Annex XV dossier

PROPOSAL FOR HARMONISED CLASSIFICATION AND LABELLING

Substance Name: Diantimony trioxide

EC Number: 215-175-0

CAS Number: 1309-64-4

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PROPOSAL FOR HARMONISED CLASSIFICATION AND LABELLING

Substance Name: Diantimony trioxide

EC Number: 215-175-0

CAS number: 1309-64-4

Registration number (s):

Purity/Impurities: A survey on the purity of commercial grades of diantimony trioxide on the EU-market has been made by a consultant on behalf of the International Antimony Oxide Industry Association, IAOIA. The purity for diantimony trioxide was given as 99.3 to 99.5 % (with the exception of wetted forms, for which a lower specification limit of 95 % was given). The only two relevant impurities are arsenic and lead. As of June 2006 all diantimony trioxide used within the EU will contain less than 0.1 % As (before this date approximately 3.6 % of the diantimony trioxide used in the EU contained between 0.1 and < 0.2 % As, the rest < 0.1 % As). The range given by EU producers is 0.0040 to 0.0860 % As. The content of lead in diantimony trioxide used in the EU is less than 0.25 % Pb.

Other impurities occurring in trace amounts: Cu, Fe, Ni, SO_4^{2-}, Si, Mn, Mg, Sn, Al, Ag, Cd, Bi, V, and Se.

The impurities present primarily depend on the geographical mineralogy from which the raw material is derived.

The commercially available form of diantimony trioxide has no stated additives.

(EU Risk Assessment Report)

Proposed classification based on Directive 67/548/EEC criteria:

Xi; R38 (Irritating to skin)
(Note: No change to the current classification with Carc Cat. 3; R40 (Limited evidence of a carcinogenic effect) in Annex I of Directive 67/548/EEC is proposed.)

Proposed classification based on GHS criteria:

Skin Irrit. 2 H315 (Causes skin irritation)

Proposed labelling:

Xi; 24 – 28

(Note: No change to the current labelling with Xn; S2 - 22 - 36/37 is proposed.)

Proposed specific concentration limits (if any): -

Proposed notes (if any): -

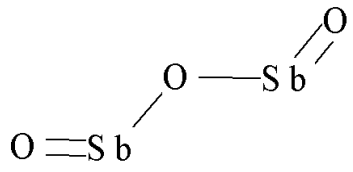
JUSTIFICATION

1 IDENTITY OF THE SUBSTANCE AND PHYSICAL AND CHEMICAL PROPERTIES

1.1 Name and other identifiers of the substance

Chemical Name:	Diantimony trioxide
EC Name:	Diantimony trioxide
CAS Number:	1309-64-4
IUPAC Name:	Dioxodistiboxane
Synonyms:	Antimony (III) oxide Antimony (3+) oxide Antimony oxide (Sb2O3) Antimony peroxide Antimony trioxide Antimony oxide Antimony sesquioxide Antimony white Flowers of antimony Senarmontite Valentinite Sesquioxide C.I. Pigment White 11 C.I. 77052

1.2 Composition of the substance

Chemical Name:	Diantimony trioxide
EC Number:	215-175-0
CAS Number:	1309-64-4
IUPAC Name:	Dioxodistiboxane
Molecular Formula:	Sb_20_3
Structural Formula:	
Molecular Weight:	291.52
Typical concentration (% w/w):	
Concentration range (% w/w):	

The commercial product is a white, odourless, crystalline powder.

Diantimony trioxide has two molecular arrangements:

- Senarmontite [CAS No. 12412-52-1] below 570°C - colourless cubic crystals.
- Valentinite [CAS No 1317-98-2] above 570°C - white orthorhombic crystals which becomes yellow when heated but turns white again on cooling.

At higher temperatures, the stable form is the orthorhombic valentinite, which consists of infinite double chains. The orthorhombic modification is metastable below 570°C; however it is sufficiently stable to exist as a mineral.

Since diantimony trioxide can and will exist in both these modifications at environmental conditions, and no data are available to differentiate between the two as regards exposure and effects, the intention of the dossier will be to cover both with the CAS number for diantimony trioxide, i.e. 1309-64-4.

Chemical Name: Senarmontite

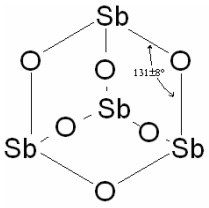
EC Number:

CAS Number: 12412-52-1

IUPAC Name:

Molecular Formula:

Structural Formula:



Molecular Weight: 291.52

Typical concentration (% w/w): -

Concentration range (% w/w): -

Chemical Name: Valentinite

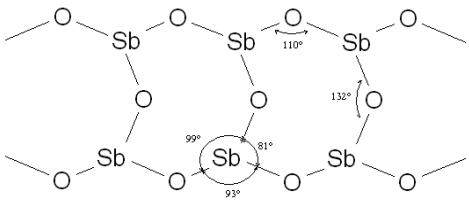
EC Number:

CAS Number: 1317-98-2

IUPAC Name:

Molecular Formula:

Structural Formula:



Molecular Weight: 291.52

Typical concentration (% w/w): -

Concentration range (% w/w): -

(EU Risk Assessment Report)

1.3 Physico-chemical properties

Table 1. Summary of physico- chemical properties of diantimony trioxide

REACH ref Annex, §	Property	IUCLID section	Value	[enter comment/reference or delete column]
VII, 7.1	Physical state at 20°C and 101.3 KPa	3.1	Solid	The commercial product is a white odourless, crystalline powder
VII, 7.2	Melting/freezing point	3.2	655°C	
VII, 7.3	Boiling point	3.3	1550°C (1013 hPa) 1425°C (1013 hPa)	
VII, 7.4	Relative density	3.4 density		
VII, 7.5	Vapour pressure	3.6	1 mmHg (~133 Pa) at 574°C	
VII, 7.6	Surface tension	3.10		
VII, 7.7	Water solubility Distilled water: Reconstituted standard water, 7 days:	3.8	 pH 5: 19.7 mg Sb_2O_3 / l pH 7: 25.6 mg Sb_2O_3 / l pH 9: 28.7 mg Sb_2O_3 / l (at 20°C) pH 8: 2.76 mg Sb/l (at 22.2°C)	Loading 100 mg Sb_2O_3/l; LISEC WE-14-018
VII, 7.8	Partition coefficient n-octanol/water (log value)	3.7 partition coefficient	Not relevant	
VII, 7.9	Flash point	3.11	Not relevant	
VII, 7.10	Flammability	3.13	No data	Diantimony trioxide is in a high oxidation state, therefore further reactions with oxygen is highly unlikely (IUCLID).
VII, 7.11	Explosive properties	3.14	No data	Diantimony trioxide exhibits no chemical groups indicating explosive properties (IUCLID).
VII, 7.12	Self-ignition temperature			
VII, 7.13	Oxidising properties	3.15	No data	Diantimony trioxide is a chemically inert substance. Based on the chemical structure it can be concluded that no oxygen is released.
VII, 7.14	Granulometry	3.5	0.2-13.89 µm (particle size) 0.92-5.96 µm (D50)	

XI, 7.15	Stability in organic solvents and identity of relevant degradation products	3.17		
XI, 7.16	Dissociation constant	3.21		
XI, 7.17,	Viscosity	3.22		
	Auto flammability	3.12	No data	
	Reactivity towards container material	3.18		
	Thermal stability	3.19		
	Specific density		5.9 g/cm^3 (at 24°C)	Density differs from crystalline structure.*

* The specific density of diantimony trioxide has been reported to be 5.9 g/cm3 at 24ºC (Smeykal, 2005). Density differs from crystalline structure: *Senarmontite:* 5.2 g/cm^3 (Budavari, 1996; Kirk-Othmer, 1992a) 5.252 g/cm^3 (Grund and Hanusch, 2000); *Valentinite:* 5.67 g/cm^3 (Kirk-Othmer, 1992a), 5.72 g/cm^3 (Grund and Hanusch, 2000).

(EU Risk Assessment Report)

2 MANUFACTURE AND USES

Import of diantimony trioxide into the EU is mainly from China (more than 90% of imported quantity in 2000) and USA. The quantity of diantimony trioxide imported/exported as a component of finished products, e g electrical and electronic articles, is not known.

Global diantimony trioxide production in 2005 was 120 000 tonnes (IAOIA, 2006) Up from 112 600 tonnes in 2002, with China producing the largest part (47%) followed by US/Mexico (22%), Europe (17%), Japan (10%) and South Africa (2%) and other countries (2%). (EURAS bvba, 2003)

Diantimony trioxide was in 2006 produced at four sites in EU15. Two sites ceased production in recent years.

Diantimony trioxide is produced via two routes:

a) Re-volatilizing of crude diantimony trioxide

b) Oxidation of antimony metal

Oxidation of antimony metal dominates in EU. Diantimony trioxide manufacturers typically buy antimony metal on the open market.

There are several processes for the production of crude diantimony trioxide or metallic antimony from virgin material. The choice of process depends on the composition of the ore and other factors. Typical steps include mining, crushing and grinding of ore, sometimes followed by flotation and separation of the metal using pyrometallurgical processes (smelting or roasting) or in a few cases (e.g. when the ore is rich in precious metals) by hydrometallurgical processes. These steps do not take place in EU but closer to the mining location.

An overview of the main uses of diantimony trioxide in the EU is summarised in Table 2.

Table 2. Use of diantimony trioxide in EU15

Use	**Quantity: tonnes/year (and % of total quantity)**	
	Year 2005 (EURAS, 2006)	Year 2000 (Docherty, 2001)
Flame-retardant in plastics (except PVC)	9 200 (38 %)	12 800 (51 %)
Flame-retardant in PVC	8 800 (36 %)	9 000 (36 %)
Flame-retardant in rubber	2 200 (9 %)	not specified
Flame-retardant in textiles	1 750 (7 %)	1 800 (7 %)
Catalyst in PET production	950 (4 %)	650 (3 %)
Additive in glass manufacture	250 (1 %)	250 (1 %)
In pigments, paint and ceramics	1 100 (5 %)	500 (2 %)
Total:	24 250	25 000

(EU Risk Assessment Report)

3 CLASSIFICATION AND LABELLING

3.1 Classification in Annex I of Directive 67/548/EEC

Carc Cat. 3; R40

Annex I Index No: 051-005-00-X

ATP inserted: 19; ATP updated: 21

3.2 Self classification(s) -

4 ENVIRONMENTAL FATE PROPERTIES

Not relevant for this type of dossier.

5 HUMAN HEALTH HAZARD ASSESSMENT

5.1 Toxicokinetics (absorption, metabolism, distribution and elimination)

Dermal

No animal data on toxicokinetics after dermal exposure could be located.

There are no quantitative data available, regarding the absorption, disposition and retention of antimony trioxide in humans after *in vivo* dermal exposure. An *in vitro* study on human skin has been performed in accordance with OECD Guideline for Testing of Chemicals, Guideline 428, and the OECD Environmental Health and Safety Publication Series on Testing and Assessment No.28. (Roper and Stupart, 2006). The aim of this study was to establish the likely dermal penetration of antimony resulting from topical exposure to diantimony trioxide. A dermal absorption of 0.26% was established. The study is described in detail in the EU Risk Assessment Report.

(EU Risk Assessment Report)

5.2 Acute toxicity

Not evaluated for this dossier.

5.3 Irritation

5.3.1 Skin

5.3.1.1 Animal studies

Rabbit:

- The skin-irritating or penetrating properties of antimony trioxide were studied in eight albino rabbits (Gross *et al*, 1955). The method of application was adapted from the procedure of Draize with minor modifications. The day before dosing the animals were clipped over the entire trunk with an electric clipper, care being taken to avoid cutting or abrading the skin. 25,000 mg of antimony trioxide dust was incorporated into an aqueous methylcellulose paste and lightly applied to the denuded skin, which comprised about two-thirds of the animals' torso. The area was covered by an impervious membrane (Vinylite) and allowed to remain in contact for one week. No significant local reaction resulted from this single application, nor was there any apparent sign of systemic toxicity.

In conclusion, antimony trioxide was not irritating to the skin of rabbits in this study.

- The potential of antimony trioxide to cause skin irritation was tested in a "range-finding toxicity study" in rabbits. The full report reads as follows. "Skin Irritation, Rabbit, Uncovered. Conditions: Standard. Dosed in mineral oil. Conclusions: No irritation on 5 rabbits from a 50% suspension of antimony trioxide in mineral oil (Carnegie-Mellon Institute of Research, 1978).

No conclusions on the irritating potential of diantimony trioxide can be drawn from this study.

(EU Risk Assessment Report)

Guinea pig:

- In a very briefly reported combined study, a 1:8 mixture of antimony oxide (Sb_2O_3) and perbromophenyl ether was tested for primary skin irritation and sensitisation (Haskell Laboratory for Toxicology and Industrial Medicine, 1970b, and personal communication from Haskell scientist via IAOIA). In the test for irritation 0.05 ml of 50%, 25% and 10% (w/v) suspensions of the mixture in a guinea pig fat/ acetone/ dioxane mix were applied to clipped intact shoulder skin of each of ten male, albino guinea pigs. It is not stated in the study report whether the application was occlusive or non-occlusive. In addition, the duration of application is not stated. "Reactions after 24 hours": No evidence of irritation.

This study shows that 0.05 ml of a 50% suspension of the mixture is not irritating to the skin of 10 male albino guinea pigs. However, the study is poorly described, the highest amount of antimony trioxide tested is only 6.25% and the volume tested is only 10 % of the volume recommended in OECD guideline 404.

Thus, this study does not allow any conclusions to be drawn on the irritating potential of antimony trioxide.

- In a similar, combined dermal irritation and sensitisation study a 6:1 mixture of hexabromobenzene and antimony oxide (Sb_2O_3) was suspended in 1:1 acetone-dioxane containing 13% guinea pig fat and applied to male albino guinea pigs (Haskell Laboratory for Toxicology and Industrial Medicine, 1970). In the test for irritation, 0.05 ml each of 50% and 25% suspensions were lightly rubbed into intact shaved skin of 10 animals each. It is not stated in the study report whether the application was occlusive or non-occlusive. In addition, the duration of application is not stated. "Primary irritation reactions" were scored at 1 and 2 days. At the "50% concentration" there were 5 animals with mild erythema and 5 with no evidence of irritation on day 1. At the 25% concentration 2 animals showed mild erythema while 8 were negative on day 1. At 2 days all animals in both groups were negative.

This study shows that 0.05 ml of a 50% suspension of the mixture cause mild erythema in 5 of the animals on day one. The 25% concentration caused mild erythema in 2 animals on day one. At day 2 no irritation was observed in any of the animals. However, the study does not include any controls and thus it is impossible to know what agent is causing the irritation seen on day one. The small volume tested, which was only 10 % of the volume recommended in OECD guideline 404, could explain the lack of response on day 2.

Thus, this study does not allow any conclusions to be drawn on the irritating potential of antimony trioxide.

(EU Risk Assessment Report)

5.3.1.2 Human studies

- White *et al* (1993) reported three cases of dermatitis in workers exposed to antimony in a melting process. Three men, between 28 and 33 years of age were employed at a brazing rod manufacturing plant. After changes at their workplace they were assigned the task of melting antimony metal and due to insufficient precautionary measures they were exposed to fumes from the melted antimony. Shortly after the process changes, they noted the onset of skin lesions. Physical examination revealed crusted follicular papules and pustules of the arms (accentuated in the antecubital fossae), trunk and forehead in two of the workers. One of these also had a dry eczematous patch on the left trunk. In the third worker erythematous follicular papules were noted on the ventral and dorsal aspects of both forearms and on the posterior legs and back. The urine antimony level, which was measured in one worker, was 53.2 μg/L, which is in the range for exposed individuals (levels in unexposed persons are less than 1.0 μg/L). None of the workers had any history of skin disease or atopy. In all three workers the dermatitis resolved with the avoidance of antimony-related work.

The authors concluded that the three workers present strong evidence for antimony related dermatosis: these workers were exposed to other metal fumes for many years without skin manifestations; lesions appeared when antimony was introduced to the process, and resolved when antimony exposure was avoided. Two of the workers had exposure only to molten metal fume, and not to metallic dust. During site visit it was noted that the temperature in the work area was quite high, and the skin of employees was damp with perspiration.

This study indicates that fumes from melted antimony, presumably antimony trioxide, may cause dermatitis in humans.

- The occurrence of a skin eruption in 23 persons amongst a population of about 150 men employed in the manufacture of antimony trioxide has also been reported and the morphology and

histology of the rash known as ”antimony spots” is described (Stevenson, 1965). Intense itching preceded the skin eruption. A diffuse blotchy erythema may occur but most commonly the early lesions are small erythematous papules and may be associated with much excoriation. The papules enlarge and in some cases become frankly pustular. The sites most commonly involved in the 23 cases were antecubital area, shins, back of neck, forearms, trunk, back of knees and face. In general, the lesions were present on those dust-laden areas most exposed to heat and therefore to sweating. Two furnacemen who presented one side of their body to heat when working had lesions only on the limbs of that side. The rash subsides in from 3 to 14 days when the worker is transferred to a cooler part of the factory. The eruption occurs in the warm summer months and is rarely seen in the winter. 17 of the 23 men affected were furnace workers and 5 were doing a different job but also under hot conditions.

Histologically, the early lesion showed epidermal cellular necrosis with associated acute dermal inflammatory cellular reaction. The lesion is closely related to sweat ducts.

This study suggests that workers exposed to antimony trioxide are liable to develop a transient skin eruption affecting areas most exposed to heat and where sweating occurs.

- In another article severe discomfort from skin irritation in warm weather was described in men working with the production of antimony oxide and the pure metal from sulphide ore by various smelting processes (McCallum, 1963). The rash consisted of papules and pustules around sweat and sebaccous glands and was compared in appearance to the lesions of chickenpox or smallpox. It affected particularly the fore arms and thighs and the flexures and did not appear on the face, hands or feet. The spots disappeared rapidly over a weekend or public holiday, but reappeared on return to work. Over hundred men were employed but the frequency of dermatitis was not stated.

This study indicates that work in various smelting processes in the production of antimony trioxide and the pure metal is connected with dermatitis under hot conditions.

- The clinical examination of 51 male workers employed in an antimony smelting plant has been reported (Potkonjak and Pavlovich, 1983; see also section 4.1.2.6, “Repeated dose toxicity” in the EU Risk Assessment Report, reference 1.). The subjects were aged between 31 and 54 years (mean 45.23), they were exposed to dust containing predominantly antimony oxide [Sb_2O_3 (38.73-88.86%), Sb_2O_5 (2.11-7.82%), SiO_2 (0.82-4.72), Fe_2O_3 (0.90-3.81%) and As_2O_3 (0.21-6.48%)], had worked in the factory from 9-31 years (mean 17.91) and had pneumoconiotic changes. Over a 25-year period they were examined 2-5 times; the evaluation included among other things a physical examination (specialist consultations were obtained when appropriate).

“Antimony dermatosis”, characterised by vesicular or pustular lesions with residual hyperpigmentation, were present in 32 of 51 exposed workers (63%), especially during the summer season and when working near the furnace where temperatures were excessively high.

This study indicates that antimony related dermatosis may occur in humans exposed to antimony trioxide at high temperatures.

- A combined test was conducted to determine the irritation and sensitisation potential of a fibre treated with a mixture of antimony oxide (Sb_2O_3) and a substance of which the identity was deleted from the report (Haskell Laboratory for Toxicology and Industrial Medicine, 1970c). The fibre contained 1% antimony oxide (by weight). One-inch squares of the test fabric were applied to the arms of ten men and to the arms or legs of ten women and held in place with adhesive tape for six days. Two weeks after removal, new patches were applied for 48 hours. Skin under the patches was examined at two and six days and on final day at patch removal. No skin reactions were seen at any of the examinations.

This study shows that one-inch squares of a test fabric of unknown identity containing 1% antimony oxide (by weight) was not irritating to the skin of 10 men and 10 women. However, the amount of antimony trioxide applied was not given and there is no information on how much of the antimony trioxide in the fibre that came into contact with the skin.

Therefore, no conclusions on the irritation potential of antimony trioxide can be drawn from this study.

- A similar patch test was performed with fibre containing Sb_2O_3 and a substance of which the identity was deleted from the report (the concentration of antimony oxide was not specified) (Haskell Laboratory for toxicity and Industrial Medicine, 1970d). One-inch squares of the test material were applied to the arms of 46 men and to the arms or legs of 127 women and held in place with adhesive tape for six days. Two weeks after removal, new patches were applied as a challenge for skin sensitisation and were removed after 48 hours. Skin under the patches was examined at two and six days and on final day at patch removal. After six days of occluded wear one subject had papules along the edge of patch area, however, similar papules were also seen under the tape area. Subjects had small indented areas under patch that appeared as red spots that coincided with the crimped pattern of this fibre. No conclusions on the irritation potential of antimony trioxide can be drawn from this study.

This study shows that one-inch squares of a test fabric of unknown identity containing an unknown amount of antimony trioxide were not irritating to the skin of 46 men and 127 women. Since the amount of antimony trioxide applied was not given and there is no information on how much of the antimony trioxide in the fibre that came into contact with the skin **no conclusions on the irritation potential of antimony trioxide can be drawn from this study.**

(EU Risk Assessment Report)

5.3.2 Eye

See Table 3 for a summary. For detailed descriptions of the studies, see EU Risk Assessment Report.

5.3.3 Respiratory tract

See Table 3 for a summary. For detailed descriptions of the studies, see EU Risk Assessment Report.

5.3.4 Summary and discussion of irritation

Table 3. Summary of irritation (as in EU Risk Assessment Report)

Reference	**Summary of findings**	
	Method/Results	**Comments**
Skin irritation: Animal studies		
Gross *et al*, 1955	Albino rabbits: not irritating	
Haskell Lab for Tox and Ind Medicine, 1970b	Albino guinea pigs: no evidence of irritation	Mixture with perbromophenyl ether. Inconclusive.

Haskell Lab for Tox and Ind Medicine, 1970	Albino guinea pigs: mild erythema in some animals on day 1. No irritation on day 2	Mixture with hexabromobenzene. No control animals. Inconclusive.
Carnegie-Mellon Inst of Research, 1978	Rabbits: no irritation	Very briefly described. Inconclusive.
Skin irritation: Human studies		
White *et al*, 1993	3 antimony related dermatosis.	Damp skin.
Stevenson *et al*, 1965	23/150 developed skin eruption.	Areas exposed to heat were affected.
Mc Callum, 1963	Skin irritation.	Skin irritation under hot conditions. The frequency not stated.
Potkonjak & Pavloviet, 1983	Dermatosis in workers.	Antimony dermatosis may occur at high temperatures.
Haskell Lab for Tox and Ind Medicine, 1970c	Patch test: no skin reactions	Amount applied not stated. Inconclusive.
Haskell Lab for Tox and Ind Medicine, 1970d	Patch test: not irritating	Amount applied not stated. Inconclusive.
Eye irritation: Animal studies		
LPT Laboratory of Pharmacology and Toxicology, 2005	Conjunctival redness was observed in 2(3) animals.	The effect does not fulfil the current EU-criteria for classification as eye irritant.
WIL Research laboratories, 1979	Necrosis of the lower conjunctivae and the nictitating membrane.	The irritation effects are not severe enough according to EU-criteria.
Eye irritation: Human studies		
Potkonjak & Pavloviet, 1983	Conjunctivitis in 14 cases (27.5%).	It is unclear if the detected effect was due to antimony or some other chemical at the melting plant.
Respiratory irritation: Animal studies		
LPT Laboratory of pharmacology and toxicology KG, 2006	No clinical signs of respiratory toxicity.	

The only animal study which can be used for risk assessment of the skin irritation potential of antimony oxide shows that antimony oxide is not irritating to rabbit skin. Contrary to the animal studies, four out of six human case report studies indicate that antimony trioxide may cause dermatitis under warm conditions. The symptoms were seen on damp skin due to perspiration. Perspiration is a known risk factor for workers in contact with some types of chemicals. Since excessive sweating can solubilise these agents increased contact and absorption by the skin may occur, resulting in an increased sensitivity to workers. This could explain why antimony-induced dermatitis has only been seen at high temperatures, and not in patch tests of humans.

Sweating in itself can cause skin problems, e.g. by increasing the friction produced by clothing, which can lead to blistering and abrasion. A hot environment, with concomitant excessive sweating and without chemical agents involved, can result in a skin condition called miliaria (also known as e.g. sweat retention syndrome or heat rash). Miliaria, which can also be seen under non-occupational conditions, is caused by excessive sweating leading to skin damage. Sweat can lead to swelling of the sweat ducts, which in turn leads to closure or narrowing of the ducts, which hinders the sweat from being expelled to the skin surface. Consequently, sweat is forced to the areas around the sweat ducts where it causes miliaria.

However, after having evaluated existing data from studies of antimony-exposed workers, our conclusion is that skin irritation is caused by antimony in combination with sweating/damp skin and not by sweating alone. This is based on:

- The three workers in White *et al* (1993) were exposed to other metal fumes for many years without skin manifestations. Lesions appeared when antimony was introduced to the process, and resolved when antimony exposure was avoided.

- It is known that antimony dust easily penetrates clothing and in both Potkonjak & Pavlovich (1983) and McCallum (1963) it is stated that good hygiene and frequent bathing decreased the suffering from dermatitis in the workers studied.

- The spots often disappear rapidly during a week-end or public holiday and reappear on return to work (McCallum, 1963), which is not normally the course with miliaria where symptoms can remain for several weeks.

The International Antimony Oxide Industry Association, IAOIA, has agreed that diantimony trioxide is a skin irritant (see technical dossier in IUCLID 5).

In conclusion, antimony trioxide should be regarded as a skin irritant in humans under conditions that evoke sweating.

Classification as Xi; R38 (Irritating to skin) according to Directive 67/548/EC is proposed.

5.4 Corrosivity

Not evaluated for this dossier.

5.5 Sensitisation

Not evaluated for this dossier.

5.6 Repeated dose toxicity

Not evaluated for this dossier.

5.7 Mutagenicity

Not evaluated for this dossier.

5.8 Carcinogenicity

No change to the current classification with Carc Cat. 3; R40 (Limited evidence of a carcinogenic effect) in Annex I of Directive 67/548/EEC is proposed.

5.9 Toxicity for reproduction

Not evaluated for this dossier.

5.10 Other effects

5.11 Derivation of DNEL(s) or other quantitative or qualitative measure for dose response

6 HUMAN HEALTH HAZARD ASSESSMENT OF PHYSICO-CHEMICAL PROPERTIES

7 ENVIRONMENTAL HAZARD ASSESSMENT

Not relevant for this type of dossier.

JUSTIFICATION THAT ACTION IS REQUIRED ON A COMMUNITY-WIDE BASIS

Studies in humans indicate that diantimony trioxide can cause dermatitis under hot working conditions. Therefore, antimony should be regarded as a skin irritant in humans under conditions that evoke sweating. Several case reports from workers at antimony plants indicate the skin irritation potential of antimony, and the substance is widely used. It is therefore important to communicate the skin irritation potential, especially to people involved in antimony manufacturing and to workers exposed to antimony trioxide. Industry's self-classification on skin irritation differs, some having classified diantimony trioxide as a skin irritant and others not. However, the International Antimony Oxide Industry Association, IAOIA, has agreed that diantimony trioxide is a skin irritant (see technical dossier in IUCLID 5). Diantimony trioxide is an existing substance and to speed up the process of harmonized classification we consider this a high priority substance.

We propose a classification with Xi; R38 (Irritating to skin) according to Directive 67/548/EEC criteria.

OTHER INFORMATION

REFERENCES

European Union Risk Assessment Report, Diantimony trioxide, Rapporteur: Sweden

IUCLID 5, technical dossier, Diantimony trioxide, International Antimony Oxide Industry Association, IAOIA