ETINSA European Tin Stabilisers Association

The following companies are members of ETINSA:

AKCROS Chemicals	BAERLOCHER	CHEMTURA
GALATA Chemicals	PMC Organometallix	REAGENS

Comments to the ECHA Public Consultation on the identification of SVHC, launched on 1st September 2014

ETINSA comments on DOTE (EC # 239-622-4 ; CAS # 15571-58-1)

Part 2 - Information on Use, Exposure and Risks

Comments on the identified Uses and Exposures:

In the Annex XV dossiers for DOTE, it was mentioned that the registrant(s) have registered the uses reported in the Tables hereafter.

The identified professional workers' uses and consumer uses reported in Tables 4 & 5 are in fact the uses of the end products, which are considered articles under REACH (Art. 3(3)), i.e. "an object which during production is given a special shape, surface or design which determines its function to a greater degree than its chemical composition". For example, such product could be rigid PVC films, it has to have certain thickness which qualifies it as an article.

Article uses are not a use under REACH (Art. 3(24)), but part of the article service life. The last use is the incorporation of the substance/mixture into an article. So there are in fact no uses by professional workers or consumers.

The exposure scenarios have been discussed with the Austrian competent Authority (Annex XV dossier Submitter) and have been adjusted in a spontaneous update of the DOTE Dossier. The uses are reported in Tables 3 to 6 of the Annex XV report on DOTE.

Comments on the likelihood of the release during article service life and waste phase:

In ECHA's General approach for prioritization of substances of very high concern (SVHCs) for inclusion in the Authorisation List (Annex XIV) document it was said:

"However, if registration data or other relevant information demonstrate that the substance ends up in articles and that there is no reliable information that releases are unlikely during article service life and waste phase, this can be taken into account in assigning the WDU score. In such case (which applies for any substance, not only for CMRs) a score between 5 and 15 can be considered, depending on the specific situation and the available information (see also Section 5.3.1 below)."

Against this, ETINSA wants to draw the reviewers' attention to the following statement:

In order to continue to stabilize the articles throughout its life-cycle stabilizers must not be washed off from the articles. Therefore those molecules are designed to have inherently low leaching rates and this is the case for octyltin stabilizers which have very low water solubility (high Octanol/Water partition coefficient). Moreover, DOTE-containing stabilizers are used extensively in rigid PVC films for food-contact and comply with the applicable Specific Migrations Limit of 6 µg/kg food, which confirms the low leaching rate in aqueous media. For many years in the USA, DOTE-based stabilizers have complied with the strict guidelines set out by NSF/ ANSI 61 standards for use in drinking water applications.

Like all additives, leaching in contact with water is limited to a thin diffusion layer and does not significantly affect the bulk of the material. This has been demonstrated indirectly by measuring the residual concentration of a tin stabilizer throughout the 6 mm wall of a 22-year old water pipe that was dug out of the ground. The depletion of tin was observed in the 1.5 micron boundary layer, representing 0.05 % of the pipe volume, whilst no depletion was observed in the bulk.

The release of DOTE during the article service life and waste phase is therefore unlikely.

END