EUROPEAN CHEMICALS AGENCY

Decision number: CCH-D-2114303348-55-01/F Helsinki, 30 June 2015

DECISION ON A COMPLIANCE CHECK OF A REGISTRATION PURSUANT TO ARTICLE 41(3) OF REGULATION (EC) NO 1907/2006

For diisotridecyl 3,3'-[(dibutylstannylene)bis(thio)]dipropionate, CAS No 84896-44-6 (EC No 284-461-5), registration number: [redacted]

Addressee: [redacted]

The European Chemicals Agency (ECHA) has taken the following decision in accordance with the procedure set out in Articles 50 and 51 of Regulation (EC) No 1907/2006 concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH Regulation).

I. Procedure

Pursuant to Article 41(1) of the REACH Regulation ECHA has performed a compliance check of the registration for diisotridecyl 3,3'-[(dibutylstannylene)bis(thio)]dipropionate, CAS No 84896-44-6 (EC No 284-461-5), submitted by [redacted] (Registrant).

This decision is based on the registration as submitted with submission [redacted], for the tonnage band of 10 to 100 tonnes per year. This decision does not take into account any updates submitted after 5 March 2015, the date upon which ECHA notified its draft decision to the Competent Authorities of the Member States pursuant to Article 51(1) of the REACH Regulation.

This compliance check decision does not prevent ECHA from initiating further compliance checks on the present registration at a later stage.

The compliance check was initiated on 14 November 2013.

On 11 April 2014 ECHA sent the draft decision to the Registrant and invited him to provide comments within 30 days of the receipt of the draft decision. That draft decision was based on submission number [redacted].

On 8 May 2014 ECHA received comments from the Registrant on the draft decision.

On 31 July 2014 the Registrant updated his registration dossier with the submission number [redacted].

The ECHA Secretariat considered the Registrant's comments and update.
On basis of this information, Section II was amended. The Statement of Reasons (Section III) was changed accordingly.

On 5 March 2015 ECHA notified the Competent Authorities of the Member States of its draft decision and invited them pursuant to Article 51(1) of the REACH Regulation to submit proposals for amendment of the draft decision within 30 days of the receipt of the notification.

Subsequently, a proposal for amendment to the draft decision was submitted.

On 10 April 2015 ECHA notified the Registrant of the proposal for amendment to the draft decision and invited him pursuant to Article 51(5) of the REACH Regulation to provide comments on the proposal for amendment within 30 days of the receipt of the notification.

The ECHA Secretariat reviewed the proposal for amendment received and amended the draft decision.

On 20 April 2015 ECHA referred the draft decision to the Member State Committee.

By 11 May 2015 the Registrant did not provide any comments on the proposal for amendment. However, the Registrant provided comments on the draft decision. The Member State Committee did not take into account the Registrant's comments on the draft decision as they were not related to the proposal for amendment made and are therefore considered outside the scope of Article 51(5).

A unanimous agreement of the Member State Committee on the draft decision was reached on 26 May 2015 in a written procedure launched on 13 May 2015.

ECHA took the decision pursuant to Article 51(6) of the REACH Regulation.

II. Information required

A. Information in the technical dossier related to the identity of the substance

Pursuant to Articles 41(1), 41(3), 10(a)(ii) and Annex VI, Section 2 of the REACH Regulation the Registrant shall submit the following information for the registered substance subject to the present decision:

1. Spectral data (Annex VI Sections 2.3.5); and

   High-pressure liquid chromatogram, gas chromatogram (Annex VI, 2.3.6.); and

   Description of the analytical methods (Annex VI, 2.3.7.) as specified in Section III.A.3 below.

B. Information in the technical dossier derived from the application of Annexes VII to XI

Pursuant to Articles 41(1), 41(3), 10(a)(vi) and/or (vii), 12(1)(c), 13 and Annexes VIII and XI of the REACH Regulation the Registrant shall submit the following information using the indicated test method and the registered substance subject to the present decision:

1. Hydrolysis as a function of pH (Annex VIII, 9.2.2.1; test method: EU C.7/OECD 111);

Pursuant to Article 41(4) of the REACH Regulation the Registrant shall submit the information in the form of an updated registration to ECHA by **7 January 2016**.

III. Statement of reasons

Pursuant to Article 41(3) of the REACH Regulation, ECHA may require the Registrant to submit any information needed to bring the registration into compliance with the relevant information requirements.

A. Information in the technical dossier related to the identity of the substance

Pursuant to Article 10(a)(ii) of the REACH Regulation, the technical dossier shall contain information on the identity of the substance as specified in Annex VI, Section 2 of the REACH Regulation. In accordance with Annex VI, Section 2 the information provided shall be sufficient to enable the identification of the registered substance.

1. Spectral data, High-pressure liquid chromatogram, gas chromatogram and description of the analytical methods (Annex VI, 2.3.5. 2.3.6. and 2.3.7.)

"Spectral data" is an information requirement as laid down in Annex VI, Section 2.3.5. of the REACH Regulation. Adequate information needs to be present in the technical dossier for the registered substance to meet this information requirement.

"High-pressure liquid chromatogram, gas chromatogram" is an information requirement as laid down in Annex VI, Section 2.3.6. of the REACH Regulation. Adequate information needs to be present in the technical dossier for the registered substance to meet this information requirement.

"Description of the analytical methods" is an information requirement as laid down in Annex VI, Section 2.3.7. of the REACH Regulation. Adequate information needs to be present in the technical dossier for the registered substance to meet this information requirement.

In IUCLID section 1.4 in the field *"Analytical methods and spectral data"* the following statement is present *"The spectral methods used to analyse n-Butyltin trichloride comprise: 1H NMR, 13C NMR, 119Sn NMR, GC-MS, UV, IR"*. ECHA notes that n-butyltin trichloride is not the registered substance. Furthermore, there is no detailed description of the GC-MS method used to quantify the constituents of the substance so the concentration ranges presented in IUCLID section 1.2 cannot be confirmed. Additionally, the method reported in the document "[redacted]" identifies "*Di-butyl-di-pentylzinn*" as the only constituent. This is not the registered substance but rather appears to be a derivatisation product. The tridecyl isopropionate moiety which would account for the reminder of the registered substance was not quantified. Finally, the ^{119}Sn NMR information provided in the report entitled "[redacted]" presents a signal identified as Bu2SnRCl which appears to represent a dibutyltin chloride constituent. ECHA notes that this substance is not listed as a constituent in IULCID section 1.2.

As a consequence of the inconsistencies and discrepancies mentioned above, ECHA considers the information provided on the spectral data and gas chromatogram as well as the description of the analytical methods as insufficient.

The Registrant shall provide consistent spectral and chromatographic data together with the description of the analytical methods used for the identification and quantification of the registered substance in section 1.4 of the dossier. The description should be given in such detail as to allow the methods to be reproduced.

Therefore, pursuant to Article 41(1) and (3) of the REACH Regulation, the Registrant is requested to submit the information derived from the registered substance subject to the present decision: correct spectral data, correct chromatographic data and correct description of the methods used to identify and quantify the registered substance as specifically explained above. The Registrant shall ensure that the information is consistent throughout the dossier.

In addition ECHA has made the following observations which the Registrant is invited to consider:

The UV/Vis spectrum appears to be recorded using a sample which is too highly concentrated. Furthermore, the maximum absorption is out of scale. The spectrum should be recorded using a sample of appropriate concentration and the maximum absorption should be clearly shown.

B. Information in the technical dossier derived from the application of Annexes VII to XI

Pursuant to Articles 10(a)(vi) and/or (vii), 12(1)(c) of the REACH Regulation, a technical dossier for a substance manufactured or imported by the Registrant in quantities of 10 to 100 tonnes per year shall contain as a minimum the information specified in Annexes VII to VIII of the REACH Regulation.

1. Hydrolysis as a function of pH (Annex VIII, 9.2.2.1)

"Hydrolysis as a function of pH" is a standard information requirement as laid down in Annex VIII, Section 9.2.2.1 of the REACH Regulation. Adequate information on this endpoint needs to be present in the technical dossier for the registered substance to meet this information requirement.

The technical dossier does not contain relevant data to fulfil this information requirement. The Registrant sought to adapt the information requirement pursuant to Annex XI Section 2 claiming that testing was *"technically not possible"* and offers results form a study on analogue substances.

OECD test guideline 111 requires both the identification of the hydrolysis rate at three different pH-values and the identification of relevant degradation products. Considering that hydrolysis products in general may have an impact on the hazard and risk assessment, it is necessary to obtain information on the degradation products of the registered substance and the kinetics of the formation thereof.

As the Registrant recognises in the adaptation justification that, for the registered substance, "no further information about hydrolysis products is available". Information on "identification of the hydrolysis products" as described by TG OECD 111 is therefore not provided.

A supporting study ([redacted]) investigating hydrolysis of other substances than the registered substance is submitted. However, the relevance of the information from these read-across substances for the endpoint in question and for the registered substance has not been demonstrated by the registrant. In addition, no degradation product(s) of the registered substance has been identified.

The latter is relevant as the relevant degradation products need to be considered for the PBT-assessment according to Annex I Section 0.6.1.-4. using the criteria of Annex XIII fifth paragraph: "The identification shall also take account of the PBT/vPvB-properties of relevant ... degradation products".

As consequence, the Annex XI Section 1.5 requirements of adequacy for the purpose of risk assessment, adequate and reliable documentation to adapt the information requirements, and coverage of the key parameters addressed in the corresponding test method have not been met.

As explained above, the information available on this endpoint for the registered substance in the technical dossier does not meet the information requirement. Consequently there is an information gap and it is necessary to provide information for this endpoint.

Therefore, pursuant to Article 41(1) and (3) of the REACH Regulation, the Registrant is requested to submit the following information derived with the registered substance subject to the present decision: Hydrolysis as a function of pH (test method: EU C.7/OECD 111).

IV. Adequate identification of the composition of the tested material

In carrying out the study required by the present decision it is important to ensure that the particular sample of substance tested is appropriate to assess the properties of the registered substance, taking into account any variation in the composition of the technical grade of the substance as actually manufactured. If the registration of the substance covers different grades, the sample used for the new study must be suitable to assess these.

Furthermore, there must be adequate information on substance identity for the sample tested and the grade(s) registered to enable the relevance of the study to be assessed.

V. Information on right to appeal

An appeal may be brought against this decision to the Board of Appeal of ECHA under Article 51(8) of the REACH Regulation. Such an appeal shall be lodged within three months of receiving notification of this decision. Further information on the appeal procedure can be found on ECHA's internet page at http://www.echa.europa.eu/regulations/appeals. The notice of appeal will be deemed to be filed only when the appeal fee has been paid.

[redacted]
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