COMMITTEE FOR RISK ASSESSMENT

BACKGROUND DOCUMENT TO THE OPINION OF THE COMMITTEE FOR RISK ASSESSMENT ON A PROPOSAL FOR HARMONISED CLASSIFICATION AND LABELLING OF

DIANTIMONY TRIOXIDE
EC number: 215-175-0
CAS number: 1309-64-4

Adopted on 3 July, 2009

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TABLES

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.

(EC, 2008)

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

RAC proposes that classification of diantimony trioxide as a skin irritant is not justified.

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

Proposed classification based on CLP criteria:

RAC proposes no change to the current classification in Annex VI.

Proposed labelling:

Note: No changes to the current labelling with Xn; S2 - 22 - 36/37 are proposed.

Proposed specific concentration limits (if any): - Not applicable

Proposed notes (if any): - Not applicable

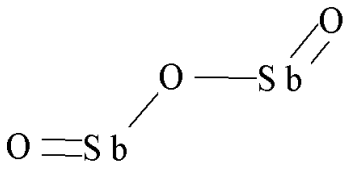
JUSTIFICATION

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 (Sb_2O_3) 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_2O_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 of diantimony trioxide 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 was to cover both with the CAS number for diantimony trioxide, i.e. 1309-64-4.

Chemical Name: Senarmontite

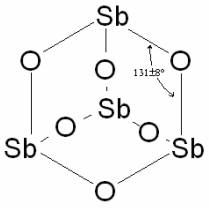
EC Number:

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

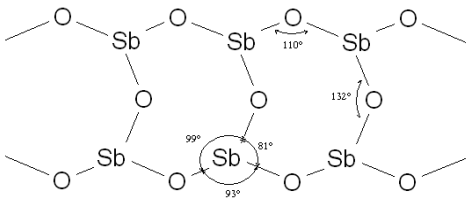
EC Number:

CAS Number: 1317-98-2

IUPAC Name:

Molecular Formula:

Structural Formula:



Molecular Weight: 291.52

Typical concentration (% w/w): -

Concentration range (% w/w): -

(EC, 2008)

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.
Density differs from one crystalline structure to another: *Senarmontite:* 5.2-5.232 g/cm^3 ; *Valentinite:* 5.67-5.72 g/cm^3.

(EC, 2008)

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 %)
Flame retardant in adhesives*		
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

(EC, 2008)

*Quantities not stated (communication from Belgium/FEICA – Association of European Adhesives and Sealant Manufacturers)

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)

Anecdotal information suggests that some companies apply Xi: R38 in addition to the classification with Carc Cat 3: R40

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 diantimony 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. The aim of that 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. (EC, 2008)

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 diantimony 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 g of diantimony 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 diantimony 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 diantimony trioxide in mineral oil (Carnegie-Mellon Institute of Research, 1978).

In view of the limited details available, no conclusions on the irritant potential of diantimony trioxide can be drawn from this study.

(EC, 2008)

Guinea pig:

- In a very briefly reported combined study, a 1:8 mixture of diantimony trioxide (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 diantimony

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 diantimony trioxide.

- In a similar combined dermal irritation and sensitisation study, a 6:1 mixture of hexabromobenzene and diantimony trioxide (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 causes 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 caused 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 diantimony trioxide. (EC, 2008)

5.3.1.2 Human studies

- White *et al* (1993) reported three cases of dermatitis in workers exposed to diantimony trioxide in a melting process. Three men, between 28 and 33 years of age were employed at a brazing rod manufacturing plant in the US. After changes at their workplace they were assigned the task of melting antimony metal (purity 99.86 %) 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 hot work.

The authors concluded that the three workers presented strong evidence for diantimony trioxide 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 exposure to fumes containing diantimony trioxide was avoided. Two of the workers had exposure only to molten metal fume, and not to metallic dust. Furthermore, the third worker who was exposed to antimony dust in addition to fumes from molten antimony, did not respond to avoidance of the antimony containing 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, but since skin lesions only

appeared when antimony was melted it is unlikely that heat in itself was the cause of the skin lesions.

This study indicates that fumes from melted antimony may cause dermatitis (observed in this study as follicular papules and pustules) in humans. The chemical composition of the fumes and the nature of the exposures leading to the adverse skin reactions were not characterised fully: the fumes were thought to have been predominantly antimony trioxide, and the exposures included hot, sweaty conditions.

- The occurrence of a skin eruption in 23 men amongst a population of about 150 workers employed in the manufacture of diantimony trioxide in the UK was reported by (Stevenson, 1965). At this plant, antimony sulphide ore was smelted at high temperatures. The fine white antimony trioxide powder that was produced contained minute amounts of lead, arsenic and iron impurities. The morphology and histology of a rash known as "antimony spots" was described Intense itching preceded the skin eruption. A diffuse blotchy erythema sometimes occurred but most commonly the early lesions were small erythematous papules, possibly associated with much excoriation. The papules enlarged and in some cases became frankly pustular. The sites on the body 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 subsided after 3 to 14 days when the affected worker was transferred to a cooler part of the factory. The eruption occurred in the warm summer months, but was rarely seen in the winter. Seventeen of the 23 men affected were described as furnace workers and another 5 were apparently doing a "different job" but also under hot conditions. No descriptions were provided of the exposures encountered; it is assumed there was exposure to fumes containing antimony trioxide.

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

This study suggests that workers exposed to diantimony trioxide under hot conditions may be liable to develop a transient skin eruption affecting the 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 diantimony trioxide and the pure metal from sulphide ore by various smelting processes (McCallum, 1963). The plant near Newcastle-upon-Tyne in UK is the same as the one described in the article by Stevenson (1965), see above. The rash consisted of papules and pustules around sweat and sebaceous glands and was compared in appearance to the lesions of chickenpox or smallpox. It affected particularly the forearms 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 diantimony trioxide and the pure metal may be connected with skin lesions under hot conditions.

The clinical examination of 51 male workers employed in an antimony smelting plant in Belgrade, in the former Yugoslavia, has been reported (Potkonjak and Pavlovich, 1983; see also section 4.1.2.6, "Repeated dose toxicity" in the EC, 2008, 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, was present in 32 of 51 exposed workers (63%), especially during the summer season and when working near the furnace where temperatures were excessively high. There is additional information in the study report indicating that the vesicles invaginated, then crusted and finally desquamated leaving residual hyperpigmentation. It is unclear whether this was seen in all of the affected workers.

This study indicates that "antimony related dermatosis" may occur in humans exposed to dust and fumes from molten antimony ore, particularly at high temperatures.

- A combined test was conducted to determine the irritation and sensitisation potential of a fibre treated with a mixture of diantimony trioxide (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 % diantimony trioxide (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 the 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 % diantimony trioxide (by weight) was not irritating to the skin of 10 men and 10 women. However, the amount of diantimony trioxide applied was not given and there is no information on how much of the diantimony trioxide in the fibre that came into contact with the skin.

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

- A similar patch test was performed with fibre containing diantimony trioxide and a substance of which the identity was deleted from the report (the concentration of diantimony trioxide 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 the 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 diantimony 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 diantimony 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 diantimony trioxide in the fibre that came into contact with the skin **no conclusions on the irritation potential of diantimony trioxide can be drawn from this study.**

(EC, 2008)

5.3.1.3 Summary on skin irritation, including classification rationale

A concise summary of the information relating to the skin irritation potential of diantimony trioxide is provided in Table 3, below.

Table 3 Concise summary of available information (as in EC, 2008)

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 cases of diantimony trioxide related dermatosis.	Damp skin (hot and sweaty conditions).
Stevenson *et al*, 1965	23/150 developed skin eruption.	Areas exposed to heat were affected.
Mc Callum, 1963	Skin irritation in antimony process workers.	Skin irritation under hot conditions. The frequency not stated.
Potkonjak & Pavlovich, 1983	"Antimony dermatosis" in workers at an antimony smelting plant.	Antimony related dermatosis occurs 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.

The most informative animal study regarding the skin irritation potential of diantimony trioxide shows that this substance is not irritating to rabbit skin.

In humans, there is information from 3 different factories to suggest that exposure of workers to fumes containing diantimony trioxide may cause dermatitis under high temperature, sweaty

conditions. The skin lesions, that some clinicians have termed “antimony spots”, appear as follicular papules and pustules.

The available data do not provide clear evidence that this substance itself has the inherent capacity to cause skin irritation. It appears not to have this intrinsic property because special conditions, namely substantial heat and sweat, were required in addition to chemical exposure in all the cases of skin effects described. Furthermore, diantimony trioxide was not the only chemical species present in the fume to which these cases were exposed.

The individual laboratory studies informing on the skin irritation potential of diantimony trioxide are all lacking in one respect or another. These animal studies were performed 30 years or more ago and do not conform to current regulatory guidelines. However, even taking these limitations into account, they provide no evidence to suggest that diantimony trioxide should be classified as a skin irritant. To fully consider the irritant potential of this substance, it is necessary to also take into account the available human evidence.

The human data can be divided into case studies and workplace observations, and patch tests.

The case studies and workplace observations relate to antimony smelter or brazing workers from factories in the US (in the 1990s), UK (in the 1960s), and in the former Yugoslavia (in the 1980s).

As described above, signs of skin irritation have been seen in smelter workers exposed to antimony fumes and possibly dusts, always in hot, sweaty conditions. It appears that repeated exposure is not necessarily a precondition for the irritant effects. It appears that the irritant hazard is significantly less, and perhaps not even present at all, in less hot and non-sweaty conditions. In the US study, it appears to have been shown that the irritant effects are linked to exposure under these conditions to molten antimony fumes, containing predominantly diantimony trioxide. The irritant effects seen are reversible on cessation of exposure, and have generally been described as being localised rashes with follicular papules and pustules. In the Yugoslavian study, however, a “residual hyperpigmentation” of the skin was noted. This was poorly reported, and it is not clear how long these affected workers were followed up and so it cannot be judged whether this ill-defined residual effect was truly persistent.

It is the opinion of RAC that these workplace studies do not provide a sufficient basis to conclude that diantimony trioxide itself has the property of a skin irritant. Therefore, RAC concludes that no classification for skin irritation properties is justified.

5.3.2 Eye irritation

Not evaluated for this dossier.

5.3.3 Respiratory tract irritation

Not evaluated for this dossier.

5.3.4 Summary and discussion of irritation

As discussed in section 5.3.1, no additional classification 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

Not evaluated for this dossier.

5.9 Toxic to reproduction

Not evaluated for this dossier.

5.10 Other effects

Not evaluated for this dossier.

6. HUMAN HEALTH HAZARD ASSESSMENT OF PHYSICO-CHEMICAL PROPERTIES

Not evaluated for this dossier.

7. ENVIRONMENTAL HAZARD ASSESSMENT

Not evaluated for this dossier.

JUSTIFICATION THAT ACTION IS REQUIRED ON A COMMUNITY-WIDE BASIS

Since the opinion of RAC is simply that the data relating to skin irritation do not justify classification for this endpoint, there is no basis to comment further on the need for action on harmonised classification and labelling at Community level. However, RAC recommends that due consideration be made by the relevant authorities and /or industry, as appropriate, to adequately control the risks of adverse effects in workers exposed to fumes or dusts containing diantimony trioxide in hot, sweaty conditions. Specifically, the concerns relate to fumes and dusts generated during smelting and processing of metallic antimony or antimony-containing ores.

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