



Brussels, 1 September 2009

To whom it may concern

**Regarding: “Skin Irritation” classification of Antimony Trioxide (ATO)**

Dear Madam/ Dear Sir,

The International Antimony Association (i2a) is a non-profit association whose mission is to conduct studies and to disseminate information concerning the safety and benefits of antimony compounds, by way of giving access to data, sharing and providing information on the content of data, for the benefit of producers and importers of antimony compounds world-wide regarding environmental, health and safety regulations of these antimony compounds.

i2a closely cooperated with the Swedish Rapporteur Keml on the EU Risk Assessment Report (RAR) of Diantimony Trioxide under Existing Substance Regulation 793/93. In this process Keml proposed that antimony trioxide be classified with Xi (irritant) and R38 (Irritating to skin) according to Directive 67/548/EEC and its amendments based on the following information:

“The only animal study which can be used for assessment of the skin irritation potential of antimony trioxide shows that antimony trioxide is not irritating to rabbit skin. However, several human case studies indicate that antimony trioxide may cause dermatitis on skin damp with perspiration and thus the lesions seem to be closely related to sweat ducts. The lack of dermal irritation in rabbits may be explained by the fact that rabbits lack sweat glands (Brewer and Cruise, 1994). In conclusion, antimony trioxide should be regarded as a skin irritant in humans (R38) under conditions that evoke sweating.” (See: <http://ecb.jrc.ec.europa.eu/esis/index.php?PGM=ora>)

i2a supported this conservative classification as the classification directive considers ‘significant’ human data sufficient to classify with Xi and R38. ‘Significant’ human data is however a vague term. We are of the opinion that the diantimony trioxide producers behaved in a responsible manner by proactively warning their workers by voluntarily classifying diantimony trioxide with Xi, R38 as of January 2009.

Industry believes that the observed skin reactions, limited to workers at a diantimony trioxide producing facility are likely to be evoked more by physically mediated processes associated with blocking of the sweat glands in the absence of any intrinsic substantial primary skin irritating potential of the substance and also in consideration of the poor solubility of ATO.



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The Swedish authorities submitted a proposal to the Committee for Risk Assessment (RAC) of the European Chemicals Agency (ECHA) that ATO should be classified as a skin irritant across the EU.

Following a public consultation, the proposal was considered by the RAC at their first meeting on July 2<sup>nd</sup>. RAC's scientific opinion is that the data available are insufficient to justify this proposal. (see ECHA press release of July 6, 2009), because special conditions, namely, substantial heat and sweat, were required in addition to chemical exposure, in all the cases where skin effects had been described in workplace observations.

Nevertheless, RAC recommended that due consideration be made by the relevant authorities and/or industry to adequately control the risks of any adverse effects to workers who are exposed in hot, sweaty conditions to fumes or dust containing ATO.

It is for these reasons that the members of the International Antimony Association (i2a) decided NOT to classify ATO any longer with Xi/R38, BUT the warning on the safety data sheets will remain in order to protect the workers exposed to fumes or dust containing ATO under hot and sweaty conditions.

Sincerely Yours,

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