



Bundesanstalt für Arbeitsschutz
und Arbeitsmedizin
Federal Institute for Occupational
Safety and Health

Justification Document for the Selection of a CoRAP Substance

Substance Name (public name): Antimony sulphide

EC Number: 215-713-4

CAS Number: 1345-04-6

Authority: DE MSCA

Date: 22/03/2016

Note

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

Table of Contents

1	IDENTITY OF THE SUBSTANCE	3
1.1	Other identifiers of the substance	3
2	OVERVIEW OF OTHER PROCESSES / EU LEGISLATION	4
3	HAZARD INFORMATION (INCLUDING CLASSIFICATION)	5
3.1	Classification	5
3.1.1	Harmonised Classification in Annex VI of the CLP	5
3.1.2	Self classification	5
3.1.3	Proposal for Harmonised Classification in Annex VI of the CLP	6
4	INFORMATION ON (AGGREGATED) TONNAGE AND USES	6
4.1	Tonnage and registration status	6
4.2	Overview of uses	7
5	JUSTIFICATION FOR THE SELECTION OF THE CANDIDATE CORAP SUBSTANCE	8
5.1.	Legal basis for the proposal	8
5.2.	Selection criteria met (why the substance qualifies for being in CoRAP)	8
5.3	Initial grounds for concern to be clarified under Substance Evaluation	8
5.4	Preliminary indication of information that may need to be requested to clarify the concern	9
5.5	Potential follow-up and link to risk management	9

1 IDENTITY OF THE SUBSTANCE

1.1 Other identifiers of the substance

Table: Other Substance identifiers

EC name (public):	antimony sulphide
IUPAC name (public):	tricyclo[3.3.1.1.1~3,7~]tetrastibathiane
Index number in Annex VI of the CLP Regulation:	-
Molecular formula:	S ₃ Sb ₂
Molecular weight or molecular weight range:	339.68 g·mol ⁻¹
Synonyms:	Antimony sulfide (Sb ₂ S ₃) Antimontrisulfid, Diantimontrisulfid

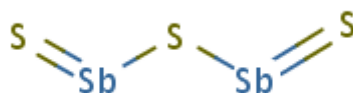
Type of substance

Mono-constituent

Multi-constituent

UVCB

Structural formula:



1.2 Similar substances/grouping possibilities

EC 215-175-0, diantimony trioxide

EC 231-146-5, antimony

2 OVERVIEW OF OTHER PROCESSES / EU LEGISLATION

Table: Completed or ongoing processes

RMOA	<input type="checkbox"/> Risk Management Option Analysis (RMOA)	
REACH Processes	Evaluation	<input type="checkbox"/> Compliance check, Final decision
		<input type="checkbox"/> Testing proposal
		<input type="checkbox"/> CoRAP and Substance Evaluation
	Authorisation	<input type="checkbox"/> Candidate List
		<input type="checkbox"/> Annex XIV
	Restriction	<input type="checkbox"/> Annex XVII ¹
Harmonised C&L	<input type="checkbox"/> Annex VI (CLP) (see section 3.1)	
Processes under other EU legislation	<input type="checkbox"/> Plant Protection Products Regulation Regulation (EC) No 1107/2009	
	<input type="checkbox"/> Biocidal Product Regulation Regulation (EU) 528/2012 and amendments	
Previous legislation	<input type="checkbox"/> Dangerous substances Directive Directive 67/548/EEC (NONS)	
	<input type="checkbox"/> Existing Substances Regulation Regulation 793/93/EEC (RAR/RRS)	
(UNEP) Stockholm convention (POPs Protocol)	<input type="checkbox"/> Assessment	
	<input type="checkbox"/> In relevant Annex	

¹ Please specify the relevant entry.

Other processes / EU legislation	<input checked="" type="checkbox"/> Other (provide further details below)
---	---

Council of Europe. Resolution AP (92) 2 on control of aids to polymerization in plastics coming into contact with food, Table 2.2, Migration limits (19 Oct 1992)

EU. Regulation No 1223/2009 on cosmetic products, Annex II, Prohibited Substances, as amended through Regulation 658/2013/EU (L190/38), 11 July 2013

EU. Toy Safety: Migration limits for certain metal elements. European Norm EN 71-3, Table 1 (as amended through 2002)

3 HAZARD INFORMATION (INCLUDING CLASSIFICATION)

3.1 Classification

3.1.1 Harmonised Classification in Annex VI of the CLP

The substance is not listed in Annex VI of the CLP regulation.

3.1.2 Self classification

- In the registration, different self classifications are notified which are affected by additives/impurities:

Carc 2 H351 (by inhalation)

Repr. 1A H360D

Aquatic Chr. 3 H412

Not classified

- The following hazard classes are in addition notified among the aggregated self classifications in the C&L Inventory (number of notifiers in brackets):

Acute Tox 4 H302 (149)

Acute Tox 4 H332 (149)

Skin Irrit 2 H315 (1)

Eye Irrit 2 H319 (1)

STOT SE 3 H355 (respiratory) (1)

Carc 2 H351 (by inhalation) (6)

Repr. 1A H360D (2x 2 (JS))

3.1.3 Proposal for Harmonised Classification in Annex VI of the CLP

Currently, no proposal for harmonized classification and labeling is available.

4 INFORMATION ON (AGGREGATED) TONNAGE AND USES²

4.1 Tonnage and registration status

Table: Tonnage and registration status

From ECHA dissemination site (accessed in April 2015)		
<input checked="" type="checkbox"/> Full registration(s) (Art. 10)	<input type="checkbox"/> Intermediate registration(s) (Art. 17 and/or 18)	
Tonnage band (as per dissemination site)		
<input type="checkbox"/> 1 – 10 tpa	<input type="checkbox"/> 10 – 100 tpa	<input checked="" type="checkbox"/> 100 – 1000 tpa
<input type="checkbox"/> 1000 – 10,000 tpa	<input 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 type="checkbox"/> Confidential

² Data taken from ECHA dissemination site (accessed in May 2015)

4.2 Overview of uses

Industrial use

Antimony sulphide is used in industrial processes such as the production of solid subricants for friction linings and brake pads and in the formulation of pyrotechnic mixtures. Although these processes are rather controlled at industrial sites, workers may be exposed during transfer operations, during blending in batch processes, manipulation of antimony bound in materials and articles (PROC 4, 8b, 9,14, 21, 22, 24, 26).

Uses by Professional Workers

Antimony sulphide is used by professional workers (including use of ammunition, recordable media, electrical and mechanical carbon products, seal and pump, carbon and graphite ceramics, solder, explosives, detonation of pyrotechnics) partially in open processes . Workers may be exposed during transfer operations, during blending in batch processes and during manipulation of antimony sulphide bound in materials and articles ((PROC 21, 26). It is anticipated that exposure of professional workers in the public domain is less well controlled than in industry.

Table: Uses

Part 1:

<input checked="" type="checkbox"/> Manufacture	<input checked="" type="checkbox"/> Formulation	<input checked="" type="checkbox"/> Industrial use	<input checked="" type="checkbox"/> Professional use	<input type="checkbox"/> Consumer use	<input checked="" type="checkbox"/> Article service life	<input checked="" type="checkbox"/> Closed system
---	---	--	--	---------------------------------------	--	---

5. JUSTIFICATION FOR THE SELECTION OF THE CANDIDATE CoRAP SUBSTANCE

5.1. Legal basis for the proposal

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

5.2. 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

5.3 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 checked="" 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 ³	
<input type="checkbox"/> PBT/vPvB	<input type="checkbox"/> Suspected PBT/vPvB ¹	<input type="checkbox"/> Other (please specify below)
Exposure/risk based concerns		
<input checked="" type="checkbox"/> Wide dispersive use	<input type="checkbox"/> Consumer use	<input type="checkbox"/> Exposure of sensitive populations
<input type="checkbox"/> Exposure of environment	<input checked="" type="checkbox"/> Exposure of workers	<input type="checkbox"/> Cumulative exposure
<input checked="" type="checkbox"/> High RCR	<input type="checkbox"/> High (aggregated) tonnage	<input checked="" type="checkbox"/> Other (please specify below)

³ 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

For higher-tier endpoints a read across to the substance antimony(III) oxide was done. Currently, antimony(III) oxide is classified as Carc. 2, H351. Due to the deviations from the OECD guidelines and the critical shortcomings in all three chronic inhalation studies, US NTP has embarked on a testing programme leading to a new, full 2-year bioassay (see <http://ntp.niehs.nih.gov>). Depending on the outcome of the NTP study a reclassification for carcinogenicity may be necessary.

The substance evaluation should clarify whether the read across to antimony(III) oxide is appropriate and a classification for carcinogenicity for antimony(III) sulphide is necessary.

Due to uses of antimony sulphide by professional workers a high potential of exposure is anticipated.

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

<input checked="" type="checkbox"/> Information on toxicological properties	<input checked="" type="checkbox"/> Information on physico-chemical properties
<input type="checkbox"/> Information on fate and behaviour	<input 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)

More Information about particle characteristics and their lower explosion limit/ minimum explosible concentration, minimum ignition energy, deflagration index (Kst) and/or maximum explosion pressure are requested to clarify under which condition /for which exposure scenarios a dust explosion hazard has to be avoided.

If the substance evaluation indicates that risks for workers cannot be excluded, further information on exposure might be necessary. Antimony trisulfide is used as solid subricant for friction lingins, brake pads and in pyrotechnic mixtures and sporting gun ammunition.

It is unclear whether antimony sulphide needs to be classified as carcinogenic and if further studies are needed to conclude on this endpoint. Antimony sulphide refers to antimony trioxide by read across approach.

5.5 Potential follow-up and link to risk management

<input checked="" type="checkbox"/> Harmonised C&L	<input type="checkbox"/> Restriction	<input type="checkbox"/> Authorisation	<input type="checkbox"/> Other (provide further details)
--	--------------------------------------	--	--

Depending on the outcome of the substance evaluation and further studies a harmonized classification for carcinogenicity might be necessary. It is unclear if a risk for workers arises and further risk management measures need to be implemented.