

AGREEMENT OF THE MEMBER STATE COMMITTEE

ON THE IDENTIFICATION OF 2-ETHYLHEXYL 10-ETHYL-4,4-DIOCTYL-7-OXO-8-OXA-3,5-DITHIA 4-STANNATETRADECANOATE (DOTE) AS A SUBSTANCE OF VERY HIGH CONCERN

According to Articles 57 and 59 of Regulation (EC) 1907/2006¹

Adopted on 9 December 2014

This agreement concerns

Substance name: 2-ethylhexyl 10-ethyl-4,4-dioctyl-7-oxo-8-oxa-3,5-dithia-4-

stannatetradecanoate (DOTE)

EC number: 239-622-4

CAS number: 15571-58-1

Molecular formula: C₃₆H₇₂O₄S₂Sn

Structural formula²:

Bu S Sn S Bu Bu

¹ Regulation (EC) No 1907/2006 of the European Parliament and of the Council of 18 December 2006 concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH), establishing a European Chemicals Agency, amending Directive 1999/45/EC and repealing Council Regulation (EEC) No 793/93 and Commission Regulation (EC) No 1488/94 as well as Council Directive 76/769/EEC and Commission Directives 91/155/EEC, 93/67/EEC, 93/105/EC and 2000/21/EC

² It is noted that DOTE contains chiral carbon atoms in the ethylhexyl residue of the acetic ester group. The indicated CAS number does not reflect any specific stereoisomeric forms. The SVHC dossier covers the substance including all possible stereoisomers.

Austria presented a proposal in accordance with Article 59(3) and Annex XV of the REACH Regulation (26 August 2014, submission number DU001774-27) on identification of *2-ethylhexyl-10-ethyl-4,4-dioctyl-7-oxo-8-oxa-3,5-dithia-4-stannatetradecanoate (DOTE)* as a substance of very high concern due to its toxic for reproduction properties.

The Annex XV dossier was circulated to Member States on 1 September 2014 and the Annex XV report was made available to interested parties on the ECHA website on the same day according to Articles 59(3) and 59(4).

Comments were received from both Member States and interested parties on the proposal.

The dossier was referred to the Member State Committee on 17 November 2014 and was discussed in the meeting on 8-11 December 2014 of the Member State Committee.

Agreement of the Member State Committee in accordance with Article 59(8):

2-ethylhexyl-10-ethyl-4,4-dioctyl-7-oxo-8-oxa-3,5-dithia-4stannatetradecanoate (DOTE) is identified as a substance meeting the criteria of Article 57 (c) of Regulation (EC) 1907/2006 (REACH) owing to its classification as toxic for reproduction category 1B³.

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³ Classification in accordance with Regulation (EC) No 1272/2008 Annex VI, part 3, Table 3.1 List of harmonised classification and labelling of hazardous substances [as amended and adapted to technical and scientific progress by Commission Regulation (EU) No 944/2013, OJ No L 235, p.5, 3.10.2013].

UNDERLYING ARGUMENTATION FOR IDENTIFICATION OF SUBSTANCE OF VERY HIGH CONCERN

Toxicity for reproduction

Toxic for reproduction 1B - Article 57 (c)

Pursuant to Annex III of Commission Regulation (EU) No 944/2013 of 2 October 2013 DOTE will be listed in Table 3.1 (List of harmonised classification and labelling of hazardous substances) of Annex VI, part 3, of Regulation (EC) No 1272/2008 as toxic for reproduction Repr. 1B, H360D (May damage the unborn child).

Therefore, this classification of DOTE in Commission Regulation (EU) No 944/2013 shows that the substance meets the criteria for classification in the hazard class:

• Reproductive toxicity category 1B in accordance with Article 57 (c) of REACH.

Reference:

Support Document *2-ethylhexyl-10-ethyl-4,4-dioctyl-7-oxo-8-oxa-3,5-dithia-4-stannatetradecanoate (DOTE)* (Member State Committee, 9 December 2014)