

## ESTABLISHING AN ANTIMONY CONSORTIUM FOR REACH

### IAOIA becomes i2a

To meet the requirements and scope of REACH, the International Antimony Oxide Industry Association (IAOIA) broadened its scope to cover other antimony compounds as well. Since January 2008, IAOIA is now called the "International Antimony Association" (i2a). The mission of i2a is to conduct studies with regard to the environmental impact, health and safety of antimony compounds, to share and provide information on the content of these studies among producers of antimony compounds worldwide and to disseminate information concerning the safety and benefits of these compounds.

33 companies have joined i2a so far. These companies include producers, importers and traders of antimony compounds and are located in Europe, Asia, America and Russia.

Members contribute according to the antimony compounds they are interested in and according to the tonnages put on the worldwide market. Different working groups will facilitate the communication among members.

### ATO and REACH

ATO is well advanced in preparing for REACH registration. Most of the necessary studies for REACH registration have already been developed in the context of the EU risk assessment for diantimony trioxide. With the new members coming on board, what remains to be checked is e.g. compliance with the production process description, impurity level and emissions from various uses. There is currently no classification resulting from this risk assessment that would render ATO subject to authorisation under REACH.

### Antimony and REACH

A literature study has unveiled which data are available for other antimony compounds. It is expected that many data gaps can be filled by reading across from the ATO data. In 2008, the antimony compounds that will be on the i2a list will go through transformation/dissolution testing, bioavailability testing and other basic read across testing. The antimony compounds will be registered according to the deadline applicable to the member with the highest tonnage band.

### JOINING i2a

Producers, importers and users are welcome to join i2a. **Deadline for joining i2a is April 30, after which an extra entrance fee will be charged.** Please contact [kvdv@antimony.be](mailto:kvdv@antimony.be) for further information.

## ATO: EU Risk Assessment Nearly Completed

### Environment: No major risk identified & no need for classification

In the EU risk assessment, all major processes during which antimony may be released to the environment due to production, use and waste disposal of diantimony trioxide were considered. EU Member State Technical Experts (TC-NES) met for the last time on 9th April 2007 to discuss the outcome of the written commenting procedure on the environmental risk assessment of Antimony Trioxide (ATO). No regional or continental risk was identified for ATO and no further studies are scheduled. Even at local level, no risk was identified for soil, freshwater, air and secondary poisoning.

Only a local risk for sediment was outlined for one ATO producer in Europe. However, emissions from this plant are low and are decreasing year by year, following changes made to the plant's waste emission process. A local risk was identified for sediment for some textile plants on a precautionary basis in view of a lack of information supplied by some of the companies from the textile industry. For all other sectors for which data was provided (including textiles), no risk for sediment was identified. The TC-NES also agreed not to assign any environmental classification to ATO.

### Health: no risk for consumers or for exposure via the environment

The health part of the risk assessment was revised by the Member State rapporteur (Sweden) in February 2008 and then discussed at TC-NES for the last time in April 2008. No risk was identified for consumers or for indirect exposure via the environment.

In brief, the outcome of the risk assessment can be summarised as follows:

- ATO is not acutely toxic via ingestion, inhalation or by skin contact
- not a sensitizer or an eye or respiratory tract irritant
- neither reprotoxic nor genotoxic<sup>1</sup> in vivo.

Despite an absence of effects in laboratory animals, ATO will be classified as "irritating to human skin (R38)" based on human evidence (workers). ATO is currently classified as a carcinogen category 3<sup>2</sup>, and a 2-year inhalation bioassay to be conducted by the US National Toxicology Program will clarify the underlying mechanism (threshold).

A more detailed summary of the currently available scientific data on antimony trioxide is available upon request and will be made available soon on our website [www.iaoia.org](http://www.iaoia.org).

For both HH and ENV, the Swedish Rapporteur will provide final drafts by May 5<sup>th</sup> after which there is a final 2-week written commenting period. The final reports will be released before May 31<sup>st</sup>.

The Rapporteur will need to write an Annex XV dossier by December 1<sup>st</sup> 2008 to transfer this Risk Assessment Report into REACH. This Annex XV dossier will include proposals for risk management measures for the few risks identified.

1- Covance, Evaluation of micronuclei and chromosome aberrations in the bone marrow of Sprague Dawley rats following a 21 day repeated exposure to antimony trioxide, May 2006

2- Substances and preparations of concern for humans because of the possible CMR effects but for which there is not enough information available to classify these substances and preparations as a category 2 (suspected CMR).

## Revision of the RoHS Directive: Antimony not included

The European Commission requested the Öko Institut to prepare a list of new substances of very high concern to be potentially added to the RoHS Directive review (Restriction of Hazardous Substances).

The first draft included Antimony Trioxide (ATO) and Antimony compounds in general. i2a sent a letter and the available scientific data to the Öko Institut requesting ATO and antimony compounds to be removed from this draft, based on the fact that:

- **ATO** does not meet the criteria established by the Commission to be selected as new RoHS candidate substances. ATO is neither a PBT, nor a vPvB substance nor an endocrine disruptor. This has been confirmed by the ATO EU risk assessment. Furthermore, in most final products, antimony trioxide is encapsulated in a matrix, in which it is either physically bound, such as in flame retarded rubbers, plastics and textile back coatings or chemically bound in a transformed state such as in PET, glass and pigments.
- The use of **Antimony compounds** in E&E does not require classification for dangerous properties (according to Directive 67/548/EEC) at the concentrations at which they are used.

Many stakeholders replied to the consultation regarding this draft list and objected to the inclusion of ATO and antimony compounds. See more details at: <http://hse-rohs.oeko.info/index.php?id=12>.

The Öko Institut has in the meantime confirmed that antimony will not be added to the new draft RoHS list that will be forwarded to the European Commission for consideration at the end of April.

## Upcoming events – Conferences attendance

- 30 April 2008: TFA Texflam Forum meeting in Huddersfield, UK
- 20/21 May 2008: Eurometaux REACH seminar
- 20/21/22 May 2008: ECHA Helsinki REACH Congress
- 19 June 2008: i2a Board of Directors meeting in Brussels
- 20 June 2008: i2a General Assembly meeting in Brussels
- 13 November 2008: i2a Board of Directors meeting in Paris
- 14 November 2008: i2a General Assembly meeting in Paris

### Organization of i2a

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