



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):** Diantimony trioxide

**EC Number:** 215-175-0

**CAS Number:** 1309-64-4

**Authority:** DE MSCA

**Date:** 22/03/2016

### 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: Other Substance identifiers

<b>EC name (public):</b>	diantimony trioxide
<b>IUPAC name (public):</b>	dioxodistiboxane
<b>Index number in Annex VI of the CLP Regulation:</b>	051-005-00-X
<b>Molecular formula:</b>	O <sub>3</sub> Sb <sub>2</sub>
<b>Molecular weight or molecular weight range:</b>	291.52 g·mol <sup>-1</sup>
<b>Synonyms:</b>	Dioxodistiboxane, antimony trioxide, Antimony oxide (Sb <sub>2</sub> O <sub>3</sub> ), diantimony Trioxide, antimony trioxide, ATO, PATOX, Diantimontrioxid

**Type of substance**     Mono-constituent     Multi-constituent     UVCB

**Structural formula:**



### 1.2 Similar substances/grouping possibilities

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## 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 <sup>1</sup>
Harmonised C&L	<input checked="" 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 checked="" 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)	

<sup>1</sup> Please specify the relevant entry.

EU. Directive 94/33/EC on young people at work, OJ (L 216) 12, 20 Aug 1994, as amended by Directive 2007/30/EC, OJ (L 165) 21, 27 Jun 2007 (updated thru table 3.2 of Annex VI to CLP, 3 Oct 2013)

EU. Commission Regulation No 10/2011 on Plastic Materials and Articles Intended to Come into Contact with Food, as amended by Regulation (EU) No 202/2014, OJ (L62) 13, 4 March 2014

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)

*The Swedish Risk Assessment Report for antimony(III) oxide was finalized in 2008.*

### 3 HAZARD INFORMATION (INCLUDING CLASSIFICATION)

#### 3.1 Classification

##### 3.1.1 Harmonised Classification in Annex VI of the CLP

**Table: Harmonised classification**

Index No	International Chemical Identification	EC No	CAS No	Classification		Spec. Conc. Limits, M-factors	Notes
				Hazard Class and Category Code(s)	Hazard statement code(s)		
051-005-00-X	Antimony trioxide	215-175-0	1309-64-4	Carc. 2	H351	-	-

##### 3.1.2 Self classification

- In the registration

The registrants have deviating classifications. Some use the harmonized classification. Others do additionally classify for Repr. 1A, H360D, STOT RE 1, H372 (nervous system, reproduction system, and 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 in brackets):

Acute Tox 4	H302
Acute Tox 4	H332
Eye Dam 1	H318
Skin Irrit 2	H315
Eye Irrit 2	H319

STOT RE 1	H372
STOT RE 2	H373 (nervous system, reproduction system, lungs)
Carc 2	H351 (by inhalation)
Repr. 1A	H360D

### 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 USES<sup>2</sup>

### 4.1 Tonnage and registration status

**Table: Tonnage and registration status**

<b>From ECHA dissemination site (accessed in April 2015)</b>		
<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 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 checked="" type="checkbox"/> 10,000+ tpa (e.g. 10+ ; 100+ ; 10,000+ tpa)		<input type="checkbox"/> Confidential

### 4.2 Overview of uses

#### Industrial use

Antimony trioxide is used in a wide variety of industrial processes such as the production of glass, enamels, functional ceramics and semi-conductors solid, pigments, paints, coatings, ceramics, brake pads and production and formulation of fine chemicals. It is also used in the plastics and rubber industry, in the manufacture of flame retarded textiles and plastics. 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, 5, 6, 7, 8a, 8b, 9,10, 13, 14, 15, 19, 21, 22, 23, 24, 26).

<sup>2</sup> Data taken from ECHA dissemination site (accessed in May 2015)

**Uses by Professional Workers**

Antimony trioxide preparations are used by professional workers (including use of pigments, paints, coatings, brakepads, ceramics, glass, enamels) partially in open processes. Workers may be exposed during transfer operations, during blending in batch processes, spraying of paints and coatings and during manipulation of antimony trioxide bound in materials and articles ((PROC 8a, 11, 13, 19, 21, 24). It is anticipated that exposure of professional workers in the public domain is less well controlled than in industry.

**Consumer use**

Service life/Use of articles with diantimony trioxide embedded into the matrix, use of back-coated textiles, wearing of articles made of PET/PES polymers and wearing of clothes containing diantimony trioxide for fire resistance is disseminated.

**Article service life**

Several article categories are disseminated which may contain diantimony trioxide related to above-mentioned 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 checked="" type="checkbox"/> Consumer use	<input checked="" type="checkbox"/> Article service life	<input checked="" type="checkbox"/> Closed system
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## 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 checked="" type="checkbox"/> C <input type="checkbox"/> M <input type="checkbox"/> R	Suspected CMR <sup>1</sup> <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 <sup>3</sup>	
<input type="checkbox"/> PBT/vPvB	<input type="checkbox"/> Suspected PBT/vPvB <sup>1</sup>	<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)

<sup>3</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



Antimony(III) oxide is used as a reducing agent for Cr(VI) in cement as a substitute for Fe(II)SO<sub>4</sub>. The Swedish RAR (2008) did not address this use. Antimony(III) oxide is harmonised classified as Carc. 2, H351. Therefore during the substance evaluation it should be examined whether antimony(III) oxide is a suitable substitute for Fe(II)SO<sub>4</sub>.

There are indications that the DNEL was not derived in accordance with the ECHA Guidance Chapter R.8 which gives rise to the concern of higher resulting RCRs than those described by the registrants.

Due to high tonnage and uses 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 checked="" type="checkbox"/> Information on exposure
<input 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)

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 required to clarify under which condition / exposure scenarios a dust explosion hazard has to be avoided.

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 antimony(III) oxide is a suitable substitute for Fe(II)SO<sub>4</sub>.

If the Substance Evaluation indicates that risks for workers arise further information on exposure might be necessary.

#### 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 NTP study and the following substance evaluation a reclassification for carcinogenicity may be necessary. It is unclear if a risk for workers arises and further risk management measures need to be implemented.