suspected CMR <sup>1</sup> <input type="checkbox"/> C <input checked="" type="checkbox"/> M <input type="checkbox"/> R	<input type="checkbox"/> Potential endocrine disruptor
<input checked="" type="checkbox"/> Sensitiser	<input type="checkbox"/> Suspected Sensitiser <sup>1</sup>	
<input type="checkbox"/> PBT/vPvB	<input type="checkbox"/> Suspected PBT/vPvB <sup>1</sup>	<input type="checkbox"/> Other (please specify below)
<b>Exposure/risk based concerns</b>		
<input checked="" type="checkbox"/> Wide dispersive use	<input type="checkbox"/> Consumer use	<input checked="" 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 type="checkbox"/> Other (please specify below)
<ul style="list-style-type: none"> <li>- There is a study available on the substance that suggests mutagenic property. In the in vitro study the substance induced chromosome aberration and sister chromatid exchange in human lymphocytes dose-dependently.</li> <li>- The self-classification in the C&amp;L inventory suggests that the substance also has sensitiser property.</li> <li>- Taking into consideration certain hazard classes given as self-classification in the C&amp;L Inventory, certain ways of exposure may raise a concern. In particular the new hazard classes and some of the uses ground the concern of environmental exposure and the possible exposure of sensitive population.</li> </ul>		

### 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)	

<sup>1</sup> 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

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

<input checked="" 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 checked="" type="checkbox"/> Information on ecotoxicological properties	<input type="checkbox"/> Information on uses
<input type="checkbox"/> Information ED potential	<input type="checkbox"/> Other (provide further details below)

- Based upon the concerns identified further information to clarify human and ecotoxicological properties of the substance may be necessary.
- Also in order to clarify the concerns related to the possible exposure to the substance, further information on exposure might be required.

#### 4.6 Potential follow-up and link to risk management

<input checked="" type="checkbox"/> Harmonised C&L	<input type="checkbox"/> Restriction	<input checked="" type="checkbox"/> Authorisation	<input type="checkbox"/> Other (provide further details)
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In case the above concerns are confirmed then a new Harmonised C&L or Authorisation seems to be the appropriate Risk Management Measure.