EUROPEAN COMMISSION

Health & Consumer Protection
Directorate-General

Scientific Committee on Health and Environmental Risks

SCHER

Opinion on the
Risk from the Use of Diantimony Trioxide in Toys

Scientific Committees
on consumer safety
on emerging and newly identified health risks
on health and environmental risks

The SCHER adopted this opinion at its 8th plenary on 1 July 2010
(modifications introduced after consultations in November 2011)

About the Scientific Committees

Three independent non-food Scientific Committees provide the Commission with the scientific advice it needs when preparing policy and proposals relating to consumer safety, public health and the environment. The Committees also draw the Commission's attention to the new or emerging problems which may pose an actual or potential threat.

They are: the Scientific Committee on Consumer Safety (SCCS), the Scientific Committee on Health and Environmental Risks (SCHER) and the Scientific Committee on Emerging and Newly Identified Health Risks (SCENIHR) and are made up of external experts.

In addition, the Commission relies upon the work of the European Food Safety Authority (EFSA), the European Medicines Evaluation Agency (EMEA), the European Centre for Disease prevention and Control (ECDC) and the European Chemicals Agency (ECHA).

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Opinions on risks related to pollutants in the environmental media and other biological and physical factors or changing physical conditions which may have a negative impact on health and the environment, for example in relation to air quality, waters, waste and soils, as well as on life cycle environmental assessment. It shall also address health and safety issues related to the toxicity and eco-toxicity of biocides.

It may also address questions relating to examination of the toxicity and eco-toxicity of chemical, biochemical and biological compounds whose use may have harmful consequences for human health and the environment. In addition, the Committee will address questions relating to methodological aspect of the assessment of health and environmental risks of chemicals, including mixtures of chemicals, as necessary for providing sound and consistent advice in its own areas of competence as well as in order to contribute to the relevant issues in close cooperation with other European agencies.

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http://ec.europa.eu/health/scientific_committees/environmental_risks/members_wg/index_en.htm

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1. BACKGROUND

With the present mandate, DG Enterprise would like to seek the opinion of the Scientific Committee on the risk to health from the presence of diantimony trioxide in toys and in particular the risk from the consumer's exposure.

Scientific information related to the risk from diantimony trioxide is already available and was referred to the European Commission together with the exemption request.

The EU Risk Assessment Report on diantimony trioxide, which was carried out under existing Substance Regulation 793/93, is available at:

http://ecb.jrc.ec.europa.eu/esis/index.php?PGM=ora

The same data was submitted at international level, and in October 2008, the same scientific results were approved at OECD level. Further information can be found at:

http://cs3hq.oecd.org/scripts/hpv/Status/DownloadFile.ASP?CASNUM=1309644&StatusCode=SIARC&DataNo=1

2. TERMS OF REFERENCE

DG Enterprise would therefore like an opinion on the followings questions:

1. Is there sufficient scientific information available to evaluate the risk to children's health from the presence of diantimony trioxide in toys, taking into account various possible exposure scenarios, such as the placing of toys in the mouth, and also the physical characteristics of the toy material (friable, non-friable, liquid/paste)?

2. On the basis of the available scientific information, is it possible to conclude that the presence of diantimony trioxide in toys would not pose a risk to the health of children? If so, please specify the maximum concentrations that could be present without posing a risk for the various exposure scenarios and specify the permitted use.

For the aforementioned questions, the Committee is asked to take into account the particularity of the consumer, who is under fourteen years old, and the particularity of the exposure scenarios (toys intended to be put in the mouth, for example), for three forms of ingested toy material currently regulated in the Toys Directive (scrape-off material with an assumed ingestion of 8 mg/d, liquid or sticky material with an assumed ingestion of 400 mg/d and brittle material with an assumed ingestion of 100 mg/d). The Committee is invited to make any additional comments it considers relevant to the presence of diantimony trioxide in toys.

3. OPINION

3.1. Introduction

According to the SCHER opinion on "Risk from organic CMR (Carcinogenic, Mutagenic or toxic for Reproduction) substances in toys" (SCHER, 2010), any evaluation of children's risk associated with exposure to chemicals in toys should be based on appropriate data that describe total oral, dermal and inhalation exposure of the chemical. Generally, CMR substances should not be present in toys. In case they are present, risk assessment requires appropriate data on potential exposure. For oral exposure, this requires data from repeated extraction studies under agitation at 37°C with appropriate artificial saliva that considers solubility of the compound and migration data in gastric juice to evaluate exposure from ingested debris. Dermal exposure data should be derived from migration studies with artificial sweat. Inhalation exposure data should also be added when relevant (depending on the physico-chemical properties of the CMR). This combined-exposure analysis needs to be related to exposures from other sources such as food, garment and air. In case a Tolerable Daily Intake (TDI) level is available, the exposure from the toy should not exceed 10% of this value.

This opinion is mostly based on the information presented in the EU Risk Assessment Report on diantimony trioxide (EU RAR 2008) and the OECD Screening Information Dataset (SIDS) initial assessment profile (OECD 2008).

3.2. Background Information

Diantimony trioxide (Sb_2O_3) is a solid substance at room temperature and is handled as solid powder, dry or in wetted form, pellets, paste, or granules. The particle size of diantimony trioxide differs between different technical products. The vapour pressure of solid diantimony trioxide is low (1.3 hPa at 574° C) and it has a low solubility in most solvents. The water solubility is between about 20 mg/L at pH 5 and 29 mg/L at pH 9.

The major use of diantimony trioxide is as a flame-retardant due to its synergistic properties for halogenated flame-retardants in plastics, paints, adhesives, sealants, rubber, and textile back coatings. Other use of diantimony trioxide is polymerisation catalyst in Polyethylene terephthalate (PET) resin manufacture and as a clarifying aid in certain glasses, and in pigments. Approximately 25 000 tonnes per year are used in the EU, mainly (>70%) in the production of flame-retarded plastics (PVC – Polyvinyl chloride and non-PVC).

Use of diantimony trioxide as flame retardant in polymers

The amount of diantimony trioxide in polymers depends on several factors such as type of the halogenated compound and polymer, required physical properties of the final polymer, flame retarding requirement, cost considerations etc. Typical content in the final polymer is up to 8%.

Use of diantimony trioxide in plastics for food-contact materials and articles

The use of diantimony trioxide as polymerisation catalyst in PET resin manufacture, destined to be in contact with food, is covered in the EU by the legislation on plastic materials and articles for food contact (EC Directive 2002/72), where a specific migration limit for diantimony trioxide in foods is set at 0.04 mg/kg food (expressed as antimony). The levels of DAT are well below 0.1% when used as a catalyst (EFSA Journal 2004)

Use of diantimony trioxide as flame-retardant in textiles

Flame-retarded textiles are used in textiles for vehicles, protective clothing, mats, curtains, upholstered furniture, tents, canvas, straps etc. Textiles are given flame-retardant properties through a number of different approaches. Diantimony trioxide is used in back-coating, where the fire-resistant layer is attached to one side of the finished textile, e.g. textile-covered articles like furniture or mattresses. Flame-retarded textiles typically contain 4 to 6% diantimony trioxide, with content in the (dry) back-coating of up to 24% (European IPPC bureau, 2002; EBRC, 2006).

Use of diantimony trioxide in pigments

Diantimony trioxide is used in the manufacturing of "Complex Inorganic Coloured Pigments" (CICP) that are used in products such as plastics, coatings, enamels and ceramics and building materials. The pigment production process involves chemical transformation of the input materials into a crystal matrix in which various metals (e.g. Ti, Ni, Cr), apart from Sb, are incorporated. Antimony is chemically bonded as Sb(V) in the rutile lattice, taking the place of some of the Ti-ions.

Once incorporated into these rutile structures, antimony is no longer present as diantimony trioxide (EU RAR 2008). For this reason, diantimony trioxide itself is not released from such pigments. Apart from the use in pigment production, uses as pigment in the ceramics industry and as flame retardant in special paints have been reported. Various antimony compounds are part of pigments used in ceramics decoration colours together with lead-, cadmium-, zinc-, and chromium-compounds. They are applied dry and "fired" at temperatures up to 1250 °C and, therefore, are not considered to be bioavailable.

According to the new Toy Safety Directive 2009/48/EC, the so-called CMR substances (categories 1A, 1B and 2) are virtually no longer allowed in accessible parts of toys. In reality, their presence is limited to a maximum concentration equal to the individual concentration limits established for the classification as CMR in mixtures. Member States and the European Parliament accepted to establish migration limits only for certain metals.

Specific limit values are laid down in Directive 2009/48/EC for arsenic, cadmium, chromium VI, lead, mercury and organic tin, which are particularly toxic and should, therefore, not be intentionally used in those parts of the toy that are accessible to children.

In order to ensure that only trace amounts will be present, their specific limit values laid down in the Directive are set at levels that are half of those considered safe according to the criteria of the relevant Scientific Committee. According to Directive 2009/48/EC, the antimony concentrations of 45 mg/kg, 11.3 mg/kg, and 560 mg/kg should not be exceeded in dry, brittle, powder-like or pliable toy material, in liquid or sticky toy material, and in scraped-off toy material, respectively.

3.3. Toxicology of Diantimony Trioxide

In accordance with Directive 67/548/EEC, diantimony trioxide is classified as dangerous. The endpoints of concern are: skin irritation, local pulmonary toxicity and carcinogenicity.

Skin irritation data in humans

The relevant effect in humans is a condition known as "antimony dermatosis", which is characterised by vesicular or pustular lesions with residual hyperpigmentation. Stevenson (1965) described the occurrence of skin eruption in 23 persons amongst a population of about 150 men employed in the manufacture of diantimony trioxide. Intense itching preceded the skin eruption. In general, the lesions were present on those dust-laden areas most exposed to heat and, therefore, to sweating. Two furnace-workers 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 occurred in the warm summer months and was rarely seen in the winter. Seventeen of the 23 men affected were furnace workers and five were doing a different job but also under hot conditions.

In another communication, severe discomfort from skin irritation in warm weather was described in men working on the production of diantimony trioxide and the pure metal from sulphide ore by various smelting processes (McCallum, 1963).

Since these transient skin eruptions of workers only occurred during and after exposure at dust-loaded areas and in skin areas most exposed to heat where sweating occurred ECHA (2009) did not propose to label diantimony trioxide as a skin irritant. Since children are not exposed to diantimony trioxide dust, the SCHER concludes that skin irritation is not relevant for the presence of the compound in toys.

Repeated toxicity studies in laboratory animals

The repeated dose toxicity of diantimony trioxide has been investigated in several animal studies via the inhalation and oral routes of exposure. The majority of these studies are considered inconclusive because they do not comply with current test guidelines, but those that are conclusive showed that diantimony trioxide is toxic to the lung.

Repeated inhalation exposure to diantimony trioxide gives local toxic effects in the lung and a No Observed Adverse Effect Concentration (NOAEC) of 0.51 mg/m^3 is derived from a 12-month-long inhalation exposure study in rats, supported by observations of acute pneumonia in a 19-days-long inhalation developmental toxicity study. No systemic toxicity was observed.

Although the mechanism for pulmonary tumour formation is still unclear, it can be assumed that particle deposition followed by macrophage infiltration, pulmonary inflammation and impaired clearance are pivotal initial steps in the process. Consequently, diantimony trioxide is regarded as a threshold carcinogen (OECD 2008). As a starting point for a quantitative risk characterisation, the NOAEC of 0.51 mg/m^3, derived for local repeated dose toxicity, is also used for lung carcinogenicity.

According to Regulation (EC) No. 1272/2008, diantimony trioxide is a Category 2 carcinogen (as defined by the Globally Harmonized System of Classification and Labelling of Chemicals or GHS). The SCHER notes that carcinogenicity only applies to the pulmonary effects, which are the inflammatory consequence of particle deposition, rather than an antimony effect.

In an OECD guideline, 90-day oral study (Hext et al. 1999), diantimony trioxide did not cause systemic toxicity at doses up to 1686 and 1879 mg/kg bw/d in male and female rats, respectively. No histopathological changes were observed in testes up to a dose of 1686 mg/kg bw/d, or in ovaries and uterus up to a dose of 1879 mg/kg bw/d. Based on these results, diantimony trioxide was not toxic to male or female reproductive tissues.

In rats, orally exposed to diantimony trioxide, a slightly lower No Observable Effect Level (NOEL) was observed: 70/81 mg/kg bw/d in m/f, treated for 13 weeks in feed (Hext et al 1999). In mice, orally treated for 14 days, the NOEL was 43 mg/kg (dose finding study NTP 1992). The relatively high NOELs are due to the low solubility of the substance. However, the highly soluble antimony potassium tartrate showed much lower Lowest Observed Effect Level (LOELs)/NOELs. In a 90-days-long drinking-water study in rats, histopathological changes in thyroid, hypophysis, spleen, thymus and liver have been observed with a NOEL of 0.06 mg antimony/kg bw per day (Poon et al 1998). Since this NOEL applies for the highly soluble antimony potassium tartrate, it is applicable as a systemic NOEL of the antimony ion.

In a lifetime study in rats, effects on the levels of cholesterol and glucose occurred at 3.7 mg/kg bw (LOEL) (Schroeder et al 1970).

Based on the study of Poon et al. (1998) on the highly soluble antimony compound, WHO (2006) proposed a TDI of 6 µg Sb/kg bw per day and a drinking water standard of 20 µg/L assuming a 60-kg adult drinking 2 litres of water per day and allocating 10% of the TDI to drinking water. The EPA drinking-water limit is 6 µg/L.

In 2004, EFSA set a limit of 40 µg/kg bw for antimony in food (specified in Directive EC 2005/79). The established EU safe limit for drinking water has been set at 5 µg /L.

3.4. Exposure assessment

General routes for exposure

Inhalation

Consistent with the SIAM 27, 14-16 October 2008, the SCHER concludes that lung toxicity can be considered as a non-specific particle effect with the possible release of small amounts of antimony ions, which is not relevant for the evaluation of possible health consequences of the use of diantimony trioxide in toys. Since the inhalation and oral studies in animals do not show systemic effects even at high exposures, it can be concluded that bioavailability of the chemical or the antimony ion is very low, so that no systemic effects are expected from inhalation.

Dermal

Dermal absorption of diantimony trioxide is considered low. This conclusion is based on an *in vitro* human skin percutaneous study which showed absorption of 0.2 $\mu g/cm^2$ or 0.325 $\mu g/cm^2$ after application of 100 and 300 mg/cm^2, respectively. A penetration rate of 0.26% was derived from this study. An NOEL for dermal exposure has not been determined.

Oral

Antimony is also a naturally occurring element. According to Moll and Moll (2000), the main contributors to antimony intake via food and beverages are cereals, sweeteners, fish and crustaceans, fruits and vegetables and alcoholic beverages.

Diantimony trioxide is released into the environment from manufacture, formulation, processing of diantimony trioxide, and from use and disposal of diantimony trioxide-containing products. In the environment, diantimony trioxide will dissolve releasing trivalent and predominantly pentavalent ions. As a consequence, the actual exposure from drinking water, food and breast milk will be to the antimony ion.

Exposure to DAT from specific products

Diantimony trioxide is used in several products, some of which are available to consumers. Some examples of end products containing diantimony trioxide and/or antimony derived from diantimony trioxide are:

- Polyethylene Terephthalate (PET)
- flat and pile upholstered furniture (residential and commercial furniture)
- cuddly toys
- upholstery seats and automobile interior textiles in private and public transportation, draperies, and wall coverings
- flame retardant treated textiles
- electrical and electronic equipment e.g. distribution boxes for electrical lines
- polyvinyl chloride wire, cable and textile coating

PET bottles

The Antimony concentrations, measured in PET-bottled water from 11 European countries before and after 6 months of storage (Shotyk and Krachler, 2007), are the most representative data available. The median concentration of antimony (0.343 µg/L) found in PET-bottled waters before storage for 6 months is estimated as the typical concentration of antimony in drinking water. This value is supported by the concentration of antimony in bottled water from the UK (median: 0.2 µg /L and 90th percentile: 0.5 µg/L) in which the effect of storage is not considered. Due to the fact that bottled water may be stored for several months before it is consumed, the effect of storage cannot be neglected. Therefore, the reasonable worst-case concentration is estimated to be 0.879 µg/L, which is the 90th percentile of the concentration of antimony in water stored in PET bottles for 6 months. Assuming that an adult drinks 2 litres per day, a worst-case exposure is 0.686 for non-stored bottles and 1.758 µg antimony/d after 6 months storage. With a body weight of 60 kg this implies a typical consumer exposure of 0.012 µg /kg/d and a reasonable worst-case consumer exposure of 0.029 µg /kg/d.

Liquids other than water do not seem to considerably increase the leakage from the PET bottle (Fordham et al 1995). Since baby’s’ food is not kept in bottles over days, the leached amounts of antimony do not contribute significantly to the background exposure of children. However, powder formulas for infants can be dissolved in water from PET bottles. In case this water contains between 0.34 and 0.9 µg/L, an infant of 5 kg and ingesting 1 L of water would be exposed to 0.07 and 0.18 µg/kg per day.

Polyester fibres

The Danish Environmental Protection Agency (Laursen et al. 2003) has made a survey of chemical compounds in 6 textile fabrics (a textile intended for use in apparel, napkins, trousers, blouse, underwear, fleece). Extractable antimony in these fabrics by artificial saliva and sweat were measured by extraction of 2 g of samples with 100 ml of solution at 40°C for 1 hour. The solution was either artificial saliva or artificial sweat. Extractable antimony was only found in one sample of artificial perspiration, and the amount extracted was 10% of the total antimony in the sample. Using these data BfR has calculated a chronic daily exposure of 0.5 µg Sb/kg bwt of a child weighting 10 kg assuming exposure to polyester fibre fabrics that contain 200 mg Sb/kg as a worst case scenario. The exposure of 0.5 µg Sb/kg is included in the exposure assessment given in Table 1. Please note that babies of different age (and weight) are exposed via specific scenarios.

<u>Flame retardant-treated textiles</u>

The University of Surrey has made a study on flame-retardant release from 2 samples of textiles (BSEF and IAOIA, 2006). As part of this study, a test to simulate the dermal exposure to diantimony trioxide from contact with flame-retarded textiles was performed. The theoretical content of diantimony trioxide in the textiles was 3.6% and 4.3%. The samples were aged thermally and with UV-radiation.

The Contact Blotting Test (US Consumer Safety Commission 1994) was used to simulate the dermal exposure to diantimony trioxide from contact with the textiles. From this test, a dermal exposure level is calculated equal to 0.11 mg/d, corresponding to $0.057 \cdot 10^{-3}$ $mg/cm^2/d$ (assuming an exposure area of 1934 cm^2). For a person weighing 60 kg, this corresponds to an exposure of 1.8 µg/kg/d or 0.3 µg/kg/d for a child of 10 kg.

This derived exposure has been seen as a worst case, because it assumes that clothing and the skin present no barrier to movement of diantimony trioxide. The release fraction from the contact-blotting test represents dermal contact with only liquid between the skin and the layer containing diantimony trioxide, and it is unlikely to occur six hours per day.

It is noted that when diantimony trioxide is dissolved and leaches from the textile matrix, it will be present in the form of the antimony ion.

Thomas and Stevens (2006) investigated the potential release of flame-retardants as debris and as volatiles from back-coated textiles. It was shown that the debris contain short and long fibres, particulates with the largest quantity in the 10-90 µm size ranges with a low quantity by weight of smaller particles. The test also revealed that emission of airborne particles in the size range 30 nm to 6.5 µm occurs. In this study, no diantimony trioxide was detected as volatiles and low levels of diantimony trioxide were detected in debris. No chemical analyses were made of the airborne particles.

<u>Cuddly toys</u>

The Danish Environmental Protection Agency (Laursen et al. 2003) has investigated five different cuddly toys made of minimum 95% natural materials and without electrical or electronic parts. In two of these toys, antimony ion was present above the detection limit of 5 mg/kg: 120 and 260 mg/kg in the fillings, and 36 mg/kg in trousers. The German Ökoinstitut identified diantimony trioxide in toys but did not report the concentrations found (Oekotest 2002).

Oral exposure was estimated for a child sucking/chewing on these toys. Several ways to predict the exposure have been considered. It was found that there is lack of information on the migration rate of antimony out of the toy and uncertainties on the time which a child sucks on a cuddly toy. An initial estimation has been made based on the following:

- The exposure comes from ingestion of toy particles,
- The content of antimony in the toy particles is the maximum found in toys in the studies presented above.

The amount of toy material ingested per day has been set to 8 mg/d based on the convention adopted for the directive on safety of toys (Directive 88/378/EEC), which has been supported by the CSTEE opinion (2004). The exposure by swallowing 8 mg of a toy particle that contains 260 mg/kg Sb is:

8 mg/d x 260 mg Sb/kg = 2.1 µg Sb/d, or 0.21 µg/kg/d for a child of 10 kg.

The dermal exposure for a child sleeping with cuddly toys is predicted to be significantly lower than the exposure from the use of flame retardant in textiles. The reasoning for this is based on the following:

- The highest concentration of antimony found in cuddly toys is significantly lower than in the back-coating of the furniture.
- A reasonable worst case would be for a child to rest its head on a cuddly toy (as a pillow), with less than half the area of the face in contact with the toy, i. e. less than that used for the textile scenario.

Due to its low volatility exposure via inhalation was not considered relevant for this specific exposure scenario.

Dust

Thompson and Thornton (1997) investigated antimony in house dust. Compared to naturally occurring amounts in soil of around 0.2 µg/g, house dust contained relatively high amounts of antimony with median values of 13 µg/g, which corresponds to 15.6 µg Sb_2O_3/g. The 90th percentile in the same publication was close to 50 µg/g, which corresponds to 60 µg Sb_2O_3/g. When taking the CSOIL (parameter set for human exposure modelling) estimate for particulate matter (dust) in indoor air of 52.5 µg/m^3 into consideration (Otte et al., 2001), 15.6 µg Sb_2O_3/g dust corresponds to 0.819 ng Sb_2O_3/m^3. This is considered a typical value. A reasonable worst-case scenario of 60 µg Sb_2O_3/g corresponds to 3.15 ng Sb_2O_3/m^3. Since house dust consists to a certain extent also of dust and soil carried into the house from the external environment, part of the antimony present will also be in the form of pentavalent and trivalent compounds. Therefore, the assumption that all antimony is present as the trioxide is a conservative assumption.

Children ingest between 50 and 100 mg of dust/d (Butte and Heinzow, 2002). Assuming that a child of 10 kg would ingest 100 mg dust/d, which contains 15.6 and 60 µg/g diantimony trioxide, this corresponds to an exposure of 0.156 µg/kg bw/d (0.1 g/d·15.6µg/g)/10 kg) and a worst-case exposure of 0.600 µg/kg bw/d (0.1 g/d·60µg/g)/10 kg).

3.5. Risk assessment

In the EU Risk Assessment Report (EU RAR 2008), the following reasonable worst-case exposures are described:

- oral exposure via food is 0.096 µg/kg bw/d for adults
- oral exposure via breast milk is 0.087 µg/kg bw/d for infants during the first three months of life
- oral exposure via drinking water is estimated to 0.029 µg/kg bw/d for adults.
- concentration in outdoor air is 3.12 ng/m^3

The actual exposure in the subsequent Scenarios 1-3 is to antimony in hydro-complexed form rather than to diantimony trioxide. The exposure in Scenario 4 is largely to diantimony trioxide.

Scenario 1: PET-bottle

The typical and reasonable worst-case oral exposure for adults is estimated to be 0.69 and 1.76 µg/d, respectively (corresponding to 0.012 and 0.029 µg/kg/d, respectively) for a person drinking 2 L water from a PET bottle. This is based on measured values. In case this water is used to prepare an infant’s food the exposure would be between 0.07 and 0.18 µg/kg per day (5 kg bwt and ingestion of 1 L water).

Scenario 2: Fabrics

According to BfR the chronic daily Sb exposure via polyester fibres is 0.5 µg/kg.

The reasonable worst-case dermal exposure is calculated to be 0.11 mg/d, corresponding to 1.8 µg/kg/d for an adult person of 60 kg bwt sitting on upholstery fabric. For a 10 kg child this amounts to a daily exposure of 0.3 µg/kg/d. The total daily exposure via fabrics and upholstery is 0.8 µg/kg.

Scenario 3: Cuddly toys

The reasonable worst-case oral exposure for children ingesting 8 mg debris of cuddly toys containing 260 mg/kg is 2.1 µg/d. This means that under the worst-case scenario the daily oral exposure to antimony for a child weighing 10 kg will be 0.21 µg/kg bw.

Scenario 4: Indoor air and dust

For exposure via indoor air to the general population, the typical and reasonable worst-case exposures of diantimony trioxide are 0.82 ng/m^3 and 3.2 ng/m^3, respectively. This exposure is negligible as compared to the other sources.

Due to specific hand-to-mouth behaviour typical and reasonable worst-case oral exposure from ingestion of house dust is 0.16 and 0.60 µg/kg/d, respectively.

Previous opinions, standards and exposure assessment

According to the Council Directive 88/378/EEC, the maximum daily exposure limit for Sb from toys is 0.0002 mg. Based on a daily intake of 8 mg, 100% bioavailability and the maximum intake levels of 0.0002 mg, the maximum concentration of Sb in toy materials has been calculated to be 25 mg/kg. In its opinion "Assessment of the bioavailability of certain elements in toys" (CSTEE 2004) has agreed with this calculation.

However, SCHER points out that the justification of the tolerable intake level for antimony in toys of 0.0002 mg is questionable. First, it does not consider the different weights of children. Second, its derivation is not risk-based. Instead, it is based on the total intake of the metal by adults, adjusted for children. The 0.0002 mg figure is not based on an existing standard or TDI, of which the intake from toys should not exceed 10% as proposed by CSTEE (2004) and recently supported by SCHER (2010).

Accordingly, SCHER starting from the Tolerable Daily Intake (TDI) of 6 µg Sb/kg as proposed by WHO, of which exposure from toys may contribute 10%, derives a maximum daily intake via toys up to 0.6 µg Sb/kg bw. As stated above (scenario 3), the reasonable worst-case oral exposure for children represents the ingestion of 8 mg debris of cuddly toys. Under this scenario, the maximum daily intake of antimony via toys (6 µg for a child of 10 kg bw)will be reached if the antimony content in the toy is above 750 mg Sb/kg . This concentration of antimony in toys corresponds to 915 mg diantimony trioxide (DAT)/kg toy. A further 50% reduction of the TDI (and by that the contribution from exposure to toys to take into account the specific sensitivity of children) is not proposed by SCHER because the TDI applies to all groups of the population (SCHER 2010). This assessment indicates that the antimony limit value for toys of 25 mg/kg approved previously by CSTEE (2004) needs to be re-readjusted.

To estimate to what extent the exposure to toys containing 750 mg antimony/kg contributes to the total intake of antimony by children, the available information on total intake via toys, drinking water, food, textiles and house dust is given in Table 1. In all these cases a 100% absorption of the Sb ion has been assumed.

Table 1: Calculation of daily exposures (µg/kg bw) for a 10 kg child ingesting 8 mg toy debris containing 750 mg Sb/kg (915 mg DAT/kg) plus Sb exposure via drinking water, or PET bottled water, or food, plus ingestion of house dust (worst case 0.6 µg/kg) plus dermal exposure from textiles (maximum exposure 0.8 µg/kg. Inhalation exposures are considered non significant. For comparison the TDI is 6 µg Sb/kg

Routes of antimony-exposure	Expos. (µg/kg)	+ 0.6 µg/kg from toys	+ 0.6 µg/kg from house dust (worst case)	+ 0.5 µg/kg from textiles (max. expos.) + 0.3 µg/kg from upholstery
1 L drinking water*	0.03	0.63	1.23	2.03
1 L PET bottle water**	0.18	0.78	1.38	2.18
Breast-milk feeding	0.09	0.69	1.29	2.09
1 kg food	0.1	0.7	1.3	2.1

* Powder formula in drinking water.

** Powder formula in 6 months stored PET-water;

Table 1 shows that the sum of estimated exposure to drinking water, or breast-milk feeding or food plus the exposure to toys, plus exposure to house dust, plus dermal contact to textiles is below the TDI of 6 µg/kg. This also applies if an infant receives 1 L of PET-water stored for 6 months.

However, no measured data are available to assess migration of antimony into saliva from mouthing the toy. Due to this uncertainty, the SCHER reduces the maximum concentration of antimony in toys by a factor of 5, which results in the maximum concentration of 150 mg antimony/kg toy.

Using the concentration of 150 mg/kg, the Sb intake from liquid or sticky material from toys with an assumed ingestion of 400 mg/d and brittle material with an assumed ingestion of 100 mg/d is calculated and presented in Tables 2 and 3.

Table 2: Calculation of daily exposure (mg/kg) of a child of 10 kg ingesting 400 mg per day of liquid or sticky material.

Liquid or sticky material	Limit Value (mg/kg)	[Sb] in 400 mg (µg)	Expos. (µg/kg bw/d)	TDI/10 (µg/kg bw/d)
Ingestion of 400 mg	150 (toys)	60	6	0.6

Table 3: Calculation of daily exposure (mg/kg) of a child of 10 kg ingesting 100 mg of brittle material.

Brittle material	Limit Value (mg/kg)	[Sb] in 100 mg (μg)	Expos. (μg/kg bw/d)	TDI/10 (μg/kg bw/d)
Ingestion of 100 mg	150 (toys)	15	1.5	0.6

Tables 2 and 3 demonstrate that the TDI for exposure via toys of 0.6 µg/kg is exceeded by a factor of 10 in case of liquid or sticky material and by a factor of 2.5 for brittle material. On the basis of this, the SCHER recommends to further reduce the maximum limit of antimony in toys by a factor of 10 to 15 mg/kg, which is equivalent to 18 mg DAT/kg. In the case of liquid or sticky material ingestion of 400 mg/d results in a daily exposure of 0.6 μg/kg, which is about 10% of the TDI.

4. RESPONSE TO THE TERMS OF REFERENCE

4.1. Question 1

The SCHER is asked if there is sufficient scientific information available to evaluate the risk to children's health from the presence of diantimony trioxide in toys, taking into account various possible exposure scenarios, such as the placing of toys in the mouth, and also the physical characteristics of the toy material (friable, non-friable, liquid/paste)?

There is insufficient information to evaluate the risk to children's health from the presence of diantimony trioxide in toys and various possible exposure scenarios, such as the placing of toys in the mouth. Only the daily exposure from ingestion of 8 mg debris or 400 mg of sticky and liquid material, or 100 mg of brittle material can be calculated assuming 100% release and absorption of the antimony. Since no data are available to take into account the physical characteristics of the toy material (friable, non-friable, liquid/paste), the exposure estimates from swallowing debris have been used for exposure assessment.

However, SCHER recognizes that DAT is rather insoluble and that the assumption of 100% migration and 100% absorption overestimates exposure. Thus, for a data based risk assessment the SCHER strongly recommends to provide appropriate migration data, which then will allow defining maximum tolerable limits for DAT in toys.

In case diantimony trioxide is present in pigments or in Complex Inorganic Coloured Pigments (CICP) where antimony is not bioavailable SCHER sees no need to limit the DAT or Sb concentration. This is supported by the SIDS Initial Assessment Profile (SIAM 15, 22-25 October 2002), which concluded that bioavailability of antimony from the pigment yellow 53 was not demonstrated.

4.2. Question 2

On the basis of the available scientific information, SCHER is asked to evaluate if it is possible to conclude that the presence of diantimony trioxide in toys would not pose a risk to the health of children? And if so, to specify the maximum concentrations that could be present without posing a risk for the various exposure scenarios and specify the permitted use.

On the basis of the available information and rough exposure estimates, the SCHER concludes that the presence of diantimony trioxide in toys does not pose a risk to the health of children under conditions as follows:

- Use in pigments or in Complex Inorganic Coloured Pigments (CICP)
- In toys at DAT concentrations of up to 18 mg/kg

The SCHER notes that the carcinogenic effects of diantimony trioxide observed in the lung is considered a particle effect and by that carcinogenicity does not apply to dermal and oral exposure. Consequently, the CMR requirements do not apply to toys, because via toys normally children are not exposed to particles of diantimony trioxide.

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