ECHA
EUROPEAN CHEMICALS AGENCY

Decision number: CCH-D-2114308124-64-01/F Helsinki, 11 September 2015

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

For dioctyltin oxide, EC No 212-791-1 (CAS No 870-08-6), 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 dioctyltin oxide, EC No 212-791-1 (CAS No 870-08-6), submitted by [redacted] (Registrant).

This decision is based on the registration as submitted with submission number [redacted], for the tonnage band of 100 to 1000 tonnes per year. This decision does not take into account any updates after the date when the draft decision was notified to the Registrant under Article 50(1) of the REACH Regulation.

The substance subject to the present decision is provisionally listed in the Community rolling action plan (CoRAP) for start of substance evaluation in 2017.

The scope of this compliance check does not include the requirements of Annex I of the REACH Regulation. Furthermore, the compliance check requirement to submit information on a two-generation reproductive toxicity study (EU B.35, OECD TG 416) or an extended one-generation reproductive toxicity study (EU B.56, OECD TG 443) has not been included in the scope of this compliance check due to the recent legislative amendments to the REACH Regulation regarding Annex IX, 8.7.3. After receiving the Registrant's comments (see below), the scope of this decision was restricted to the information requirements regarding the substance identity.

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 4 February 2015.

On 24 April 2015 ECHA sent the draft decision to the Registrant and invited him to provide comments within 30 days of the receipt of the draft decision.

On 21 May 2015 ECHA received comments from the Registrant on the draft decision.

The ECHA Secretariat considered the Registrant's comments. On the basis of this information, Section II was amended. The Statement of Reasons (Section III) was changed accordingly. In the comments on the draft decision the Registrant pointed out that there

was a change in the lead registrant for this joint registration in 2014 and that the dossier on which the present decision is based is now a joint registration member dossier. ECHA confirmed that this was the case and subsequently narrowed the scope of this decision to the information requirements regarding the substance identity. Other requirements mentioned in the initial draft decision may be considered in a future compliance check.

On 23 July 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.

As no proposal for amendment was submitted, ECHA took the decision pursuant to Article 51(3) of the REACH Regulation.

[Further steps of the procedure to be included here.]

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. Composition of the substance (Annex VI, Section 2.3.);
2. Spectral data (ultra-violet, infra-red, nuclear magnetic resonance or mass spectrum) (Annex VI, Section 2.3.5.);
3. High-pressure liquid chromatogram, gas chromatogram (Annex VI, Section 2.3.6.);
4. Description of the analytical methods (Annex VI, Section 2.3.7.).

B. Deadline for submitting the required information

Pursuant to Articles 41(4) and 22(2) of the REACH Regulation the Registrant shall submit to ECHA by **18 December 2015** an update of the registration dossier containing the information required by this decision, including, where relevant, an update of the Chemical Safety Report. The timeline has been set to allow for sequential testing as appropriate.

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. Composition of the substance (Annex VI, Section 2.3)

"Composition of the substance" is an information requirement as laid down in Annex VI,

Section 2.3. of the REACH Regulation. The substance composition corresponds to the chemical representation of what the substance consists of and is therefore an essential part of substance identification and the cornerstone of all the REACH obligations. Adequate information needs to be present in the technical dossier for the registered substance to meet this information requirement.

ECHA notes that the registration does not contain sufficient information for establishing the composition of the registered substance and therefore its identity, as required under Annex VI, Section 2.3 of the REACH Regulation.

More specifically, the Registrant reported one main constituent dioctyl(oxo)stannane (with concentration range > [redacted] w/w) and four impurities (octyl(oxo)stannanol, dichloro(dioctyl)stannane, butyl(oxo)stannanol and sodium chloride) in section 1.2 of the registration dossier.

However, the composition reported in section 1.2 is not fully in line with the results of analysis attached in section 1.4. In the analytical report attached in section 1.4 [redacted] 15 chromatographic peaks are listed in the peak table that summarizes results of the gas chromatography (GC) analysis recorded on the derivatized sample. Four of these peaks were attributed to the analytical artefacts and four others (< [redacted]% of area each) were not identified. Furthermore in the GC result table, impurities identified as dioctyl ether and isohexadecane are listed as "component in the original sample before derivatisation" but they are not included in the substance composition in section 1.2 of the dossier.

In the peak table, no reference can be found to the impurity reported in section 1.2 as dichloro(dioctyl)stannane. No analytical result or evidence of identification and quantification for the sodium chloride content is included in the dossier. In addition, no information about how the substance composition is established based on the analytical results (taking into account the derivatisation and the complex manipulation of the substance sample) have been provided in the dossier.

Therefore, the Registrant shall revise the information in section 1.2 such that they are consistent with the analytical results.

According to the Guidance for identification and naming of substances under REACH and CLP (Version: 1.3, February 2014), for mono-constituent substances impurities present in a concentration ≥ 1% (or above any lower concentration limit, if relevant for the classification of the substances) should be specified by at least one of the chemical identifiers (EC number and EC name, CAS number and CAS name, IUPAC name). For each impurity the concentration (typical and range) shall be given in % (w/w). The concentration range values must be representative for the registered substance as manufactured. If known, the number and total concentration of non-specified impurities shall be specified to make the total concentration complete up to 100%.

Regarding how to report the composition in IUCLID, the following applies: the Registrant shall indicate the composition of the registered substance in IUCLID Section 1.2. For each constituent and impurity, a chemical name, molecular and structural information, as well as the minimum, maximum and typical concentration, shall be reported in the appropriate fields in IUCLID.

2. Spectral data (ultra-violet, infra-red, nuclear magnetic resonance or mass spectrum) (Annex VI, Section 2.3.5.)

"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.

ECHA notes that the registration does not contain all of the spectral data which is required according to Annex VI, Section 2.3.5 of the REACH Regulation to support the indicated substance identity.

More specifically, the only spectral data is the mass spectra (MS) for specific peaks provided as part of the GC-MS analysis, which is as such not sufficient to unambiguously identify the registered substance. In addition the attached MS spectra are illegible and results about the fragmentation of the ions and their masses are not provided to enable ECHA to verify the conclusions about the identification of the substance and impurities.

ECHA however points out that spectral data is a standard requirement of Annex VI, Section 2.3.5. Therefore, the Registrant is requested to submit ultra-violet (UV), infrared (IR) and nuclear magnetic resonance (NMR) spectra. As an alternative to the NMR spectrum, a mass spectrum of the registered substance can be provided.

As for the reporting of the spectral data in the registration dossier, the spectra and description of relevant methods should be attached in IUCLID section 1.4.

3. High-pressure liquid chromatogram, gas chromatogram (Annex VI, Section 2.3.6.)

"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.

The GC chromatogram and the GC-mass spectra attached in section 1.4 are illegible which do not allow verification of the result of the chromatographic analyses.

Therefore the Registrant shall provide legible copy of the GC chromatogram and corresponding mass spectra.

As for the reporting of the data in the registration dossier, the information should be attached in IUCLID section 1.4.

The Registrant shall also ensure consistency between the analytical data provided in section 1.4 and composition reported in section 1.2.

4. Description of the analytical methods (Annex VI, Section 2.3.7.)

"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.

ECHA observes that the Registrant did not provide sufficient and appropriate description of the analytical methods used for the identification and quantification of the constituents and groups of constituents required to be reported in the composition of the registered substance in accordance with Annex VI section 2.3.7.

More specifically, the Registrant provides information on the Sn and NaCl content and loss on drying value range in the analytical report, but this information is not supported by any

analytical data. In addition the Registrant provided the quantification of the main constituent with GC, however a detailed description of the method is missing and in particular, no information is provided about how the derivatives and analytical artefacts are correlated to the original analytes and how the calculations are made considering the complex manipulation of the sample.

The Registrant is accordingly requested to provide a description of the analytical methods used to determine the Sn and NaCl content and loss on drying analysis. The Registrant is also requested to provide a sufficiently detailed description of the GC method. The description shall be sufficient for the methods to be reproduced and shall therefore include details of the experimental protocol followed, any calculation made and the results obtained. For chromatographic methods, the following are expected as a minimum: details on reagents, sample and standard preparation, instrumentation and equipment including column specification and instrumental conditions, the identity of carrier gas/eluent and detector type, required calculations and results.

As for the reporting of the data in the registration dossier, the information should be attached in IUCLID section 1.4.

The Registrant shall ensure that the composition reported in the dossier is consistent with the analytical results obtained.

IV. 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.

Authorised[1] by Ofelia Bercaru, Head of Unit, Evaluation

[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.