International **Antimony** Association

Brussels, 4 April 2014

Concerning: supporting information for removal of antimony trioxide (‘ATO’; CAS 1309-64-4) from the proposed priority list under RoHS

Dear Madam, Sir,

We are contacting you on behalf of the members of the International Antimony Association (i2a). We are an international non-profit association whose mission is to gather, study and disseminate information on the safe use of antimony and antimony compounds, especially with regard to the relevant environmental, health and safety regulations.

We highly appreciate you contacted us as stakeholder for the revision of the restricted substances-list under RoHS. The i2a members are committed to working with you and in sharing the scientific data we possess and that we believe are relevant for the assessment:

° ATO is a potential inhalation carcinogen
° the inhalation hazard disappears once ATO is encapsulated in a polymer matrix
° uses of ATO are safe for human health and the environment
° waste from production and use of ATO is safe
° there are no suitable alternatives for ATO:BFR systems for some uses in E&E
° WEEE which contains ATO can effectively and safely be recycled.

Further explanation for the individual points is provided in annex to this letter.

Based on the scientific data we have gathered till now, and on the conclusions of the independent international assessments on ATO, **we believe ATO should not be restricted under EU-RoHS**. We want to mention that ATO was proposed for inclusion in the ‘Restricted Substances’-list under RoHS in 2010; based on scientific data, it was correctly concluded by the regulators at that time to remove ATO from the list. Since then, to our knowledge, no scientific evidence became available supporting a restriction for ATO under EU-RoHS.

Please do not hesitate to contact us should you have questions on the information presented here or about ATO, antimony or other antimony substances in general.

Best regards,

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Annex

ATO is a potential INHALATION carcinogen

Antimony trioxide is classified as Carcinogen Cat 2 (*harmful*; H351 '*suspected of causing cancer via inhalation*') according to CLP Regulation (EC)1272/2008. This classification is based on effects observed in 3 rat studies. These studies have been discussed at length in the EU Risk Assessment Report (EU-RAR; 2008; available at http://esis.jrc.ec.europa.eu/doc/risk_assessment/REPORT/datreport415.pdf) with Sweden as the rapporteur Member State. It was agreed by expert toxicologists of TC NEC (*Technical Committee for New and Existing Substances*) that these effects are most likely caused by particle overload and impaired clearance of the rat lungs that were for a long time exposed to very high ATO dust concentrations, ultimately leading to the formation of tumours in the rat lungs. Antimony trioxide does not require a classification as mutagenic. In other words, the effects observed in the rat lung are caused by the inhalation of inert dust particles, not by the antimony ions.

It is questionable if the overload effects observed with rats are relevant for humans due to:

° species related morphological differences between rats and humans
° different particle size distributions of ATO dust used in rat experiments and in ATO production plants.

In the absence of mechanistic data, it must be assumed that the rat model of tumorigenicity can identify potential carcinogenic hazards to humans and the rat presently remains the appropriate model for both neoplastic and non-neoplastic responses to PSP exposure (ILSI Risk Science Institute Workshop Participants., 2000).

The carcinogenicity hazard does not apply via dermal or oral exposure. This is confirmed in the EU-RAR (2008), and was explicitly cited in the '*SCHER opinion on the risks of antimony trioxide in toys'* (November 2011; available at http://ec.europa.eu/health/scientific_committees/environmental_risks/docs/scher_o_125.pdf):

> *'Consistent with the SIAM 27, 14-16 October 2008, the SCHER concludes that lung toxicity can be considered as a non-specific particle effect with the possible release of small amounts of antimony ions, which is not relevant for the evaluation of possible health consequences of the use of diantimony trioxide in toys. Since the inhalation and oral studies in animals do not show systemic effects even at high exposures, it can be concluded that bioavailability of the chemical or the antimony ion is very low, so that no systemic effects are expected from inhalation.'*

and

> *'The SCHER notes that the carcinogenic effects of diantimony trioxide observed in the lung is considered a particle effect and by that carcinogenicity does not apply to dermal and oral exposure. Consequently, the CMR requirements do not apply to toys, because via toys normally children are not exposed to particles of diantimony trioxide.'*

ATO is considered a threshold carcinogen with an OEL of 0.5 mg/m³ (the critical concentration is expected to be 10 times higher). More details on this are provided in the EU-RAR (2008).

The conclusions of the EU-RAR were in 2008 accepted at OECD level under the SIAP process (2008 available at http://webnet.oecd.org/Hpv/UI/handler.axd?id=13e93c97-6605-4eac-961f-8af23cc6ad32). Independent assessments of ATO by the Canadian (2010; available at https://www.ec.gc.ca/ese-ees/9889ABB5-3396-435B-8428-F270074EA2A7/batch9_1309-64-4_en.pdf), Dutch (2011; available at http://www.gezondheidsraad.nl/sites/default/files/201133_Antimony_and_compounds.pdf) and US (draft version released in 2012; available at http://www.epa.gov/oppt/existingchemicals/pubs/TSCA_Workplan_Chemical_Risk_Assessment_of_ATO.pdf) governments confirm the conclusions of the EU-RAR.

The inhalation hazard disappears once ATO is encapsulated in a polymer matrix

ATO is usually added as a flame retardant synergist with halogenated flame retardants to a polymer in the form of a masterbatch. Masterbatches typically contain 10-90% ATO. ATO gets mixed homogeneously into the polymer matrix during the extrusion process. As a result, ATO is not present in a respirable form anymore, and the inhalation exposure potential to workers and consumers is negligible. This is confirmed by exposure measurements at the workplace as reported in the EU-RAR (cfr further in this section).

For the EU RAR, the potential release of ATO from masterbatch material was tested. A representative polyethylene-based masterbatch (<30% ATO) was subjected to a leaching test in water and mechanical agitation for a total of 96 hours. Because the friability of the granulate material is negligible, release of ATO under the conditions of handling and use at the masterbatch workplaces is minimal:

° Sb levels in water were all <0.5 mg/L
° inhalation exposure potential was negligible (merely 0.1% of generated particles had a physical diameter <8 µm, and <0.001% one of <0.2)).

Electron microscopy confirmed that ATO was homogeneously contained in the resin matrix and was also firmly bound to the surface of pelletized material.

Inhalation exposure to ATO from masterbatch handling poses NO RISK. In a worst-case simulation of workplace condition, the release of ATO during pelletizing operations for a FR treated engineering polymer (<10% ATO) was measured. A commercially available grinder was operated to grind the polymer to pellets, operating at 10-fold its practical grinding performance, and airflow in the operating room was minimized by closing doors and windows and switching off the local exhaust ventilation. Total and respirable dust was measured at levels ranging approx. 1-1.5 mg/m³, but Sb in all samples was below detection limit (<0.02 mg/m³).

Uses of ATO are safe for human health and the environment

An assessment of the risks to human health and the environment of all identified uses of ATO (including the use as flame retardant synergist in polymers) shows safe use. The only potential inhalation risk is situated in ATO production plants where the workers might be chronically exposed to high ATO dust concentrations. However, exposure can be perfectly controlled by using respiratory protection (dust mask, exhaust ventilation…) ensuring worker's safety on the long-term.

Safe use is shown in the exposure assessment of ATO in the EU-RAR (2008) under REACH (limited data accessible via http://echa.europa.eu/information-on-chemicals/registered-substances).

In the OECD SIAP (2008), the following is written with regard to human exposure to ATO:

> *'Occupational exposure through inhalation of airborne dust and dermal contact with powder, pellets, paste, granules or final products is possible. Consumer exposure may occur through inhalation, ingestion and dermal contact with articles containing diantimony trioxide or domestic dust, but the exposure levels are low. (~60.000 times lower than the NOAEC established in long-term repeated dose inhalation study)'*

and

> *'Diantimony trioxide is released to the environment via emissions to air, waste water, surface water and soil from manufacture, formulation, processing, use and disposal of diantimony trioxide, but also via coal combustion and refuse incineration, non-ferrous metal production (e.g. Cu), and road traffic. Humans may be exposed via the environment by inhalation of particles in air or ingestion of contaminated food and water, but the exposure levels are low*.'

Waste treatment from production and use of ATO is safe

Waste resulting from manufacturing, industrial use and consumer use of ATO and ATO containing products (amongst which E&E) does not pose any risk to human health and the environment:

° the inhalation hazard of ATO is no longer applicable once ATO is encapsulated in a polymer matrix (cfr earlier in this document), and it can reasonably be assumed that treatements such as dismantling or shredding E&E do not pose any risk to human health considering the safety of grinding operations of masterbatches with a much higher total Sb concentration than E&E polymers (EU-RAR, 2008)
° waste treatment (landfilling/incineration/recycling) does not pose any risk to the environment (Arche, 2012).

These data are included in the ATO REACH dossier (accessible via http://echa.europa.eu/information-on-chemicals/registered-substances).

There are NO SUITABLE ALTERNATIVES available for some uses in E&E

The use of Brominated Flame Retardants (BFRs) together with ATO as synergist is for certain applications indispensable. Some examples:

-ABS and HIPS are today the preferred (technically and economically) polymers for E&E enclosures. ATO:BFR is still the most cost-effective FR system, as confirmed by our members and their customer base. They stress that alternatives often do not fulfil the same combination of functionalities as ATO:BFR. Only replacement into an alloy is possible but nearly twice the price and still up to 0,5% halogen PTFE is needed.
-The BFR:ATO system is often a material of choice for thermoplastic elastomers used in cabling for E&E.

WEEE which contains ATO can effectively and safely be recycled

E&E waste can perfectly be recycled, the presence of BFR:ATO in polymers does not affect the efficiency of the recycling process or the quality of the recyclate (EFRA, 2013; Tange et al, 2012;

Tange et al, 2013) and the antimony present in the E&E can to a large extent be recovered (Brusselaers et al, 2006).

Antimony, being a non-ferrous metal, can be endlessly recycled, without loss of mass or quality. Recycled Sb has exactly the same properties as Sb originating from production out of ores (mining). A main advantage is that each recycle step is only using a small fraction of the energy needed for primary production, without any additional environmental impact.

References

Arche (2012) Exposure scenario building and environmental release estimation for the waste life stage of the manufacture and use of antimony and antimony compounds. Prepared on behalf of the International Antimony Association. Final report December 2012.

Brusselaers et al (2006) Using metal-rich WEEE plastics as feedstock / fuel substitute for an integrated metals smelter. Available at http://www.plasticseurope.org/document/using-metal-rich-weee-plastics-as-feedstock-fuel-substitute-for-an-integrated-metals-smelter.aspx?Page=DOCUMENT&FolID=2

EFRA (2013) Recycling of Plastics from LCD Television Sets - Pilot project on mechanical plastics recycling from post-consumer flat panel display-LCDs

Tange et al (2012) Recycling of plastics with flame retardants of electronic waste, a technical and environmental challenge for a sustainable solution. Available at http://www.plasticseurope.org/documents/document/20120803145646-lein_tange_abstract_efra_plastics_recycling_identiplast_f.pdf.

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