

**AGREEMENT OF THE MEMBER STATE COMMITTEE**

**ON THE IDENTIFICATION OF**

**Diocetyl tin dilaurate, stannane, dioctyl-, bis(coco acyloxy) derivs., and any other stannane, dioctyl-, bis(fatty acyloxy) derivs. wherein C12 is the predominant carbon number of the fatty acyloxy moiety**

**AS SUBSTANCES OF VERY HIGH CONCERN**

**According to Articles 57 and 59 of  
Regulation (EC) 1907/2006<sup>1</sup>**

**Adopted on 9 December 2020**

**This agreement concerns**

**Substance name: Diocetyl tin dilaurate, stannane, dioctyl-, bis(coco acyloxy) derivs., and any other stannane, dioctyl-, bis(fatty acyloxy) derivs. wherein C12 is the predominant carbon number of the fatty acyloxy moiety**

**EC number: -**

**CAS number: -**

**Molecular formula: C<sub>40</sub>H<sub>80</sub>O<sub>4</sub>Sn**

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<sup>1</sup>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

Sweden presented a proposal in accordance with Article 59(3) and Annex XV of the REACH Regulation (25 February 2020) on identification of *Dioctyltin dilaurate, stannane, dioctyl-, bis(coco acyloxy) derivs., and any other stannane, dioctyl-, bis(fatty acyloxy) derivs. wherein C12 is the predominant carbon number of the fatty acyloxy moiety (EC No. -)* as substances of very high concern due to their toxic for reproduction properties.

The Annex XV dossier was circulated to Member States on 01 September 2020 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 16 November 2020 and was discussed in the meeting on 8-10 December 2020 of the Member State Committee.

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

***Dioctyltin dilaurate, stannane, dioctyl-, bis(coco acyloxy) derivs., and any other stannane, dioctyl-, bis(fatty acyloxy) derivs. wherein C12 is the predominant carbon number of the fatty acyloxy moiety* are identified as substances meeting the criteria of Article 57 (c) of Regulation (EC) 1907/2006 (REACH) as these substances meet the criteria for classification as toxic for reproduction category 1B in accordance with Regulation (EC) No 1272/2008<sup>2</sup>.**

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<sup>2</sup> Regulation (EC) No 1272/2008 of the European Parliament and of the Council of 16 December 2008 on classification, labelling and packaging of substances and mixtures, amending and repealing Directives 67/548/EEC and 1999/45/EC, and amending Regulation (EC) No 1907/2006.

## **UNDERLYING ARGUMENTATION FOR IDENTIFICATION OF A SUBSTANCE OF VERY HIGH CONCERN**

### **Toxicity for reproduction:**

*Diocetyl tin dilaurate, stannane, dioctyl-, bis(coco acyloxy) derivs., and any other stannane, dioctyl-, bis(fatty acyloxy) derivs. wherein C12 is the predominant carbon number of the fatty acyloxy moiety* are covered by index number 050-031-00-9 of Regulation (EC) No 1272/2008<sup>3</sup> in Annex VI, part 3, Table 3.1 (the list of harmonised classification and labelling of hazardous substances) and they are classified in the hazard class toxic for reproduction category 1B (H360D<sup>4</sup>).

Therefore, this classification of the substances in Regulation (EC) No 1272/2008 shows that they meet the criteria for classification as Toxic for reproduction category 1B in accordance with Article 57 (c) of the REACH Regulation.

### **Reference:**

Support Document (Member State Committee, 9 December 2020)

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<sup>3</sup> COMMISSION DELEGATED REGULATION (EU) 2020/1182 of 19 May 2020 amending, for the purposes of its adaptation to technical and scientific progress, Part 3 of Annex VI to Regulation (EC) No 1272/2008 of the European Parliament and of the Council on classification, labelling and packaging of substances and mixtures. Official Journal of the European Union, L261/2, 11.8.2020.

<sup>4</sup> H360D: 'May damage the unborn child'.