

International ANTIMONY OXIDE Industry Association

Antimony Trioxide Frequently Asked Questions:

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Q1: What is antimony trioxide?

A: Antimony is a naturally occurring elemental metal, and is found in group VA of the periodic table. It occurs in the tri- (+3) and pentavalent (+5) forms and is found in the earth's crust (average ca. 0.25 mg/kg) mostly associated with sulfur as stibinite. The manufacture of antimony trioxide (ATO) involves a sublimation reaction with oxygen that results in a cuboidal crystalline lattice formation. Antimony trioxide is a white powder of a ceramic character with very low solubility in water.

Q2: What is it used for?

A: The major use of ATO is as flame retardant synergist in plastics, paints, adhesives, sealant, rubber and textile back coatings where it is co-used with appropriate halogenated compounds usually chlorine or bromine based. ATO increases the flame retardant effectiveness of the halogenated compound thereby minimising its addition level. Without ATO synergists, around twice as much halogen compound would be needed to confer levels of flame retardancy required by legislation. Minor uses of ATO include: as catalyst in the production of polyethylene terephtalate (PET) bottles, films and polyester fibres (about 10%), as a clarifying aid in certain glasses, as a coating used on certain grades of TiO2 pigments, as a stabiliser in certain pigments based on chromate's and molybdate's and as an opacifier in cast iron bath and sinking enamelling.

Thousands of lives have been saved and tens of thousands of disfiguring burn injuries have been avoided by the use of antimony trioxide as a flame retardant synergist. Currently there is no known effective alternative to antimony trioxide in this application.

Q3: Why is antimony trioxide going through a risk assessment and who is the Rapporteur?

Antimony trioxide was published by the European Commission on the fourth priority list of the Existing Substance Regulation 793/93 in October 2000. This regulation on the evaluation and control of existing substances requires the real or potential risk for man and the environment of priority substances to be assessed, using specific principles, laid out in the Technical Guidance Document. Risk assessments are carried out by competent authorities designated by the responsible Member State to act as rapporteur. Sweden chose to be rapporteur for the risk assessment of antimony trioxide. They wanted to investigate if the 'concerns' they have regarding the possible toxicological and/or ecotoxicological characteristics of antimony trioxide are scientifically justifiable or not.

Q4: Is the general public exposed to antimony?

Yes, the general public is exposed to very low levels every day. Antimony is a naturally occurring elemental metal and therefore can be found in drinking water, the air that we breathe and in food. The daily intake from food and water ranges from to 10 to 70 micrograms (μ g) per day. In 2003, the World Health Organization (WHO) has raised the Tolerable Daily Intake (TDI) for antimony from 0.86 μ g/kg/day to 6 μ g per kilogram of body weight (360 μ g per day for an individual weighing 60 kg). WHO has also established a guideline value of 20 μ g/l in drinking water. The European Food Safety Authority (EFSA) has recently raised the specific migration limit of antimony from plastics materials and articles into foodstuffs from10 μ g/kg to 40 μ g/kg of food. The main sources of antimony in urban air are from industrial dust, car emissions and fuel oil combustion, but still are very low (0.15 μ g/kg/day).

Q5: Is antimony trioxide harmful to the health of the general public or consumers?

Small levels of exposure to ATO such as those found in the environment (0.15 μ g/kg/day) are not harmful to human health. The European Food Safety Authority (EFSA) has doubled the restriction of 0.02 mg/kg food to 0.04 mg/kg food, which translates into a SML (specific migration limit) of 40 ppb (expressed as antimony), which has been confirmed by the inclusion into Directive 2005/79/EC. As usual, these limits have been established applying very conservative safety factors. The consumer or the general public is therefore not exposed to any levels which could pose a health risk.

Q6: Is antimony trioxide harmful to the environment?

No, antimony trioxide is not harmful to the environment. Antimony trioxide is very insoluble in water, therefore, the toxicity to fish and other aquatic organisms is very low. The acute and chronic toxicity to aquatic life is above the level of the dissolution potential under "worst case" environmental conditions. Antimony trioxide does not require labeling with R phrases that indicate toxicity to the aquatic environment.

Q7: Why should we use flame-retardants?

Flame retardants are used in plastics as well as in textiles, to prevent deaths and injuries from fire. Flame retardants are used in textile backcoating in furniture so that upholstered furniture can meet the UK and Irish fire safety standards, the highest standards in the world. These standards have resulted in over 3,000 lives being saved in 10 years according to UK government calculations (see

http://www.dti.gov.uk/homesafetynetwork/bs_rfffr.htm)

Other European countries limit their fire safety requirements to furniture in public places, such as cinemas, theatres, hospitals, trains and buses.

Q8: Why is antimony trioxide used in conjunction with flame retardants?

By using antimony trioxide as a synergist in combination with brominated or chlorinated flame retardants and polymers, lower volumes (2 to 3 times, depending on the application) of flame retardants are needed for the production of plastics. The advantage is that less resource is used (one of the principles of sustainable development); the properties of the plastic are better maintained (technical advantage), while a high level of fire safety for consumer goods is ensured (legal fire safety requirements).

Q9: Which consumer products require the use of antimony trioxide as a flame retardant?

Antimony trioxide is used in combination with halogenated flame retardants and polymers such as PVC, for a wide range of applications including paints and surface coatings, textiles for furniture, curtains and drapes, particularly in public buildings and transport and in plastics used in e.g. computers, TV sets, electric and electronic equipment, cables, building and automotive applications in order to meet fire safety requirements.

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Q10: Why is PET manufactured mainly from antimony (Sb), but also from germanium (Ge) and titanium (Ti) based catalysts?

Use of germanium is mostly linked to historical reasons; Japanese fibre producers selected it because the resulting white shade of fabrics was appreciated by consumers. When they began production of bottle-grade PET, they retained the same catalyst system. Antimony trioxide is the major catalyst used in the rest of the world. Despite all attempts to find improved catalysts, the cost/performance ratio of antimony is still considered optimal by industry. A few PET grades are manufactured with titanium based catalytic systems or with combination of antimony, titanium, and germanium. These catalysts are a relatively new development in the PET catalyst market and are mainly used in fibre and film applications - continued development may result in a more general acceptance for bottle-grade PET, but currently they are either less efficient or more expensive than antimony (or both).

Q11: Could disposal of PET bottles cause accumulation of antimony in the environment?

Antimony trioxide (the major use catalyst for PET manufacture) is not classified as "Dangerous to the Environment" (symbol N).

Additionally, the European Chemical Bureau is currently carrying out a risk assessment on this substance. The second draft (very close to the final version) of the environmental risk assessment section is already available. There is no proposal to classify it as "Dangerous for the Environment" (symbol N) or as bio-accumulative. According to the Organisation for Economic Co-operation and Development (OECD) guidelines, because of the low solubility of antimony trioxide no acute or chronic ecotoxicity classification is required either. Hence, the risk of bioaccumulation is negligible.

Q12: Are the antimony levels found by Professor Shotyk of Heidelberg University below the established legal safety limits for drinking water and foodstuffs?

The highest concentration that Prof. Shotyk measured is 630 parts per trillion (ppt); more than sixty times lower than the legally established safety limit (Specific Migration Limit = 40 ppb). It is also important to note that the legal limit has been established by applying very conservative safety factors to the concentrations that were found to have no adverse effects.

Prof. Shotyk clearly states in his recent paper (Contamination of Canadian and European bottled waters with antimony from PET containers):

"The motivation for our study has been to demonstrate that bottled waters cannot be used to study the natural abundance of Sb in groundwaters".

"We wish to emphasise that all of the waters (packed in PET and glass) measured in our lab to date were found to contain Sb in concentrations well below the guidelines commonly recommended for drinking water which are as follows:

World Health Organisation (WHO), 20ug/l; United States of America (US) Environmental Protection Agency (EPA), 6ug/l; Health Canada and the Ontario Ministry of Environment, 6ug/l; German Federal Ministry of Environment, 5ug/l; Japan, 2 ug/l. "

Please note that the European Food Safety Authority (EFSA) has doubled the restriction levels from 0.02 mg/kg food to 0.04 mg/kg for food, which has been confirmed by the inclusion into Directive 2005/79/EC (amending Directive 2002/72/EC relating to plastic materials and articles intended to come into contact with food). From Directive 2005/79/EC, the specific migration limit for antimony trioxide has been doubled to 40 ppb (expressed as antimony).

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Q13: Why is ATO classified under a risk phrase of carcinogenicity?

ATO in powder form is classified under the risk phrase R40 according to a potential hazard in relation with abnormally high inhalation exposures of the substance (higher than 10 times the TLV). These high exposures can be easily avoided and should never occur in practice. At present, there are no recognised studies that demonstrate any carcinogenic effect via ingestion of antimony trioxide. Any potential impact on health is primarily observed in professional environments and through inhalation. Industry also provides so-called 'dust-free' types of antimony trioxide to reduce the likelihood of accidental inhalation exposure. Antimony trioxide can be wetted to reduce the exposure to dust. For flame retardant applications, antimony trioxide is usually mixed with a polymer into masterbatches that encapsulate the substance. Masterbatches do not need to be labelled with the R40 phrase. Same applies for plastics or articles made thereof e.g. PET bottle or TV backplate.

Consumers handling plastics containing ATO or eating food stored in these plastics are not exposed by inhalation, as ATO is encapsulated in the polymeric matrix.

Q14: ATO has been classified as possibly carcinogenic by the International Agency for Research on Cancer (IARC) and by the European Union. Does this mean it causes cancer?

No, the international IARC classification 2b (possible carcinogen) or category 3 by the European Union, indicates that there is inadequate evidence of carcinogenicity in humans, but limited evidence of carcinogenicity in experimental animals together with supporting evidence from other relevant data. There is no allocation in available scientific studies indicating that ATO is harmful to the health of the general public, at least not in the quantities found in the environment. $(0.15 \,\mu g/kg/day)$

Q15: How can I find out more about the issues covered in these FAQ?

More information about ATO is available on the IAOIA website: www.iaoia.org. The website contains the IAOIA Newsletters, the history of the IAOIA, the members and contact persons and links to other useful websites.