ECHA
EUROPEAN CHEMICALS AGENCY

Decision number: CCH-D-0000004261-84-03/F Helsinki, 4 August 2014

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

For Propylidynetrimethanol, ethoxylated, esters with acrylic acid, CAS No 28961-43-5 (EC No 500-066-5), 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 Propylidynetrimethanol, ethoxylated, esters with acrylic acid, CAS No 28961-43-5 (EC No 500-066-5), 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 06 March 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 June 2013.

On 06 November 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.

On 05 December 2013, ECHA received comments from the Registrant. ECHA considered the comments received and reflected its views in the statement of reasons (Section III). However, these comments did not affect the outcome of the draft decision (Section II).

On 06 March 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 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:

A. Information in the technical dossier related to the identity of the substance

1. Name or other identifier of the substance (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 **11 November 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.

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 identifier of the substance (Annex VI, 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 an Unknown or Variable composition, Complex reaction products or Biological materials (UVCB). Information required to be provided 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: 1.2, March 2012) - referred to as "the Guidance" thereinafter. ECHA observes that the Registrant did not provide any information on manufacturing process description.

The information currently provided by the Registrant on the composition of the registered substance indicates that this substance consists of a complex set of constituents with different levels and arrangements of ethoxylation as well as different degrees of

esterification. As a result, the registered substance cannot be fully identified and named on the basis of its chemical composition alone without further detail on the manufacturing process, as explained in chapter 4.3 of the Guidance. The manufacturing process description, which is currently missing from the dossier, shall consist of the chemical identity of the starting materials actually used and information on the most relevant steps of the manufacturing process and the associated process parameters, as also specified in chapter 4.3 of the Guidance. For UVCB substances such as the registered substance, this information accordingly functions as a baseline for the following:

- Chemical name and ratio of all starting materials used;
- Description of the manufacturing steps in the order they occur. Each process step, including any relevant preliminary steps as well as the steps involving chemical transformations, isolation and purification shall be specified.
- For each step, all relevant process parameters that determine the composition, including the parameters used to control the degree of oligomerisation and esterification shall be clearly defined.

Within its comments to the draft decision, in accordance with Article 50(1) of the REACH Regulation, the Registrant argued that the manufacturing process of the substance is considered confidential information and the request to provide this information should be made to the members of the joint submission and then answered separately by these. ECHA agrees that, pursuant to Article 11(1), third indent, of the REACH Regulation, the manufacturing process description is an individual information requirement for every registration dossier. This means that, in a joint submission, each registrant, including the lead, should include individual information on the manufacturing process in its own dossier. Therefore, since the subject of this compliance check decision is specifically the lead's registration dossier (and not those of the members), the issue of confidentiality does not arise and the Registrant shall provide a description of its manufacturing process.

Therefore, pursuant to Article 41(1)(a) and (3) of the REACH Regulation, the Registrant is requested to submit a description of the manufacturing process as specifically explained above and derived from the substance subject to the present decision.

Regarding how to report the manufacturing process, the chemical name and manufacturing process description shall be specified in the "IUPAC name" and "Description" fields in IUCLID section 1.1, respectively.

2. -Composition of the substance (Annex VI, 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.

ECHA notes that the registration does not contain sufficient information for establishing the composition of the specific registered substance and therefore its identity, as required under Annex VI, Section 2.3 of the REACH Regulation. More specifically, the Registrant reported in the dossier the constituents having the same degree of esterification and specified their overall upper, lower and typical concentration values. Within both the groups of ethoxylated propylidenetrimethanol constituents that are either fully acrylated and not acrylated, the

Registrant furthermore specified the approximate quantitative contribution of the constituents presenting the same number of ethoxy units. However, ECHA notes that the registrant did not report individually each constituent required to be specified in the dossier with information on the upper and lower concentration levels. The current information indicates for instance that the approximate concentration of the ethoxylated propylidenetrimethanol constituent that is fully acrylated and has one ethoxy unit is at least [redacted]%. However, the Registrant did not report the concentration range of this predominant constituent. ECHA also notes that the report from the chromatographic analysis indicates the presence of other predominant constituents which have not been reported individually. Furthermore, the reported composition does not include any information on the variability in the concentration of constituents presenting the same level of ethoxylation.
ECHA therefore concludes that the composition has not been reported to the required level of detail.

According to chapter 4.3 of the Guidance, the Registrant shall 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
- Unknown constituents or groups of constituents shall be identified as far as possible by a generic description of their chemical nature. For substances such as the registered substance, the reporting of unknown oligomeric constituents according to their degree of polymerisation and degree of esterification is suitable necessary as a baseline.

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

Within its comments to the draft decision, in accordance with Article 50(1) of the REACH Regulation, the Registrant proposed to update the substance identity according to the request including all substances above 1% in the Lead dossier to cover all registrants. However, pursuant to Article 11 (1), third indent, of the REACH Regulation, the composition of the substance is an individual information requirement for every registration dossier. This means that, in a joint submission, each registrant should include individual information on the composition of the substance in its own dossier. Therefore, since the subject of this compliance check decision is specifically the lead's registration dossier (and not those of the members) the Registrant shall provide sufficient information for establishing the composition of its registered substance and therefore its identity.

Therefore, pursuant to Article 41(1)(a) and (3) of the REACH Regulation, the Registrant is requested to submit information on the composition of the registered substance to the required level of detail as specifically explained in the present decision. Every constituent with a concentration ≥ 10 % shall be identified and reported individually (all predominant constituents according to the chromatographic analysis must be reported individually). Also, the reported composition must include information on the variability in the concentration of constituents presenting the same level of ethoxylation.

The information shall be derived from the registered substance subject to the present decision. The Registrant shall provide any information which is suitable and necessary to

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

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, 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 – Part 18: How to report the substance identity in IUCLID 5 for registration under REACH (version: 2.0, July 2012) on the ECHA website.

3.- Description of the analytical methods (Annex VI, 2.3.7.)

"Description of the analytical methods" for the identification of the substance 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.

The Registrant did not provide any description of the analytical method used for the quantification of the constituents required to be reported in the dossier. ECHA notes that the Registrant provided a chromatogram and a peak table with retention times and area. However the report does not provide any information as to how the result from the chromatographic analysis relates to the composition of the substance. ECHA therefore concludes that the description of the analytical methods used for the quantification of the constituents are currently missing from the dossier.

Within its comments to the draft decision, in accordance with Article 50(1) of the REACH Regulation, the Registrant claimed that the analytical data is reported individually and the request to provide this information should be made to the members of the joint submission and then answered separately by these. ECHA agrees that, pursuant to Article 11 (1), third indent, of the REACH Regulation, the description of the analytical methods is an individual information requirement for every registration dossier. This means that, in a joint submission, each registrant, including the lead, should include individual information on the analytical methods in its own dossier. Therefore, since the subject of this compliance check decision is specifically the lead's registration dossier (and not those of the members) the Registrant shall provide description of the analytical methods used for the characterisation of its registered substance subject to this compliance check.

Therefore, pursuant to Article 41(1)(a) and (3) of the REACH Regulation, the Registrant is requested to submit a description of the analytical methods used for the quantification of the constituents and groups of constituents required to be reported in the composition of the registered substance. The information shall be derived from the registered substance subject to the present decision.

The description shall be sufficient for the methods to be reproduced and shall therefore include details of the experimental protocol 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 composition reported in the dossier is consistent with the analytical 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://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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