Decision number: CCH-D-2114313281-65-01/F Helsinki, 05 January 2016

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

For dodecane-12-lactam, manufacturing of, by-products from, distillation residues, EC No 923-400-5 (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 dodecane-12-lactam, manufacturing of, by-products from, distillation residues, EC No 923-400-5 (CAS No N/A), submitted by [redacted] (Registrant).

The scope of this compliance check decision 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 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 4 February 2015.

The decision making followed the procedure of Articles 50 and 51 of the REACH Regulation:

On 11 May 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 17 June 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 29 October 2015, ECHA notified the draft decision to the competent authorities of the Member States for proposal(s) for amendment(s).

As no amendments were proposed, ECHA took the decision according 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. Composition of the substance (Annex VI, Section 2.3.), as specified under section III.A.1 below;
2. Name or other identifier of the substance (Annex VI, Section 2.1.), as specified under section III.A.2 below.

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 **12 April 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. 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.

In that respect, according to 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, the Registrant should note that for UVCB substances (substances of Unknown, or Variable Composition, or of Biological origin) presenting a large number of constituents, 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 constituents relevant for the classification and/or PBT assessment of the registered substance shall be identified and reported individually; and
- Other constituents shall be identified by a generic description of their chemical nature.

ECHA has observed the following interrelated deficiencies in the Registrant's description of the composition of the substance:

a) Broad concentration range of the constituent dodecane-12-lactam

ECHA notes that Registrant has indicated broad concentration ranges (from [redacted]% up to [redacted]%) for one of the constituents listed in section 1.2, namely dodecane-12-lactam. Furthermore, ECHA notes that in the analytical data provided in the dossier, the Registrant has provided information about the concentration of this constituent in different manufacturing batches from 2009-2011 (Figure 5 and Table 4 of the document attached to IUCLID section 1.4 "[redacted]"). This information shows that the concentration of the constituent ranges from [redacted]% (minimum concentration) to [redacted]% (maximum concentration).

ECHA notes that in the scenario where the concentration of the dodecane-12-lactam constituent is [redacted]% (minimum concentration value provided in section 1.2), the total sum of the concentration of the remaining constituents is at most [redacted]% of the substance, as per the information in section 1.2 of the IUCLID dossier. In such a scenario a significant part of the registered substance (up to [redacted]%) is unaccounted for. The analytical information provided in Section 1.4 of the IUCLID dossier also provides no additional information on this unidentified part of the registered substance.ECHA acknowledges the comments by the Registrant and notes that he agrees to clarify the substance composition by revising the concentration ranges and including the typical concentrations of the constituents in the updated registration dossier. The information to be provided by the Registrant will only be assessed on the basis of an updated dossier.

b) Lack of clarity on the identity of the constituent "Azacyclotridecan-2-one, homopolymer"

ECHA notes that according to the information included in Section 1.2 of the IUCLID dossier, the constituent Azacyclotridecan-2-one, homopolymer, (CAS 25038-74-8) comprises [redacted]% percent of the registered substance. ECHA notes that the Registrant has described this constituent as a polymer, with a molecular formula of (C12H23NO)x. The structural formula provided for this constituent suggests that the substance may be formed by ring opening polymerisation of dodecane-12-lactam. However, the Registrant has not provided sufficient information on the identity of this particular constituent. Based on the name of this constituent, the "azacyclotridecan-2-one, homopolymer", may in itself be a UVCB composed of different possible constituents.

Therefore, pursuant to Article 41(1) and (3) of the REACH Regulation, the Registrant is requested to revise the compositional information of the registered substance.

In particular for the constituent Azacyclotridecan-2-one, homopolymer, (CAS 25038-74-8), the Registrant shall identify the individual constituents of this broad entry, as described above. The Registrant is requested to report separately the different constituents based on the degree of polymerisation/oligomerisation of these constituents. The Registrant shall provide sufficient analytical information to enable the identification of each entry.

The concentration range values must be representative for the registered substance as manufactured and it shall be clarified how the minimum and maximum values for each constituent or group of constituents were obtained (i.e. information on the batch selection, sampling procedure, the measured values, calculations used etc.). Without this information ECHA is not able to conclude on the representativeness of these values.

The Registrant shall ensure that the information is consistent throughout the dossier.

ECHA notes that in the event the Registrant covers different compositions of the registered substance in the present registration dossier, he shall report separately the compositional information of each composition. 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.

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&A 8 of that manual.

The Registrant shall ensure that there is sufficient analytical information included in Section 1.4 of the IUCLID dossier to identify and quantify the substance and to verify the information in Section 1.2.ECHA acknowledges the comments provided by the Registrant on the identity of the constituent "Azacyclotridecan-2-one, homopolymer" (polyamide-12). As specified above, the Registrant is requested to report separately the different constituents (based on the degree of oligomerisation) of this homopolymer. The table included in the attached report (Registrant's comments to the draft decision) with the results based on Size Exclusion Chromatography (SEC) shows further estimation of the molecular weight distribution of "Azacyclotridecan-2-one, homopolymer". This analytical data may serve as a basis for the requested way of reporting of the oligomeric species based on their molecular weights but is not providing in itself the requested information on this constituent. Therefore it needs to be included in an updated registration dossier as a starting point and complemented further. The compositional data in section 1.2 needs to be consistent with this information.

If the SEC analysis does not provide reliable results on the individual constituent(s) of the "Azacyclotridecan-2-one, homopolymer" different alternative analytical techniques may also be considered by the Registrant to obtain an appropriate quantitative estimation of the constituents or groups of constituents of the above homopolymer. Regardless of the analytical method followed, any uncertainty in the quantification of the substance needs to be taken into account in the concentration ranges of the constituents to be reported in the composition.

In addition, as stated in the Registrant's comments "the polymer chain length is proportional of catalyst amount and also of course of the catalyst nature". Therefore the manufacturing process circumstances (e.g. the nature of catalyst and the amount used) need to be taken into account for determination of the degree of oligomerisation.

The information to be provided by the Registrant will only be assessed on the basis of an updated dossier.

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

"Name or other identifier of the substance" is an information requirement as laid down in Annex VI, Section 2.1. of the REACH Regulation. The name and other identifiers are used to identify the substance in an unambiguous manner and are therefore fundamental for substance identification. Adequate information needs to be present in the technical dossier for the registered substance to meet this information requirement.

ECHA notes that the Registrant identified the registered substance as of Unknown or Variable composition, Complex reaction products or Biological materials (UVCB). 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 Registrant did not provide sufficient information on the manufacturing process, as explained thereinafter.

(i) ECHA observes that no chemical name was provided in the "IUPAC name field" and according to the name assigned by the Registrant in the "EC name" field in section 1.1 of the IUCLID dossier, the substance corresponds to "dodecane-12-lactam, manufacturing of, by-products from, distillation residues". For this substance, the Registrant provided in sections 1.1 and 3.1 of the IUCLID dossier, only a brief generic description of the manufacturing process, where the substance is described as "complex substance (known as uvcb), generated during one of the purification steps in lactame 12 production". However, no further information on the identity of the starting materials, process steps and parameters is provided in either section 1.1 or 3.1 of the IUCLID dossier. ECHA considers that this limited information provided on the chemical name and manufacturing process is insufficient to identify the registered substance, and therefore a key element of the identification of the registered UVCB is missing.

Accordingly, pursuant to Article 41(1) and (3) of the REACH Regulation, the Registrant is requested to provide a representative chemical name in the IUPAC name field of the IUCLID dossier.

The Registrant shall ensure that the chemical name is representative of the specific substance which is covered by this registration and that the information on the name and is consistent throughout the dossier.

ECHA acknowledges the Registrant's comments regarding the current chemical name "dodecane-12-lactam, manufacturing of, by-products from, distillation residues" to be included in the IUPAC name field.

The information to be provided by the Registrant will only be assessed on the basis of an updated dossier.
(ii) Furthermore, ECHA notes that the composition of the registered substance reported in section 1.2 of the IUCLID dossier and as addressed above in Section III.A.1, indicates that it contains not only by-products from the manufacturing of dodecane-12-lactam (12-aminododecanoic acid and azacyclotridecan-2-one, homopolymer), as would be expected from the EC name, but also dodecane-12-lactam itself, that may be present as the major constituent. The significant variation of the latter constituent from [redacted]% up to [redacted]%, cannot be justified by variations that are inherent to the manufacturing process due to lack of details in the process description. A high variability in composition may indicate that different manufacturing processes may have been applied, which may imply generation of multiple compositional grades of the same substance or multiple substances. While in some instances it may be possible for a constituent to have a broad concentration range as an inherent result of the manufacturing process of the substance, the dossier itself does not contain sufficient information about the manufacturing process to conclude whether these variations are related to the composition of the same substance. A detailed description of the manufacturing process, including the chemical identity of the source and information on the most relevant steps and parameters of the manufacturing process, is therefore required.

Accordingly, pursuant to Article 41(1) and (3) of the REACH Regulation, the Registrant is requested to provide a more detailed information on the process used for the manufacturing of the registered substance. The manufacturing process description shall include:

- The identity and composition of the starting materials or reactants, as well as ratio of these reactants;
- Relevant process parameters, for example temperature and pressure;
- The distillation parameters – pressure and temperature range (boiling point range) shall be specified (if distillation was applied), information on relevant steps taken during the manufacturing process, including the purification and isolation steps of lactam 12 leading to the registered substance.

The Registrant shall ensure that the information is consistent throughout the dossier. The information shall be sufficient to account for the variability in the composition of the substance (as noted in Section III.A.1. above).

If the substance covered by the registration is manufactured according to different manufacturing processes, including the use of different sources, steps and/or processing parameters, then the detailed description of the manufacturing process required hereinabove shall be reported separately for each manufacturing process. A manufacturing process may be considered different when the relevant processing steps and/or processing parameters are different.

The Registrant shall note that substances manufactured according to different manufacturing processes may indicate multiple substances and consequently the requirement for multiple registrations.

Regarding how to report the chemical name and description of the UVCB substance, this information shall be included in the in the "IUPAC name" and Description field in IUCLID section 1.1, respectively. Further technical details on how to report the chemical name and manufacturing process description of UVCB substances in IUCLID are available in 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.

ECHA acknowledges and agrees with the Registrant's comments to the draft decision to provide further details on the manufacturing process description. ECHA notes that the Registrant provided a manufacturing process description in the report attached (Registrant's comments to the draft decision) and he agrees that the dossier will also be updated by including this new information. However, the provided manufacturing description lacks certain information:

- no explanation on the variability in the composition (e.g. [redacted] % w/w for dodecane-12-lactam);
- use of different organic solvent for purification ([redacted]) without further specifying what is exactly used and how it may affect the composition of the registered substance.

The above missing information need to be further clarified and included in the manufacturing description of the registered substance together with any other relevant parameter.

However, the information to be provided by the Registrant will only be assessed on the basis of an updated dossier.

IV. Information on right to appeal

This decision can be appealed to the Board of Appeal of ECHA within three months of its notification. An appeal, together with the grounds thereof, shall be submitted to ECHA in writing. An appeal has suspensive effect and is subject to a fee. Further details are described under http://echa.europa.eu/regulations/appeals.

Authorised[1] by Guilhem de Seze, Head of Unit, Evaluation, E1.

[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.