EUROPEAN CHEMICALS AGENCY

Decision number: CCH-D-2114292247-43-01/F Helsinki, 27 January 2015

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

For 3,6,9,12-tetraazatetradecamethylenediamine, EC No 223-775-9 (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 3,6,9,12-tetraazatetradecamethylenediamine, **EC No 223-775-9 (CAS No NS)**, 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 30 October 2014, 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 28 October 2013.

On 09 April 2014 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 12 May 2014 ECHA received comments from the Registrant on the draft decision.

On 08 August 2014 the Registrant updated his registration dossier with the submission number [redacted].

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

On 30 October 2014 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 identifier of the substance: provision of a detailed description of the manufacturing process (Annex VI, 2.1.)
2) Composition of the substance (Annex VI, 2.3.)
3) Description of the analytical methods (Annex VI, 2.3.7.)

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 **4 May 2015**.

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.

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 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.

The naming of UVCB substances 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.

Following receipt of the draft decision, the registrant updated the initial registration dossier (submission number [redacted]) with submission number [redacted] (the updated dossier). In the updated registration dossier the Registrant provided a suitable chemical name. However, the description of the manufacturing process already present in the initial dossier was not updated.

ECHA observes that the description present in the dossier is not sufficiently detailed to understand how the registered substance is manufactured and how the compositions covered by this registration are obtained. The Registrant stated in the description that the different products and side products of the reaction are separated in different sections of the plant; however it is not clear how the fraction containing the constituents of the registered substance, as reported in sections 1.2/1.4 of the registration dossier, is obtained during the separation process.

Accordingly, the Registrant is requested to submit more detailed information on the description of the process used for the manufacturing of the registered substance. The description shall specify the method used and respective parameters applied (e.g. distillation temperature) to separate the fraction containing the constituents of the substance as reported in sections 1.2/1.4 of the registration dossier. It shall be clearly indicated which step of the manufacturing process leads to extraction/separation of the fraction containing the constituents of the registered substance as reported in sections 1.2/1.4 of the registration dossier.

If the substance covered by the registration is manufactured according to different manufacturing processes, the detailed description of the manufacturing process required for the identification of a UVCB substance shall be reported separately for each manufacturing process. A manufacturing process may be considered different when the sources, the processing steps and/or processing parameters are different. The Registrant shall note that substances manufactured according to significantly different manufacturing processes may result in multiple substances and consequently the requirement for multiple registrations.

Regarding how to report the description of the manufacturing process of a UVCB substance, the information shall be included in the Description field in IUCLID section 1.1.
The Registrant shall ensure that the information is consistent throughout the dossier.
ECHA highlights that compositions for which a manufacturing process description is not provided may not be considered being covered by the registration.

2) Composition of the substance (Annex VI, 2.3)

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.

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, in line with chapter 4.3 of the Guidance referred to as "the Guidance" thereinafter), the compositional information provided in IUCLID section 1.2 and in the analytical report in section 1.4 describes a UVCB substance.

Following chapter 4.3 of the Guidance, the Registrant should note that for reporting the composition of 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 constituents relevant for the classification and/or PBT assessment of the registered substance shall be identified and reported individually; and
- Unknown constituents shall, whenever possible, be identified by a generic description of their chemical nature.

For each constituent and group of constituents, the typical, minimum and maximum concentration levels shall be specified.
ECHA notes that the information provided in IUCLID section 1.2 and 1.4 is contradictory. More specifically, in section 1.2 the compositional information describes a substance composed by two well defined constituents (Pentaethylenehexamine (PEHA) and Tetraethylenepentamine (TEPA)) and a constituent with variable composition (HEPA). In section 1.4 the analytical report describes a substance composed by three generic groups of constituents with variable composition (branched, linear and cyclic isomers of PEHA, TEPA and HEHA).

ECHA notes that the well-defined constituents pentaethylenehexamine (PEHA) and tetraethylenepentamine (TEPA) shall not be used to describe generic groups of constituents (such as linear, branched and cyclic isomers of pentaethylenehexamine (PEHA) and linear, branched and cyclic isomers of tetraethylenepentamine (TEPA)). Similarly, if the third reported generic constituent refers to hexaethyleneheptamine linear, branched and cyclic isomers, the generic reference to polyethylenepolyamines (EC number 268-626-9, CAS number 68131-18-5) is overly broad (refers to an undefined number of ethylene and amine parts in the substance, unlike hexaethyleneheptamine) and thus does not allow ECHA to establish the composition of the registered substance.

The Registrant stated in the official comments he provided that "*we cannot describe the composition of the HEPA (...) in any more detail.*" ECHA understands that HEPA is a UVCB constituent and that part of its composition might be unknown, but the same level of detail is expected for HEPA on the composition as for the other UVCB groups of constituents present in the substance (isomers of TEPA and PEHA).

Therefore, the Registrant is requested to report individually all different groups of isomers of pentaethylenehexamine (PEHA) and tetraethylenepentamine (TEPA), i.e.:

- linear isomers of pentaethylenehexamine (PEHA)
- branched isomers of pentaethylenehexamine (PEHA)
- cyclic isomers of pentaethylenehexamine (PEHA)
- linear isomers of tetraethylenepentamine (TEPA)
- branched isomers of tetraethylenepentamine (TEPA)
- cyclic isomers of tetraethylenepentamine (TEPA).

Any constituent present at concentration ≥ 10 % shall be identified and reported individually.

If the third reported generic constituent refers to hexaethyleneheptamine linear, branched and cyclic isomers, it shall be sub-divided similarly. The information provided shall be consistent throughout the dossier.

Regarding how to report the composition of the registered substance in IUCLID, the following applies: The Registrant shall report the composition 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, 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: How to report the substance identity in IUCLID 5 for registration under REACH (version: 1.0, June 2010) on the ECHA website.
If the Registrant covers different grades (i.e. compositions resulting from a specific manufacturing process) 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. Corresponding analytical data to enable the identity and composition of each grade listed in 1.2 to be verified shall be included in Section 1.4. Information on how to report several compositions in IUCLID is specified in paragraph 2.3, Q&A 8 of the "Data Submission Manual – Part 18: How to report the substance identity in IUCLID 5 for registration under REACH".

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. The Registrant should also note that multiple compositions may indicate multiple substances and consequently the requirement for multiple registrations.

3) Description of the analytical methods (Annex VI, 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 notes that the Registrant has not provided detailed description of the analytical method used for the quantification of the different constituents present in the composition of the registered substance, which is required according to Annex VI, Section 2.3.7.

Although a gas-chromatographic (GC) analysis has been provided in the registration dossier to quantify the concentrations of the constituents, the data submitted is not sufficient to verify the composition of the sample to the level of detail as requested in section III 2. Therefore, the composition of the registered substance (including identification of the constituents present at ≥ 10% and of linear, branched and cyclic isomers) cannot be confirmed.

The Registrant stated in the formal comments that the group of constituents HEPA is a UVCB *substance "...for which no analytical methods exist to accurately determine the composition."* ECHA understands that HEPA is a UVCB constituent and that no analytical method can accurately derive its composition, however, as for the other UVCB groups of constituents present in the substance (isomers of TEPA and PEHA), it is expected that generic information on the type of isomers (linear, branched and cyclic isomers) can be obtained by existing analytical methods .

Accordingly, the Registrant is requested to submit the information derived from the registered substance subject to the present decision: correct description of the method used to quantify the registered substance (chromatographic analysis or an alternative method). For chromatographic methods a chromatogram, peak list containing the retention times, individual peaks area % and peak allocation shall be submitted. ECHA underlines that the compositional information reported in IUCLID Section 1.2. shall be consistent with information provided in IUCLID Section 1.4. Where different compositions of the substance are reported in Section 1.2, sufficient data that will enable each composition to be verfied shall be included.

As for the reporting of the data in the registration dossier, the information should be attached in IUCLID section 1.4. The information shall be sufficient for the methods to be reproduced and shall therefore include complete details of the experimental protocol followed, the calculation made and the 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.

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