EUROPEAN STABILISER PRODUCERS ASSOCIATION

ETINSA European Tin Stabilisers Association

The following companies are members of ETINSA:

AKCROS Chemicals	BAERLOCHER	CHEMTURA
GALATA Chemicals	PMC Organometallix	REAGENS

Regulatory Update Nr 4/2014 – December 2014

Classification of Dioctyltin bis(2-ethylhexyl mercaptoacetate)

Short names: DOTE ; $DOT(EHMA)_2$
EC number: 239-622-4 ; CAS number: 15571-58-1 ; IUPAC name: 2-ethylhexyl 10-ethyl-4,4-dioctyl-7-oxo-8-oxa-3,5-dithia-4stannatetradecanoate

ETINSA, which represents the producers of tin stabilisers in Europe, want to update you on the Classification of DOTE which is used as a stabiliser for PVC processing.

This substance was REACH-registered by November 2010 with a proposed CLP* classification for Reproductive Toxicity Category 2 (*suspected human reproductive toxicant*). This category was estimated to reflect adequately the conclusions of the available studies, taking into account the uncertainties of some of the results and short-comings in the study protocols.

Subsequently the Committee for Risk Assessment (RAC) of ECHA**, reviewed the toxicological information available for this substance and recommended classification with Reproductive Toxicity Category 1B (*presumed human reproductive toxicant*) instead.

Classification Reprotoxic Cat. 1B

As a consequence the 5th ATP*** amending the CLP regulation, issued in October 2013, listed DOTE with the classification Reprotox Cat. 1B, which has to be applied latest by 1st January 2015. Your suppliers will soon reflect the new classification in their Safety Data Sheets for the EU accompanying their products containing this substance.

It must be noted that the toxicology of the substance remains unchanged: in particular the DNEL (Derived No-Effect Level) is the same, as well as the Risk Characterisation Ratio (from which it is derived), used to establish the Exposure Scenario. Consequently there is no change in the transport classification. Additionally, DOTE remains approved for pharmaceutical and food packaging applications.

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Identification of DOTE as SVHC

In September 2014 DOTE was included in the list of substances subject to a Public Consultation (PC) for identification as an SVHC[*4], on the basis of its Classification CMR[*5] Cat. 1B, which is sufficient for being identified as an SVHC and subsequently become included in the Candidate List for Authorisation.

ETINSA members and downstream users (DU) of DOTE provided comments to the PC, highlighting that the risk management measures in place ensure safe use. In addition the registrants of DOTE presented new evidences and results of new studies which challenge the classification adopted on the basis of the studies available at that time. However those new evidences were not taken in consideration at this stage of the process, considering the existence of an official classification Repro 1B for this substance which was based on read across data. The new studies do not support classification of DOTE as reprotoxic 1B.

The Lead Registrant is pursuing his efforts to ascertain the appropriate classification of DOTE. Meanwhile, however, the Downstream Users of this substance will have to comply with the obligations of information in the supply chain foreseen in REACH Art. 33 (see hereunder).

It should be noted that while a reaction mass of DOTE and MOTE has also been added to the SVHC list, MOTE itself is not classified as reprotoxic. ECHA highlighted this point in their report when they wrote: "Available data indicate that MOT compounds do not have adverse effects on the reproductive system, thus the adverse effects of the reaction mass DOTE:MOTE is related to the presence of DOTE".

What is the direct consequence for substances identified as SVHC?

For manufacturers/importers and downstream users in the EEA (EU-28 + Iceland, Liechtenstein and Norway), REACH Art. 33 imposes, among others, several obligations of information in the supply chain:

- In accordance with REACH Article 31, a Safety Data Sheet (SDS) is required for mixtures identifying such a constituent if contained above 0.1 % (weight by weight). At the usual level of addition, DOTE-stabilized PVC compounds may exceed this limit, depending on the proportion of DOTE in the stabiliser mixture.

- The supplier of an article containing a substance identified as SVHC and in a concentration above 0.1% (weight by weight), has the duty to communicate to its customers sufficient information (including at least the name of that substance) to allow safe use of the article ; similar information shall be provided to a consumer within 45 days of the receipt of the request.

Additional details can be found on the ECHA website, in particular in the guidance "Requirements for Substances in Articles" which can be downloaded at: http://echa.europa.eu/documents/10162/13632/articles_en.pdf.

Definitions

"Articles" are defined as follows in Art. 3, points 3, of the REACH regulation:

"Article: means an object which during production is given a special shape, surface or design which determines its function to a greater degree than does its chemical composition."

For so-called "semi-finished" articles, e.g. a sheet, the distinction may not be obvious ; the ECHA guidance "Requirements for Substances in Articles" provides examples as well as a decision tree to help determining the status.

It must be highlighted that classification and labelling does not apply to articles.

Should you need any further clarification please feel free to contact ETINSA.

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ETINSA (European Tin Stabilisers Association) is a sub-association of ESPA, the European Stabiliser Producers Association. ESPA aisbl is affiliated to Cefic (The European Chemical Industry Council)

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* CLP: Regulation (EC) N° 1272/2008 on Classification, Labelling and packaging of substances and mixtures)

** ECHA: European Chemical Agency, Helsinki

*** ATP: Adaptation to Technical Progress

http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2013:261:0005:0022:EN:PDF - p. 261

*[4] SVHC: Substances of Very High Concern

*[5] CMR: Carcinogenic, Mutagenic, Reprotoxic