ECHA
EUROPEAN CHEMICALS AGENCY

Decision number: CCH-D-2114308117-59-01/F Helsinki, 31 August 2015

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

For [redacted], EC No 939-629-9 (CAS No NS), 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 [redacted], EC No 939-629-9 (CAS No NS), submitted by [redacted] (Registrant).

The scope of this compliance check decision is limited to the standard information requirement[s] 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 4 June 2015, i.e. 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 5 March 2015.

On 4 June 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.

By 13 July 2015 the Registrant did not provide any comments on the draft decision to ECHA.

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.

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 (ultra-violet, infra-red, nuclear magnetic resonance or mass spectrum) (Annex VI, Section 2.3.5.), High-pressure liquid chromatogram, gas chromatogram (Annex VI, Section 2.3.6.), Description of the analytical methods (Annex VI, Section 2.3.7.)
2. Composition of the substance (Annex VI, Section 2.3.);
3. Name or other identifier of the substance (Annex VI, Section 2.1.);

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 **7 December 2015** 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. Spectral data (ultra-violet, infra-red, nuclear magnetic resonance or mass spectrum) (Annex VI, Section 2.3.5.), High-pressure liquid chromatogram, gas chromatogram (Annex VI, Section 2.3.6.), Description of the analytical methods (Annex VI, Section 2.3.7.)

ECHA notes that the Registrant has not included sufficient spectral and chromatographic data, including description of analytical methods, as required for the identification and quantification of the registered substance per Annex VI sections 2.3.5-7. Moreover, according to Article 5 of the REACH Regulation and p 5, 7.6 and 8.1.1-2 of the Guidance for identification and naming of substances under REACH and CLP (Version: 1.3, February 2014) – referred to as "the Guidance" thereinafter, the reported composition and the analytical data shall be based on the substance as it is manufactured or imported.

However, ECHA notes that the qualitative and quantitative analytical data included in section 1.4 were generated on a laboratory sample and not on the substance as it is manufactured or imported by the Registrant.

Based on the description included in section 1.4 of the IUCLID dossier, the registered substance is manufactured from [redacted]

The sample used in the analysis was however synthesised in the laboratory by reacting [redacted] The process conditions, such as temperature, time, etc. may influence the composition of the sample which could significantly differ from the manufactured substance. Therefore, the composition of the registered sample is expected to be much more complex, namely containing possible constituents that are not present in the laboratory sample.

Based on the process description attached in section 1.4, ECHA also observes that the manufactured substance contains not only [redacted] but potentially also other constituents or groups of constituents such as:

- [redacted]

ECHA notes that the presence of these constituents is neither reflected in the composition nor in the analytical information.

Furthermore, the ratio of reactants used in the manufacturing process [redacted] is unclear, as ambiguous information is provided. It is stated that "*the substance was synthesised in the laboratory by* [redacted], however the reaction scheme highlights that other ratios of the reactants [redacted] It could indicate that different compositional grades of the registered substance may be manufactured, including grades where excess of [redacted] is expected to be present in the composition.

Although the analysis of the laboratory sample may serve as a reference for further studies of the composition of the registered substance, the composition of this synthetic model is not representative for the substance as actually manufactured or imported.

Consequently, the Registrant has not submitted the required spectral and chromatographic data recorded on the substance registered by his legal entity, that would enable the verification of its identity and composition.

In line with Annex VI sections 2.3.5-6, the Registrant is requested to submit spectral and chromatographic data generated on the registered substance as manufactured or imported by the Registrant. This data shall be sufficient to enable the identity and composition of the registered substance to be verified.

In line with Annex VI section 2.3.7, the Registrant shall also include a description of each analytical method used to identify the substance and quantify its composition and the results thereof. The methods used shall be sufficient to enable the substance identity to be verified. The description of each method shall be reported in sufficient detail that the method may be reproduced. Specifically, for chromatographic methods, the method description should include a peak table, containing the retention times, identifiers, peak areas, peak area % and concentration %(w/w) of the identified constituents.

As for the reporting of the data in the registration dossier, the information should be attached in section 1.4 of the IUCLID dossier. The Registrant shall ensure that the composition reported in section 1.2 of the dossier is consistent with the analytical results obtained.

The Registrant shall ensure that the information is consistent throughout the dossier. As for the reporting of the chromatographic data in the registration dossier, the relevant chromatograms shall be attached in IUCLID section 1.4.

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

Annex VI, section 2.3 of the REACH Regulation requires that each registration dossier contain sufficient information for establishing the composition of the registered substance and therefore its identity. Article 5 of REACH obliges EU manufacturers of substances to register the substances as manufactured.

- In that respect, according to chapter 4.3 of the Guidance, the Registrant should note that for UVCB substances (substances of Unknown, or Variable Composition, or of Biological origin) presenting a large number of constituents, all constituents present with a concentration of ≥ 10 % or relevant for the classification and/or PBT assessment of the substance shall be identified and reported individually. In addition, other constituents shall be identified by a generic description of their chemical nature.

However, 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, as explained in details in Section III.A.1 above, ECHA notes that the composition provided in section 1.2 of the IUCLID dossier was not derived based on the substance as it is manufactured by the Registrant but on a sample synthesised and isolated in the laboratory. Moreover, the presence of the constituents highlighted in Section III.A.1 above is not reflected in the reported composition either.

ECHA therefore concludes that the compositional information has not been provide to the required level of detail.

The Registrant is accordingly requested to correct the information provided on the composition of the registered substance.

According to chapter 4.3 of the Guidance, for UVCB substances such as the registered substance, the Registrant shall note the following:

- 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; and
- Unknown constituents shall be identified as far as possible by a generic description of their chemical nature. The identification of these other constituents must be provided in order to allow ECHA to establish the composition of the substance as

manufactured and to use the compositional information as one identifier for the registered substance. This information must also allow ECHA to verify that the composition is consistent with the chemical name reported for the registered substance.

The composition shall represent the registered substance as it is manufactured. As stated above in section III.A.1, the Registrant shall consider whether constituents other than [redacted] contribute to a significant concentration level in the composition of the manufactured substance. In such case, these constituents shall be identified and reported in the compositional data in section 1.2 of the registration dossier as part of the substance.

- In case the [redacted] is part of the manufactured substance, the Registrant is requested to include its constituents / groups of constituents in the composition of the registered substance. For the [redacted] the reporting of the [redacted] and the [redacted] is necessary as a baseline to establish the composition of the substance. For each group of constituents, quantitative information on the carbon number distribution shall also be specified to conclude on the compositional profile of the constituents within the group.

- In case when the registered substance contains unreacted starting material(s) [redacted] the Registrant shall report these constituents/groups of constituents in section 1.2 of the registration dossier. The grouping of the constituents of the [redacted] The residual [redacted] could also be reported as such in section 1.2.

Where the Registrant covers different compositional grades of the same substance in a registration, the Registrant shall report separately the compositional information of each grade.

This means that if the substance covered by the registration has two (or more) different compositions, then these must be presented separately. Information on how to report several compositions in IUCLID is specified in paragraph 2.3, Q&A8 of the "Data Submission Manual – Part 18: How to report the substance identity in IUCLID 5 for registration under REACH" (version: 2.0, July 2012), available on the ECHA website.

ECHA highlights that failure to report separately the compositional information of each grade of a substance may result in one or more grades not being covered by this registration.

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 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, should 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, should be

reported in the appropriate fields in IUCLID. The Registrant shall ensure that the provided information is consistent throughout the dossier.

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 – Part 18: How to report the substance identity in IUCLID 5 for registration under REACH (version: 2.0, July 2012) on the ECHA website. Information on how to report several compositions in IUCLID is specified in paragraph 2.3, Q&A8 of that manual.

3. Name or other identifier of the substance (Annex VI, Section 2.1.);

ECHA notes that 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: (i) the chemical name and (ii) a more detailed description of the manufacturing process, as indicated in chapter 4.3 of the Guidance.

ECHA observes that the registered substance is identified as [redacted]. Only generic information on the manufacturing process is provided in section 1.1 and 3.1 of the registration dossier indicating that the substance is [redacted] More detailed description is attached in section 1.4 of the dossier, however, as already pointed out in Section III.A.1 above, ECHA notes that key elements of the manufacturing process description which are essential for the identification of the registered substance are missing from the dossier.

(1) Concerning the name of the registered substance

Based on the process description attached in section 1.4, ECHA observes that the manufactured substance contains not only [redacted] highlighted in Section III.A.1 above. However, these constituents are not reflected in the chemical (IUPAC) name.

ECHA therefore concludes that the Registrant did not provide to a representative chemical name for the registered substance.

(2) Concerning the manufacturing process of the registered substance

ECHA noted in Section III.A.1 above, that the ratio of reactants used in the manufacturing process [redacted] is unclear and that different compositional grades of the registered substance may be manufactured, including grades where excess of [redacted] is used and consequently [redacted] is present in the composition.

ECHA therefore concludes that the manufacturing process has not been provided to a sufficient level of detail for the identification of the registered substance. As a consequence, the identity and composition of the registered substance including the solvent used remain unclear.

Therefore, pursuant to Article 41(1) and (3) of the REACH Regulation the Registrant shall provide the missing information on the manufacturing process description. This information shall include:

- [redacted] and

- Ratio of reactants used to manufacture the registered substance, and
- Specifications of all relevant process parameters, including temperature and pressure values, and any other process steps and their parameters including purification step(s) (if any) which are necessary to obtain the registered substance and which may affect the substance composition.

In line with the above, the Registrant shall provide detailed information on the status of [redacted] in the registered substance to allow ECHA to conclude whether these constituents are part of the registered substance. ECHA points out that according to the substance definition under REACH article 3(1), solvents which may be separated without affecting the stability of the substance or changing its composition should be excluded. Therefore, the amount of solvent that cannot be removed without affecting the stability of the registered substance should be considered as its integral part.

Therefore, the Registrant shall consider whether constituents other than [redacted] contribute to the composition of the registered substance. In such case, these constituents shall be identified and reported in the compositional data in section 1.2 of the registration dossier as part of the substance (as explained in section III. A.2) and, if present at a significant concentration level, shall be reflected in the chemical name of the registered substance.

Where the Registrant covers different compositional grades of the substance in a registration, the Registrant shall report separately the starting materials, their ratio and manufacturing process description of each compositional grade. ECHA highlights that compositional grades for which a manufacturing process description is not provided may eventually not be considered being covered by the registration.

Regarding how to report the description of the manufacturing process of the UVCB substance, the information shall be included in the "Description" field in IUCLID section 1.1. The Registrant shall ensure that the chemical name, the identifiers and the manufacturing process description to be reported according to Annex VI, Section 2.1 of the REACH Regulation are consistent with each other and with the composition required to be provided according to Annex VI, Section 2.3 of the REACH Regulation.

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 Guilhem de Seze, 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.