



Justification Document for the Selection of a CoRAP Substance

Substance Name (public name):	Antimony
EC Number:	231-146-5
CAS Number:	7440-36-0
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	5
4	INFORMATION ON (AGGREGATED) TONNAGE AND USES	6
4.1	Tonnage and registration status	6
4.2	Overview of uses	6
5	JUSTIFICATION FOR THE SELECTION OF THE CANDIDATE CORAP SUBSTANCE	7
5.1.	Legal basis for the proposal	7
5.2.	Selection criteria met (why the substance qualifies for being in CoRAP)	7
5.3	Initial grounds for concern to be clarified under Substance Evaluation	7
5.4	Preliminary indication of information that may need to be requested to clarify the concern	8
5.5	Potential follow-up and link to risk management	8

1 IDENTITY OF THE SUBSTANCE

1.1 Other identifiers of the substance

Table: Other Substance identifiers

EC name (public):	Antimony
IUPAC name (public):	Antimony
Index number in Annex VI of the CLP Regulation:	-
Molecular formula:	Sb
Molecular weight or molecular weight range:	121.760 g·mol ⁻¹
Synonyms:	Antimon; Antimony; Antimony powder; Antimoni

Type of substance Mono-constituent Multi-constituent UVCB

Structural formula:

Sb

1.2 Similar substances/grouping possibilities

EC 215-175-0, diantimony trioxide (DE/2018)

EC 215-713-4, antimony sulphide (DE/2018)

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

¹ Please specify the relevant entry.

EU. Directive 2012/18/EU on major accident hazards involving dangerous substances, Annex I, OJ (L197)1, 24 July 2012 (SEVESO III)

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

No harmonised classification is available.

3.1.2 Self classification

- In the registration

Antimony powder (Representative sample)
No Classification

Antimony powder (Representative sample) - proposed alternative
classification
Carc. 2 H351

Antimony massive (Representative sample)
No classification

Antimony massive - Composition high As
Aquatic Chronic 3 H412

- The following hazard classes are in addition notified among the aggregated self classifications in the C&L Inventory (Number of Notifiers)

Acute Tox 4, H302 (137)
Acute Tox 4, H332 (155)
Acute Tox 2, H300 (28)
Acute Tox 2, H310 (28)
Acute Tox 3, H301 (22)
STOT RE 2, H373 (respiratory) (17)
STOT SE 3, H335 (respiratory) (3)
Carc 2, H351 (by inhalation) (70)
Aquatic Chronic 2, H411 (176)
Not classified (43)

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 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 type="checkbox"/> Confidential

4.2 Overview of uses

Table: Uses

Industrial use

Antimony and antimony containing materials are used in a wide variety of industrial processes such as production of diantimony trioxide/sulphide, production of alloys in foils, use of ammunition, batteries, extruded pipe and tube, use of antimony metal in electrical and mechanical carbon products, seal and pump industry, impregnating agent for porous carbon and graphite ceramics, recordable media and use in explosives.

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, 8a, 8b, 9, 13, 14, 21, 22, 23, 24, 26).

Uses by Professional Workers

Antimony metal preparations (including ammunition, recordable media, electrical and mechanical carbon products, seal and pump, carbon and graphite ceramics, solder, explosives) are used by professional workers partially in open processes. Antimony metal or antimony containing alloys are also used in the production of alloys in foils, batteries, extruded pipe and tube and impregnating agents. Workers may be exposed during transfer operations, during blending in batch processes and during manipulation of antimony bound in materials and articles (PROC 0, 21, 22, 24, 25). It is anticipated that exposure of professional workers in the public domain is less well controlled than in industry.

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 checked="" type="checkbox"/> Consumer use	<input checked="" type="checkbox"/> Article service life	<input type="checkbox"/> Closed system
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² Data taken from ECHA dissemination site (accessed in May 2015)

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 checked="" 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 all 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 is necessary.

Due to the high tonnage (> 1000 t) and open uses of antimony metal and metal preparations by professional workers a high potential of exposure is anticipated. The RCR is close to one.

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 may be 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.

It is unclear whether antimony needs to be classified as carcinogenic and if further studies are needed to conclude on this endpoint. Antimony 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)
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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.