

The following companies are members of ETINSA:

AKCROS Chemicals

BAERLOCHER

CHEMTURA

GALATA Chemicals

PMC Organometalix

REAGENS

Regulatory Update Nr 3/2014 – September 2014

Classification of Dioctyltin bis(2-ethylhexyl mercaptoacetate)

Abbreviation: DOT(EHMA)₂ CAS number: 15571-58-1 EC number: 239-622-4 Index number: 050-027-00-7 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 dioctyltin bis(2-ethylhexyl mercaptoacetate) 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**, which is responsible for proposing harmonized classifications for CMR*** end-points of substances, reviewed the toxicological information available for this substance and recommended classification with Reproductive Toxicity Category 1B (*presumed human reproductive toxicant*) instead. Their formal opinion is available on the ECHA website.

On 2nd October 2013 the EU Commission issued the 5th ATP*⁴ amending the CLP regulation. In this ATP dioctyltin bis(2-ethylhexyl mercaptoacetate) is listed with the classification Reprotox Cat. 1B. This classification has to be applied latest by 1st January 2015.

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.

Your suppliers will soon reflect the new classification in their Safety Data Sheets accompanying their products containing this substance.

On 1st September 2014 DOT(EHMA)₂ was included in the list of substances subject to a Public Consultation (PC) for identification as an SVHC^{*5}. Classification with CMR Cat. 1 is sufficient for being identified as an SVHC and subsequently become included in the Candidate List for Authorisation. ETINSA members intend to provide comments to the PC.

Definitions

“Mixtures” and “Articles” are defined as follows in Art. 3, points 2 and 3 respectively, of the REACH regulation:

- “Mixture: means a mixture or solution composed of two or more substances.”
- “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.”

As such, a hose is clearly an article because the shape is essential to perform its function of transporting a liquid. For so-called “semi-finished” articles, like a profile or a sheet, the distinction may be less obvious because in many cases they will be transformed further by another downstream user to give them their definitive shape. However most will also fall under the definition of articles: the shape of a sheet is essential for making blister packaging by thermoforming or to laminate onto a flat surface (e.g. credit cards), whilst the shape of a profile is needed for making a window frame; the opposite will not work.

It must be highlighted that classification and labelling apply to substances and mixtures only (and not to articles).

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

Contact: Dr. Alain Cavallero - ESPA Secretary General – aca@cefic.be

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)

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

** ECHA: European Chemical Agency, Helsinki

*** CMR: Carcinogenic, Mutagenic, Reprotoxic

^{*4} ATP: Adaptation to Technical Progress

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

^{*5} SVHC: Substances of Very High Concern

