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Sb_2O_3

- **Present situation: January 2003**

⇨ Antimony trioxide (ATO) is currently undergoing a Risk Assessment under the EU's Existing Substances Regulation (793/93/EEC) with Sweden as Rapporteur. The Risk Assessment is broad in its coverage and will address human toxicity (potential cancer and non-cancer hazards), environmental fate and ecotoxicity and human and environmental exposure, including potential exposures from downstream uses of antimony trioxide in various consumer applications. Campine is intensively cooperating via the IAOIA (International Antimony Oxide Industry Association). An IAOIA Newsletter is available at www.iaoia.org or via www.campine.be via regulatory affairs.

⇨ Some of the current planned, ungoing and finished studies include:

1. inhalation developmental toxicity study in rats (teratogenicity study): results expected half 2003
2. ecotox classification studies: results available
3. soil and sediment testing: including an "Acute toxicity test of $SbCl_3$ on survival and reproduction of Enchytraeus crypticus" and "Whole sediment Acute Toxicity test for measuring the effects of $SbCl_3$ on survival of Hyalella azteca". Results expected beginning of 2003.
4. occupational and environmental exposure assessment (results of the questionnaire sent to the Rapporteur in January 2002) Further information is needed by the end of January 2003.
5. end-user dermal, oral and inhalation exposure to flame retardants in furnishing fabrics. The project started in November 2001 and is to be completed by mid 2003.

⇨ Classification and labelling in accordance with EC-directives 67/548/EC and 1999/45/EC and latest amendments:

Xn : Harmful
R40: Limited evidence of a carcinogenic effect.
S22: Do not breathe dust
S36/37: Wear suitable protective clothing and gloves

Antimony trioxide is NOT ecotoxic.
No labelling required when Sb_2O_3 is encapsulated in a resin.

- **Benefits**

The major use of antimony trioxide is as flame retardant synergist in plastics, paints, adhesives, sealants, rubber and textile back coatings where it is co-used with chlorine or bromine-based compounds. Without ATO synergists, around twice as much halogen compound would be needed to confer levels of flame retardancy required by legislation.
ATO is also used as a PET-catalyst.

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- **Overview toxicology**

Ecotoxicity:
EC50-48 (Daphnia Magna): > 1000 mg/l (Janssen Biotech 8/6/90)
LC50-96 (Brachydan.Rerio): > 1000 mg/l (Janssen Biotech 8/6/90)
EC50-72 (Sel.Capricornut.): > 2.4 mg/l (Lisec 08/2001)

Among the three tested species, Algae appear to be the most sensitive to Sb_2O_3. This EC50-72 value for Sel.Capricornut is not relevant since the toxicity level is much higher than the solubility level of Sb_2O_3 in water. Solubility is defined at 1.86 mg/l (pH 8, 100 mg Sb_2O_3 charge/ l, 24H) After 72 hours, only 9% reduction in growth was measured, which indicates that no acute ecotox classification is necessary.

The only possible classification remaining would then be R53 for long-term adverse effects. The 28 days, chronic transformation/dissolution test gave 0.118 mg/l solubility. The NOEC derived from the algae test is 0.323 mg/l. A literature study provided enough reliable chronic data. The Swedisch rapporteur, KemI accepted that antimony trioxide does not need any ecotox classification.

According to a literature review in 1998, the bioaccumulation potential of antimony, describing the transfer of contaminants from the external environment to an organism, is only moderate. Moreover, since the data concerning the occurrence of antimony in the environment suggest that antimony is only present in low concentrations, it can be concluded that biomagnification, expressing the transfer of contaminants through the food chain in higher organisms, will not occur.

General toxicity:

Concerning the effects of single exposure of animals to antimony oxides, it could be concluded that Sb_2O_3 is of low acute toxicity by the oral, dermal and intraperitoneal route.

Antimony oxide did not cause skin irritation in animal studies. However, it was severely irritating to the eye. The results of irritation and sensitisation studies in humans show that antimony trioxide can cause skin lesions known as 'antimony spots'. However, it is not clear if many of the skin lesions reported among antimony workers were attributable to an irritant or sensitisation reaction.
The acute oral toxicity (LD_{50}) is more than 20 000 mg/kg bodyweight.
The most important route of exposure is inhalation.
Genotoxicity:

The APME study performed in 1998 indicated that although Sb_2O_3 shows in vitro clastogenic activity, it is not an in vivo genotoxic and therefore does not pose any genotoxic hazard to man.

Carcinogenicity:

Sb_2O_3 has produced tumours in rat lungs after a one-year exposure period by the inhalation route. The study of Groth (1986) showed the presence of lung neoplasms in 27% of females exposed to Sb_2O_3. Watt (1983) induced lung tumours in rats with lower concentrations and a NOAEL of 4 mg Sb/m^3 has been identified for Sb_2O_3. However, it is not clear if tumours would have developed at the lower dose levels tested had rats been exposed for the two years required for modern regulatory bioassays, a reason why this NOAEL may not accurately reflect the true activity of Sb_2O_3.
Other studies such as the Bio/Dynamics study (1990) did not observe lung tumours, notwithstanding the fact that similar concentrations had been used as in the study performed by Watt. A possible explanation for these conflicting results, could be the differences in the amount of antimony deposited in the lungs. The degree of pigmentation in the lungs was greater in the lungs of rats from the Watt study compared to those from the Bio/Dynamics study.
There could be a 'foreign body' neoplastic effect in overloaded rat lungs resulting from the prolonged contact with the non-cleared particles.

Sb_2O_3 is according to directive 67/548/EC and adaptations, classified as Xn Carcinogen Class 3. ⇒ R40 : Limited evidence of a carcinogenic effect

- **National and international activities:**

⇨ **WHO** is revising its drinking water guidelines for antimony; a peer reviewed document will probably be published on their website soon, where it will be open for comments. Final decision needs to be published in February 2003.

⇨ **WEEE/RoHS Directive**: On Friday 11 October 2002, the European Parliament and the EU council of Member States came to a final agreement on the draft directives on Waste Electrical and Electronic Equipment (WEEE) and on the Restriction of Hazardous Substances (RoHS).

The RoHS directive requires the substitution of mercury, lead, hexavalent chromium, cadmium, PBB and certain PBDE's in electrical and electronic equipment. The ban of these substances will start on 1 January 2006. Every antimony trioxide contains small amounts of lead as an impurity, originating from the antimony ores. The RoHS directive does not restrict the use of any impurities. It concentrates on the lead used in EEE for soldering in printed circuit boards, as radiation shielding in Cathode Ray tubes, for soldering in light bulbs and in the glass of light bulbs and in the glass of electronic components and lead applications used for coatings.
Antimony trioxide is not mentioned in the WEEE, but will be affected because of the co-use with certain brominated flame retardants (BFR) in E&E. More information on the BFR's can be found on www.ebfrip.com.
The text of both directives has been approved by Council and European Parliament.Transposition into national law in each Member State is due by mid 2004.

⇨ **The European Commission's White Paper on the revision of the Chemicals Policy,** adopted in February 2001, outlines a strategy for the future assessment of

chemicals. It will be up to industry to proof that their substances are safe to use. (reversal of burden of proof). If information is not provided within a certain time limit, market restrictions will be enforced until the safety of the substance is proven. No data: no market. All industry will be affected: producers, importers and users will be obliged to provide specific information on the properties of their substances and their impact on the environment and human health via the REACH system.(Registration Evaluation and Authorisation of Chemicals). The Greek presidency (first 6 months of 2003) has not prioritised the New Chemicals Management Policy on the top of the working program for the Environmental Council.

- **Conclusions:**

⇨ It is clear that there is an increasing pressure on antimony either directly or via the brominated flame retardants especially from Scandinavian countries. To our present knowledge, antimony trioxide is not banned via any European Directive at this moment, except via certain voluntary eco-labels.

⇨ Campine, as member of the IAOIA (international antimony oxide industry association), will remain actively involved in the risk assessment of antimony trioxide. New scientific data will make sure that antimony trioxide is being used in a safe way.

⇨ The EU New Chemicals Policy will force industry to proof that their products are safe to use. It will also prevent the forced use of unsafe alternatives. The new policy will have far reaching effects on our industry and will in time reshape the future EU's chemical market.

- **References**

⇒ Toxicological Risks of Selected Flame-Retardant Chemicals, National Research Council, National Academy Press, 2000

⇒ Literature review on the hazards to man and the environment of antimony oxides used in flame retardants and other antimony compounds, ET&C, sponsored by Campine, 1998

⇒ Antimony and Antimony compounds: Criteria document for an occupational exposure limit; UK HSE books in Sudbury/Suffolk, 1996

⇒ www.iaoia.org

⇒ www.campine.be