~~Confidential~~

Helsinki, 16 June 2021

Addressees
Registrants of JS_3648-18-8 listed in the last Appendix of this decision

Date of submission of the dossier subject of a decision
31/10/2018

Registered substance subject to this decision, hereafter 'the Substance'
Substance name: Dioctyltin dilaurate
EC number: 222-883-3
CAS number: 3648-18-8

Decision number: Please refer to the REACH-IT message which delivered this communication (in format TPE-D-XXXXXXXXXX-XX-XX/F)

DECISION ON TESTING PROPOSAL(S)

Based on Article 40(3)(d) of Regulation (EC) No 1907/2006 (REACH), the testing proposal listed below is rejected:

A. Testing proposal under Annex IX to REACH

1. Pre-natal developmental toxicity study (EU B.31./OECD TG 414) using the Substance.

Reasons for the rejection of your proposal are explained in Appendix A.

Appeal

This decision can be appealed to the Board of Appeal of ECHA within three months of its notification. An appeal, together with the grounds thereof, has to be submitted to ECHA in writing. An appeal has suspensive effect and is subject to a fee. Further details are described under: http://echa.europa.eu/regulations/appeals.

Approved[1] under the authority of Christel Schilliger-Musset, Director of Hazard Assessment

[1] As this is an electronic document, it is not physically signed. This communication has been approved according to ECHA's internal decision-approval process.

Appendix A: Reasons for the decision

This decision is based on the examination of the testing proposal you submitted.

A. Reasons to reject testing proposal under Annex IX to REACH

1. Pre-natal developmental toxicity study

A pre-natal developmental toxicity (PNDT) study (OECD 414) in one species is an information requirement under Annex IX to REACH (Section 8.7.2.).

1.1. Information provided to fulfil the information requirement

Data on pre-natal developmental toxicity (PNDT) study (OECD 414) in one species is not available from the registration dossier under evaluation.

You have submitted a testing proposal for a PNDT study according to OECD TG 414 by the oral route. The test material refers to the Substance (dioctyltin dilaurate, EC No. 222-883-3) and to Stannane, dioctyl-, bis(coco acyloxy) derivs. (EC No. 293-901-5).

ECHA requested your considerations for alternative methods to fulfil the information requirement for Developmental toxicity. You provided your considerations concluding that there were no alternative methods which could be used to adapt the information requirement(s) for which testing is proposed.

1.2. Consideration of the need for testing

According to Annex IX, Section 8.7., Column 2, if a substance is known to cause developmental toxicity, meeting the criteria for classification as toxic for reproduction category 1B (H360D) and the available data are adequate to support a robust risk assessment, no further testing on developmental toxicity will be necessary.

The Substance has a harmonised classification for development, Repr. 1B (H360D) (Annex VI to CLP, 15th ATP). This information is sufficient to enable the registrants to perform a robust risk assessment.

In your considerations of alternatives, you raised that the above harmonised classification is based on an invalid read-across from data on Dioctyltin dichloride. You note that coordination with other species of the complex mixture of breakdown products cannot be proven or excluded, based on the *in vitro* data supporting similar hydrolysis products. You state that the main part of the breakdown products in the *in vitro* metabolism study has been described as a complex of Dioctyltinoxide with other organotin species. Furthermore, you have the opinion that the toxicological behaviour of the registered substance in rats after oral (dietary) administration will be more comparable to the toxicological behaviour of Dioctyltin oxide (EC no. 212-791-1).

In response ECHA firstly notes that you appear to be indirectly challenging the Commission's and ECHA's Risk Assessment Committee's read-across assessment which formed the basis of the harmonised classification of the substance as toxic for reproduction category 1B. ECHA considers that the evaluation procedure is not the correct process for re-assessing this. Indeed, pursuant to Article 37(6) of Regulation 1272/2008 (CLP Regulation) manufacturers, importers and downstream users who have new information which may lead to a change of the harmonised classification and labelling elements of a substance in Part 3 of Annex VI shall submit a proposal in accordance with the second subparagraph of paragraph 2 of Article 37(6)

of the CLP Regulation to the competent authority in one of the Member States in which the substance is placed on the market. Accordingly, any new information you have in order to discuss the validity of the harmonised classification of the substance should be submitted in accordance with Article 37(6) of the CLP Regulation.

Secondly, ECHA notes that the common dioctyltin group is considered the toxic component and therefore the hypothesis of common intermediates and subsequent similar systemic exposure is supported. The source substance and the target substance behave similarly in water at neutral and low pH and hydrolyse to common intermediate(s), e.g. same tin-species. The similar behaviour is in accordance to established chemistry for dialkyltins under aqueous conditions and therefore supports the read-across approach for these dioctyltin substances. Furthermore, it was on this basis that the Commission concluded that the Substance met the criteria for the above-mentioned harmonised classification.

ECHA therefore considers that a PNDT study in a first species is not necessary.

1.3. Outcome

Under Article 40(3)(d) of REACH, the proposed test is rejected.

Appendix B: Procedure

ECHA started the testing proposal evaluation in accordance with Article 40(1) on 24 February 2020.

ECHA held a third party consultation for the testing proposal(s) from 23 March 2020 until 7 May 2020. ECHA did not receive information from third parties.

ECHA followed the procedure detailed in Articles 50 and 51 of REACH.

ECHA notified you of the draft decision and invited you to provide comments.

ECHA did not receive any comments within the commenting period.

ECHA notified the draft decision to the competent authorities of the Member States for proposals for amendment.

As no amendments were proposed, ECHA adopted the decision under Article 51(3) of REACH.

Appendix C: Addressees of this decision and the corresponding information requirements applicable to them

You must provide the information requested in this decision for all REACH Annexes applicable to you.

Registrant Name	Registration number	Highest REACH Annex applicable to you
[redacted]	[redacted]	[redacted]

Where applicable, the name of a third party representative (TPR) may be displayed in the list of recipients whereas ECHA will send the decision to the actual registrant.