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Successful REACH registration confirms no risk related to the use of ATO

The members of the International Antimony Association (i2a) have successfully started the REACH registration of our three first substances for the 2010 deadline: antimony metal, diantimony trioxide (ATO) and sodium hexahydroxoantimonate (SHHA). The lead dossier of the joint submission includes the Chemical Safety Report part B, the classification and labelling of all compositions (depending on the physical state and the impurity level) and the (robust) study summaries, while the member dossiers contain the company-specific information such as the uses and the tonnage band, the Chemical Safety Report part A and the Guidance on Safe Use. In all three dossiers, all uses have been analysed as SAFE for consumers, general public and workers and for the environment under the conditions described in the respective exposure scenarios. Full exposure scenarios will be made available to the customers via the extended safety data sheet.

The ATO REACH dossier confirms the results of the published <u>EU Risk Assessment Report</u>; released by Sweden in 2008. Based on the scientific evidence currently available on ATO, it is a fact that ATO in its form of a fine inert dust can cause overload effect of the lungs if inhaled at high concentrations that do not occur at normal workplace situations. Once the powder is encapsulated in plastics, rubber or textile or reacted to another antimony compound as PET catalyst or in pigments, there is no inhalation risk whatsoever and a safe use can be guaranteed to all downstream users.

Companies have a choice between Membership and Letter of Access

As the REACH registration has started, all companies wishing to register one of these 3 antimony substances can buy the needed data from i2a. Companies are given the choice between membership and a letter of access. Detailed conditions and prices are available on our <u>website</u>.

Key market players will be encouraged to go for the membership option to ensure all key players take up their responsibility together. i2a and its members take regulatory issues very seriously and continue to invest in scientific research not only for REACH purposes, but to comply with worldwide regulations/legislations. At all times will i2a ensure that our financial agreements are fair, transparent and non-discriminatory as required by REACH.

Notification of classification to ECHA

Please note that for our 3 first substances the different classifications (depending on the physical state and the impurity level) are available on the i2a website. These are the harmonised and self classifications that cover our members' needs.

Companies REACH registering in 2010 do not need to notify their classification separately to ECHA's CLP Inventory, but those who intend to register this substance after 2010, should be aware that they will need to do their classification notification separately by 3rd January 2011. Please regularly check <u>our website</u> for further information on notification of the classification and labelling to ECHA. An e-mail has been sent to all members of the SIEF of each of the 3 first substances to inform them that registration has started and to explain the notification procedure.

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i2a continues to argue against proposed wider RoHS ban that includes ATO

As reported in our <u>newsletter of December 2009</u>, antimony trioxide is not included in the Commission's proposal for the revised EU Directive on the restriction of hazardous substances in electrical and electronic equipment (RoHS in E&E), which is due to be adopted by Parliament and Council by end 2010 if agreement is reached in first reading.

There is currently still a debate ongoing between EU Parliament, Council and the Commission whether or not the Annex III should be deleted from the proposal of UK MEP Mrs Jill Evans of the Green/EFA group. Annex III is a candidate list for potential future inclusion on the RoHS list four years from now.

In a letter received from Mr Janez Potočnik on September 1st, European Commissioner for the Environment, he states that: "ATO is not one of the substances listed in Annex III of the Commission proposal of December 2008. (...) The Commission's view remains that any restriction of hazardous substances under the RoHS Directive in order to guarantee a high level of protection of the environment and of human health needs to be evidence based. When presenting the recast proposal the Commission felt that the evidence available did not justify the inclusion of antimony trioxide in Annex III."

i2a will therefore continue to defend the fundamental principle that technical performance parameters and scientific research continue to be the basis of future decisions on which substances to use in what applications.

SCHER opinion on the use of ATO in toys

The revised toys Directive (2009/48/EC) from the European Commission bans the use of materials containing carcinogens in categories 1, 2 and 3 from use in the manufacture of toys, which would mean that Diantimony Trioxide (ATO), an inhalation carcinogen cat 3, could no longer be used in toys. As ATO is encapsulated in the plastic or textile toy which prohibits inhalation exposure, i2a asked the Commission to mandate the relevant Scientific Committee, SCHER, to re-evaluate ATO and grant an exemption from this ban, if the substance has been found acceptable for use in toys by the Scientific Committee. The SCHER opinion was published mid-August and was discussed with the Member States experts Committee of DG Enterprise in September 2010. SCHER correctly concludes that "the carcinogenic effects of ATO observed in the lung is considered a particle effect and by that does not apply to dermal and oral exposure. Consequently, the CMR requirements do not apply to toys, because via toys children are not exposed to those particles."

Upcoming events

16 March 2011: i2a Board of Directors (BOD) meeting in London 17 March 2011: i2a General Assembly (GA) meeting in London

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