EUROPEAN CHEMICALS AGENCY

Decision number: CCH-D-2114321389-47-01/F Helsinki, 08 March 2016

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

For Isononyl isononanoate, EC No 609-993-0 (CAS No 42131-25-9), 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 Isononyl isononanoate, EC No 609-993-0 (CAS No 42131-25-9), submitted by [redacted] (Registrant).

The scope of this compliance check decision is limited to the standard information requirement 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 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.

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 2 October 2014.

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. That draft decision was based on submission number [redacted].

On 26 May 2015 ECHA received comments from the Registrant on the draft decision.

The ECHA Secretariat considered the Registrant's comments. The information is reflected in the Statement of Reasons (Section III) whereas no amendments to the Information Required (Section II) were made.

On 21 January 2016 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.

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. Name or other identifiers of the substance (Annex VI, Section 2.1.)
2. Description of the analytical methods (Annex VI, section 2.3.7)
3. Composition (Annex VI, Sections 2.3)

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 **15 September 2016** an update of the registration dossier containing the information required by this decision.

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. Name or other identifiers of the substance (Annex VI, Section 2.1)

The Registrant identified the registered substance as of Unknown or Variable composition, Complex reaction products or Biological materials (UVCB). Information required to be provided according to Annex VI, Section 2.1 of the REACH Regulation on the naming of UVCB substances, such as the registered substance, shall consist of two parts: (1) the chemical name and (2) a more detailed description of the manufacturing process, as indicated in chapter 4.3 of the Guidance for identification and naming of substances under REACH and CLP (Version: 1.3, February 2014) – referred to as "the Guidance" thereinafter. Other identifiers, including any CAS number (if available) and EC number (if available and appropriate) corresponding to the substance, shall also be reported.

The following manufacturing process description has been provided in IUCLID section 3.1: "[redacted]", where the [redacted] was identified using both a generic ([redacted]) and a specific ([redacted]) name, and the [redacted] was identified using a generic name ([redacted]). Also, the IUPAC name and CAS information provided by the Registrant are not consistent. More specifically, the IUPAC name refers to "[redacted]" (generic

and specific parts), whereas the CAS information refers to "[redacted]" (two generic parts). In addition, further inconsistencies are present in comparison to the information reported in IUCLID section 1.2, where the substance has been described as: "[redacted]". The identity of the substance was not supported by structural or molecular formulae.

Therefore, ECHA concludes that the Registrant did not provide appropriate information on the identification of the registered substance. More specifically, ECHA considers that:

i) The manufacturing process description is not sufficient to identify the registered substance. The starting materials have been ambiguously identified by inconsistent identifiers ([redacted]). In addition, the description of the manufacturing process does not contain any details on the relevant manufacturing process parameters.

ii) The IUPAC name and CAS information do not correctly identify the substance as the prefix [redacted] is ambiguous and can be understood in different ways and in addition the IUPAC name is not consistent with the CAS information.

Accordingly, the Registrant is requested to provide a clear and unambiguous identification of the starting materials (including their composition), as well as the relevant manufacturing process parameters, which may influence the composition of the registered substance (ratio of reactants, details of the parameters used to control the composition of the manufactured substance and description of the purification/isolation steps). Also, the Registrant is required to provide a IUPAC name that reflects the exact identity of the registered substance, avoiding the use of the ambiguous prefix [redacted] The current numerical identifiers (EC number 609-993-0 and CAS number 42131-25-9) do not correctly identify the registered substance, and they will need to be revised. The Registrant shall delete from the dossier the CAS entry currently assigned to the substance and provide instead any available CAS information specifically corresponding to the substance.

As for the reporting of the information in IUCLID, the chemical name and the manufacturing process description shall be specified in the "IUPAC name" and "Description" fields in IUCLID section 1.1, respectively. Any available CAS information shall be reported under the CAS information header of the reference substance in IUCLID section 1.1.

For technical reasons the Registrant is requested at this stage, not to remove or modify the EC entry in the updated dossier. As this registration is linked to this EC entry in REACH-IT, the IT system will not accept the updated dossier as an update when the EC entry has changed. The Registrant shall instead include the following in the "Remarks field" of the reference substance: "This EC entry is not appropriate to identify the registered substance. This identifier cannot be modified in the present registration at this stage for technical reasons."

The CAS entry 42131-25-9 would need to be removed from the "CAS information" field and included in the "Related CAS information" field.
The Registrant shall ensure that appropriate and consistent identifiers are used throughout the registration whenever reference to the specific substance which is the subject of this registration is made.

In the comments to the draft decision, the Registrant provided clarification on the identity of the starting materials (especially concerning the [redacted]) and acknowledged the complexity of

the [redacted] used. However, ECHA notes that this information needs to be included in the dossier and the identity of the [redacted] (and consequently of the [redacted]) should be described consistently throughout the dossier.

In addition, the Registrant expressed concerns for changing the current CAS entry, as the letter of access and the studies are linked to the used CAS identifier. ECHA notes that the letter of access to the respective study is not affected by the change of the CAS identifier in the IUCLID dossier. However, the registrant is advised to clarify how the tested material relates to the substance subject to the present decision. ECHA reminds that it is the Registrant's obligation to assure that the studies have been performed on test material relevant for the registered substance, regardless of the numerical identifiers used.

The Registrant expressed a concern regarding the confidential nature of the used [redacted]. ECHA points out that it is a Registrant's right to claim confidentiality for the IUPAC name. This can be done following the indication provided in the manual that can be found in the ECHA website (REACH-IT Data Submission Manual Part 17).

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

The REACH regulation (Annex VI, 2.3.7) requires the description of the analytical methods to be provided for the identification of the substance, including its constituents.

The Registrant has provided in section 1.4 a gas chromatogram that shows the presence of several peaks, with area% ranging from [redacted] up to [redacted]%. However, the (relevant) peaks were not identified, and therefore it is not possible to verify the composition of the substance. ECHA tried to link the peaks of the chromatogram to the groups of constituents reported in the description field in section 1.2. However, a direct connection could not be done, due to the differences in the values between the area% of the peaks and the reported concentrations ([redacted]%, <[redacted]% and <[redacted]%).

Consequently, ECHA concludes that the description of the analytical methods used for the quantification of the constituents and/or group of constituents is not sufficient, as the identification of the peaks is currently missing in the dossier.

The Registrant shall provide the identification of the peaks, and clear information on the analytical methods used for the identification and quantification of the constituents and/or groups of constituents required to be reported in the composition of the registered substance.

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.

In the comments to the draft decision, the Registrant indicates that it is not possible to identify all the peaks/groups of constituents present in the [redacted] and that the complexity of the [redacted] is due to the complexity of the [redacted] (the chromatogram of the [redacted] resembles that of the [redacted]). The Registrant agreed to find more suitable analytical technique(s) to determine the [redacted] ECHA acknowledges the complexity of the starting materials and of the registered substance. Therefore, ECHA is not expecting full separation, identification and quantification of all constituents. Grouping according to

carbon number, and general nature ( ) may be regarded as sufficient. For guidance, please refer to the OECD guidance

3. Composition (Annex VI, Section 2.3 of the REACH Regulation)

Annex VI, section 2.3 of the REACH regulation requires that each registration dossier contains sufficient information for establishing the composition of the registered substance and therefore its identity.

In that respect, according to chapter 4.3 of the Guidance, for a UVCB 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 identified and reported individually;
- Unknown constituents shall be identified as far as possible by a generic description of their chemical nature.
- For each constituent (or group of constituents), the typical, minimum and maximum concentration levels shall be specified.

As mentioned in the section above, the Registrant has reported one generic constituent (i.e.) at a concentration of % (w/w) with the following description: "*According to the available information, this complex substance is composed of , the representative constituents being*

Based on this statement, and supported by the results of the gas chromatography showing several peaks, ECHA concludes that the composition reported in the current dossier is not sufficient for the identification of the registered substance. More specifically, ECHA considers that the composition has not been reported according to the Guidance, as at least groups of constituents were identified, and thus should have been reported individually.

Accordingly, the Registrant is requested to report the identified constituents and/or groups of constituents in section 1.2 of the registration dossier. For each constituent and/or group of constituents, the minimum, maximum and typical concentration values shall be provided. The information reported in Section 1.2 shall be consistent with the analytical data provided in Section 1.4.

Regarding how to report the composition of the registered substance in IUCLID, the following applies: the Registrant shall indicate the composition in Section 1.2. For each constituent required to be reported individually, the IUPAC name, CAS name and CAS number (if available), molecular and structural formula, as well as the minimum, maximum and typical concentration, shall be reported in the appropriate fields in IUCLID. For the other constituents to be reported under a generic description, a generic chemical name describing the group of constituents, generic molecular and structural information (if applicable), as well as the minimum, maximum and typical concentration, shall be reported in the appropriate fields in IUCLID. Further technical details on how to report the composition of UVCB substances in IUCLID are available in paragraphs 2.1 and 2.2.2 of the Data Submission Manual 18 on the ECHA website.

In the comments to the draft decision, the Registrant pointed out that the complexity of the registered substance is mainly due to the nature and complexity of the [redacted] starting material. The Registrant claimed the need to rely on the information available from the supplier of this precursor. However, the Registrant has agreed to clarify the substance composition with additional analytical investigation. Any uncertainty in the quantification can in principle be taken into account in the concentration ranges of the constituents to be reported in the composition. Any eventual analytical limitation in establishing the composition of the registered substance can be reported transparently in the registration dossier.

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, Claudio Carlon, Head of Unit, Evaluation E2

[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.