EUROPEAN CHEMICALS AGENCY

Decision number: CCH-D-0000003571-78-03/F Helsinki, 9 October 2013

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

For Diundecyl phthalate, CAS No 3648-20-2 (EC No 222-884-9), 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 Diundecyl phthalate, CAS No 3648-20-2 (EC No 222-884-9) submitted by [redacted] (Registrant). The scope of this compliance check is limited to the standard information requirements of Annex VI, section 2 of the REACH Regulation.

This decision is based on the registration as submitted with submission number [redacted] for the tonnage band of 1000 tonnes or more per year. This decision does not take into account any updates submitted after 9 July 2013, 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 3 December 2012.

On 26 April 2013 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 27 May 2013 ECHA received comments from the Registrant.

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

On 9 July 2013 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 to amend the draft decision within 30 days of the receipt of the notification.

Subsequently, Competent Authorities of the Member States did not propose amendments to the draft decision and ECHA took the decision pursuant to Article 51(3) of the REACH Regulation.

II. Information required

Pursuant to Articles 41(1)(a), 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. Name or other identifier of the substance (Annex VI, 2.1.), as specified under section III.1) below;
2. Structural information of the substance (Annex VI section 2.2 of the REACH Regulation)
3. Composition of the substance (Annex VI Section 2.3. of the REACH Regulation) as specified under section III.2) below;
4. High-pressure-liquid chromatogram or gas chromatogram (Annex VI, 2.3.6.), as specified under section III.3) below;
5. The description of the analytical methods or the appropriate bibliographical references (Annex VI, 2.3.7.), as specified under section III.A.3) below.

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 **9 January 2014**.

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.

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. Name or other identifier of the substance (Annex VI, 2.1. of the REACH Regulation)

ECHA notes that, based on the registrant's comments to the draft decision, the information required to be provided according to Annex VI section 2.1 of the REACH Regulation on the naming of the registered substance should refer to a substance of Unknown or Variable composition, Complex reaction products or Biological materials (UVCB). According to chapter 4.3 of the Guidance for identification and naming of substances under REACH and CLP (Version 1.2, March 2012) – referred to as "the Guidance" thereinafter, this information shall consist of two parts: (1) the chemical name and (2) a more detailed description of the manufacturing process. Other identifiers, including EC number (if available and appropriate) and any CAS number (if available) corresponding to the registered substance shall also be submitted. ECHA observes that the Registrant did not provide sufficient and appropriate information on the naming of the registered substance (as explained under points (i) and (ii) thereinafter, including also the assigned EC and CAS numbers (as indicated in points (iii)).

(i). A chemical name representative for the registered substance must be submitted

The chemical name assigned by the registrant to the registered substance, "diundecyl benzene-1,2-dicarboxylate", refers to a dialkyl dicarboxylate mono-constituent substance where the dialkyl group is linear. However, based on the

clarifications provided by the Registrant in his comments the draft decision, "*[t]he substance object of this registration is produced by* [redacted] *)*". The substance would therefore consist of dialkyl dicarboxylates where the alkyl groups independently are linear or branched. Therefore the chemical name "diundecyl benzene-1,2-dicarboxylate" is not appropriate as it does not describe the actual composition of the registered substance.

The Registrant is therefore requested to replace the chemical name currently specified for the registered substance by a chemical name which is representative of the identity of the registered substance, including its composition.

(ii). A detailed manufacturing process description must be submitted by the Registrant

The Registrant has provided in section 3.1 of the IUCLID dossier a brief description of the manufacturing process. However, in line with the Registrant's comments, the information includes a misprint regarding the name of the manufactured substance. In addition, the substance would normally be regarded as a UVCB substance. For these substance types, the chemical composition alone is not sufficient for the substance identification. Details of the source, the processing steps and the corresponding relevant process parameters are essential identifiers of the substance. However, the following elements of the description are currently missing from the dossier:

- Compositional information of the starting material in terms of identity and upper and lower concentration levels of the individual alcohols used;
- The ratio of the starting materials used;
- The process parameters determining the composition of the manufactured substance. ECHA notes in particular that the registrant specified that "*[t]he reaction ends when the quality specifications of* [redacted] *are achieved. The conversion is above* [redacted]*% w/w*". However it is unclear whether the specified conversion refers to the proportion of specific alcohols used in the process, the phthalic anhydride that has reacted or the phthalic anhydride converted into dialkyl dicarboxylate.

The Registrant is accordingly requested to address the misprint on the name of the manufactured substance in the brief process description. Furthermore, the Registrant is requested to specify the abovementioned missing elements of the manufacturing process description.

(iii). EC and CAS numbers corresponding to the registered substance must be submitted

The chemical names associated with the EC and CAS numbers currently assigned in the dossier refer to the mono-constituent substance, "diundecyl benzene-1,2-

dicarboxylate". In accordance with the explanations provided under point III.1.(i) of this decision, ECHA considers that these identifiers do not correspond to the registered substance. ECHA takes also note to the fact that the registrant himself proposed in his comments to amend the EC and CAS information for the registered substance.

The Registrant is accordingly requested to delete from the dossier the CAS number currently assigned to the registered substance. The registrant shall not remove or modify at this stage the EC entry currently assigned to this registration for technical reasons, the registration being linked to that entry in REACH-IT. To ensure an unambiguous identification of the registered substance, the Registrant shall however specify in the dossier that the EC entry currently assigned does not correspond to the registered substance and shall refer to any available and appropriate EC number specifically corresponding to the substance.

As for the reporting of the information in IUCLID, the chemical name and the description should be specified in the "IUPAC name" and "Description" fields in IUCLID section 1.1, respectively. The registrant shall ensure that the brief manufacturing process description in IUCLID section 3.1 of the dossier refers to the registered substance.

Any available CAS information should be reported under the CAS information header of the reference substance in IUCLID section 1.1. The Registrant should specify, in the "Remarks" field of the reference substance in IUCLID section 1.1, the following: "The EC entry 222-884-9 currently assigned does not specifically correspond to the registered substance. This identifier can technically not be modified or deleted at this stage in the present registration update". The Registrant shall also specify, in the same IUCLID field, any available and appropriate EC number for the substance.

2. Structural information of the substance (Annex VI section 2.2 of the REACH Regulation)

ECHA note that the structural information assigned by the registrant to the registered substance, including the structural formula, SMILES notation and InChI, refers to "diundecyl benzene-1,2-dicarboxylate". In accordance with the explanations provided under point III.1.(i) of this decision, ECHA considers that this information does not correspond to the registered substance.

The Registrant is accordingly requested to delete from the dossier the structural information currently assigned in IUCLID section 1.1 of the registration dossier to the registered substance. For UVCB substances such as the registered substance, the registrant may provide a generic structural formula representing the registered substance.
As for the reporting of the structural formula of the registered substance in IUCLID, the information should be provided in the relevant field of the reference substance in IUCLID section 1.1.

3. Composition of the substance (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 corner stone of all the REACH obligations.

ECHA notes that the registration does not contain sufficient and appropriate 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 has reported in section 1.2 of the IUCLID dossier "diundecyl benzene-1,2-dicarboxylate" as the main constituent and has specified the typical concentration of this constituent as [redacted] % (w/w) and the concentration range as [redacted] – [redacted] %(w/w). However the gas chromatogram attached in section 1.4 of the IUCLID dossiers indicates the presence of a number of constituent in the substance. These constituents have not been reported in section 1.2 of the IUCLID dossier. Based on the number and intensity, these peaks cannot be associated only with the [redacted] impurities indicated in section 1.2 of the IUCLID dossier. In addition, in line with the comments received from the Registrant, the registered substance includes, besides the well-defined constituent " diundecyl phthalate", [redacted] which have not be referred to in the composition. ECHA therefore concludes that the reported composition is not appropriate for the identification of the registered substance.

According to ECHA Guidance chapter 4.3 on the identification and naming of substances under REACH, the Registrant should note that, for UVCB substances such as the registered substance, the following applies:

- All constituents present in the substance with a concentration of ≥ 10 % shall be identified and reported individually;
- All known constituents and constituents relevant for the classification and/or PBT assessment of the registered substance shall be reported individually; and
- Other constituents shall be identified by a generic description of their chemical nature. For substances such as the registered substance, the reporting of unknown dialkyl dicarboxylate constituents according to the type of dialkyl group combinations (branched-branched; mixed linear and branched) is necessary as a baseline. For each group of unknown constituents, information on the carbon number distribution of each alkyl chain shall be provided..

For each constituent and group of constituents, the minimum, maximum and typical concentration, shall be reported.

In line with the above, the Registrant is requested to provide any information which is suitable and necessary for ECHA to use the compositional information as one identifier for the registered substance. The Registrant must provide any information which is suitable and necessary to meet these objectives.

Regarding how to report the composition of UVCB substances in IUCLID, further technical information is provided in paragraphs 2.1 and 2.2.2 of the Data Submission Manual 18 available on the ECHA website.

The Registrant shall ensure that the information provided on the composition of the substance is confirmed by the required analytical data included in IUCLID section 1.4. The registrant shall ensure in particular to remove any analytical information which has not been generated on the substance which is the subject of this registration and replace it with data carried out on the registered substance, as appropriate.

4. High-pressure-liquid chromatogram or gas chromatogram (Annex VI point 2.3.6.)

ECHA notes that the copy of a gas chromatogram has been attached to the dossier. However, ECHA observes that the registrant did not provide any report from the chromatographic analysis. In particular, a peak table with the associated retention times

and peak area has not been included. ECHA points out that this information is required since it constitutes a numerical representation of the chromatogram.

Accordingly, the Registrant is requested to provide the report from the gas chromatographic analysis of the registered substance.

As for the reporting in the registration dossier, the information should be included in IUCLID section 1.4.

5. The description of the analytical methods (Annex VI, 2.3.7.)

ECHA observes that the Registrant did not provide sufficient description of the analytical methods used for the identification and quantification of the constituents and group of constituents as requested according to Annex VI, Section 2.3.7 of the REACH Regulation.

More specifically the Registrant indicated in section 1.2 of the IUCLID dossier the presence of "diundecyl benzene-1,2-dicarboxylate" at a concentration of [redacted] %-[redacted] % [redacted] % impurities. However the provided GC-MS analysis shows the presence of a number of peaks which have not been identified and reported in section 1.2 of the IUCLID dossier. In addition, the Registrant clarified in his comments to the draft decision that "diundecyl benzene-1,2-dicarboxylate" encompasses in fact linear, branched and mixed linear and branched dicarboxylates. However, the dossier does not include any description of the methods for their identification and quantification.

Therefore the Registrant is requested to provide the description of the analytical methods for the quantification and identification of the constituents and groups of constituents required to be reported in the composition of the registered substance. The description shall be sufficient for the methods to be reproduced and shall therefore include details of the protocols followed, any calculation made and the results obtained.

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 description of the analytical methods included in the dossier specifically refer to the well-defined mono-constituent substance which is the subject of the registration. The Registrant shall note that, if the analysed sample refers to a different substance than the registered mono-constituent substance diundecyl phthalate, separate registration obligations pertain to such other substance.

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://echa.europa.eu/appeals/app_procedure_en.asp. The notice of appeal will be deemed to be filed only when the appeal fee has been paid.

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