ECHA
EUROPEAN CHEMICALS AGENCY

Decision number: CCH-D-2114308285-54-01/F Helsinki, 28 October 2015

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

For Fatty acids, C18-unsatd., dimers, reaction products with polyethylenepolyamines, EC No 614-452-7 (CAS No 68410-23-1), 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 Fatty acids, C18-unsatd., dimers, reaction products with polyethylenepolyamines, EC No 614-452-7 (CAS No 68410-23-1), 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 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 12 March 2015.

On 05 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 10 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 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. Name or other identifier of the substance (Annex VI, 2.1.), as specified under section III.A.1 below;
2. Composition of the substance (Annex VI, 2.3.), as specified under section III.A.2 below;
3. Description of the analytical methods or bibliographical references (Annex VI, 2.3.7.), as specified under section III.A.3 below.

Taking into consideration the data currently available in the dossier, ECHA considers the following. Section III below specifies in detail all the information that ECHA considers appropriate in order to identify any substance of Unknown or Variable composition, Complex reaction products or Biological materials (UVCB). UVCB substances cannot be sufficiently identified by their chemical composition, because the number of constituents is relatively large; and/or the composition is, to a significant part, unknown; and/or the variability of composition is relatively large or poorly predictable. As a consequence, UVCB substances require other types of information for their identification, in addition to what is known about their chemical composition.

As a result, ECHA cannot be in a position, before receiving suitable information, to determine precisely the other types of information that is actually required to identify a specific UVCB substance. Only the Registrant of that UVCB substance knows the details of its identity. Based on this knowledge, he may consider that some of the information requested by ECHA is not suitable and necessary in order to identify the substance. Nevertheless, in that case it is the Registrant's exclusive responsibility 1) to ensure that ECHA is in a position to identify precisely the substance and 2) to justify the reasons for which some information requested may have been omitted.

Therefore, if the Registrant eventually decides to submit only part of the detailed information specified in Section III and if the submitted information does not enable ECHA to establish and verify the identity of the substance actually covered by the dossier, the registration will not be considered valid.

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 **4 February 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 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: (1) the chemical name and (2) a more detailed description of the manufacturing process, as indicated in section 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" hereinafter. According to the Guidance, the description of the manufacturing process shall include information on the chemical identity of the starting materials (see point (i), below) and information on the most relevant steps of the process (see point (ii), below). Any other identifier, including any CAS number (if available) and any EC number (if available and appropriate) for the substance shall also be reported.

(i). Identity of the starting materials

According to the chemical name assigned by the Registrant to the registered substance, this registration refers to a UVCB substance obtained from the following starting materials: a fatty acid dimer and polyamines.

a. Identity of the fatty acid dimer starting material

The Registrant specified the following information on the identity of the fatty acid dimer starting material used for the manufacturing of the registered substance:

- The chemical name assigned by the Registrant to the registered substance indicates that this starting material is "Fatty acids, C18-unsatd., dimers". Similarly, in sections 1.1 and 3.1 of the IUCLID dossier as well as in the analytical report attached in IUCLID section 1.4, the Registrant specified that the fatty acid dimer starting material used corresponds to a dimeric tall-oil fatty acid with CAS number [redacted]
- In the analytical report, the Registrant specified that this starting material consists of ≥[redacted]% dimers, ≤[redacted]% trimers and ≤[redacted]% monomers.

The Registrant shall however note that the EC number [redacted] used to identify this starting material is for a no-longer polymer. As indicated in the No-Longer Polymer (NLP) list (version 3, available on EU Bookshop website managed by the Publications Office of the European Union in Luxembourg at https://bookshop.europa.eu), "*Mixture of oligomers or isomer mixtures are generally listed in the no-longer polymer list with the name of the main component only when present in the mixture with 80% or more*". The "main

component" designates in this case constituents or group of constituents presenting the same level of oligomerisation (e.g. dimers). The starting material corresponding to the NLP entry for "[redacted]" should therefore contain ≥80% dimers. However, this concentration is not compatible with the information provided by the Registrant in the analytical report.

The Registrant is accordingly requested to clarify the identity of this starting material. For this purpose, the typical and upper concentration level in monomers, dimers and trimers for this starting material shall be indicated. The Registrant shall ensure that the chemical name used to designate this starting material is representative of its composition. ECHA considers that the identification of this substance as "[redacted]" is appropriate provided that it typically consists of ≥80% dimers. Otherwise, the substance should be identified by reflecting that the level of oligomerisation cannot be represented by referring to dimers only in the name of the starting material.

b. Identity of the polyamine starting material

The following information related to the identity of the polyamine starting material used for the manufacturing of the registered substance has been submitted by the Registrant:

- The chemical name assigned by the Registrant to the registered substance indicates that this starting material refers to "polyethylenepolyamines". Similarly, in the analytical report attached in IUCLID section 1.4, the Registrant identified the [redacted] starting material using the EC number [redacted], EC name "[redacted]-" and the CAS number [redacted].

- ECHA also notes that, in the same analytical report attached in IUCLID section 1.4, the Registrant reported the compositional profile of the starting material. According to this information, its composition can cover [redacted] (EC: [redacted], CAS RN: [redacted], with concentration range of [redacted]%), [redacted] (EC: [redacted], CAS RN: [redacted], with concentration range of [redacted]%) and unspecified polyethylenepolyamines (also referred to as "[redacted]" EC: [redacted], CAS RN: [redacted], with concentration range of [redacted]%). The Registrant shall note that the concentration values provided are not consistent: the sum of the concentration levels of these three groups of constituents exceeds the value [redacted]%.

- However, ECHA notes that, in sections 1.1 and 3.1 of the IUCLID dossier, the Registrant specified that the [redacted] used for the manufacturing corresponds to the substance [redacted] with EC number [redacted] and CAS number [redacted]. The Registrant shall note that these identifiers correspond to the specific mono-constituent substance [redacted]. ECHA stresses that such starting material would not be adequately and univocally identified by the chemical name [redacted] specified in the name of the registered substance.

- Finally, in the composition of the registered substance specified in section 1.2 of the IUCLID dossier, the Registrant reported the presence of [redacted]

Based on the above, ECHA concludes that the information submitted by the Registrant regarding the identity of the polyamine starting material used for the manufacturing refers to different substances:

[redacted]

The Registrant is accordingly requested to clarify the identity of the polyethylenepolyamine starting material used for the manufacturing of the registered substance by specifying consistently its identity throughout the dossier.

(ii). Description of the manufacturing steps

According to the description provided by the Registrant in section 1.1 of the Registration dossier, the process used for the manufacturing of the registered substance is a [redacted]. During the reaction, [redacted]

Section 3.1 of the IUCLID dossier also specifies process parameters used for the manufacturing. In particular, it is indicated that the [redacted]. The Registrant also indicated that "[redacted]".

The Registrant furthermore indicated, in the Description field of the first listed group of constituents of the registered substance in IULCID section 1.2, that the ratio between the fatty acids dimers and the polyethylenepolyamine is within the range of [redacted] and stated that the residual polyethylenepolyamine starting material in the manufactured substance does not exceed [redacted]%.

ECHA however considers that the description of the manufacturing steps reported in the dossier is not sufficiently detailed for the following reasons:

- The Registrant did not indicate if the process parameter used for the manufacturing of the substance (in this case the temperature) effectively promotes the formation of [redacted] constituents.
- The Registrant did not describe the steps applied to isolate the substance, including any eventual purification steps undertaken.

The Registrant is accordingly required to provide details of the manufacturing processing steps that are applied to the starting materials. The information submitted by the Registrant must at least include the following:

- A description of the manufacturing steps in the order they occur, including any preliminary step, the steps involving chemical transformation as well as the isolation and purification steps carried out for the synthesis.

- For each step, all relevant process parameters that affect the composition and therefore the identity of the substance must be provided. For the step involving chemical transformations, the Registrant must indicate if the selected process parameter (in this case the temperature) promotes the formation of [redacted].

ECHA recognises that the Registrant may cover different grades of the same substance in a registration based on different sources and/or different manufacturing processes. In these cases, the Registrant shall provide the required information on the source, manufacturing process and constituents of each grade. ECHA underlines that the reporting of a generic process description covering the manufacturing of different grades may prevent ECHA from concluding that the manufacturing of other substances is not covered by that description. In addition, ECHA highlights that grades for which a description would not be provided may eventually not be considered as being covered by the registration.

The Registrant shall also note that substances manufactured according to different manufacturing processes may indicate multiple substances and consequently the requirement for multiple registrations. In addition, for substances such as the registered substance (UVCB sub-type 2 according to chapter 4.3.1.2.4 of the Guidance), the identification is based on the starting materials for the reaction and the reaction process. Accordingly, the use of different starting materials (e.g. the use of different polyamines, different fatty acid dimers) would normally be expected to lead to the manufacturing of different substances. ECHA has set up a process enabling registrants to adapt their registration in such cases. Should the Registrant consider that his dossier actually concerns several substances, he is thus encouraged to contact ECHA for a possible adaptation of the registration.

As for the reporting of the information in IUCLID, the chemical name and the manufacturing process description for the registered substance shall be reported in the "Description" field of the reference substance in IUCLID section 1.1. Any CAS number specifically corresponding to the registered substance shall be reported under the "CAS information" header of the reference substance in IUCLID section 1.1.

The Registrant shall ensure that the chemical name and other identifiers reported in section 1.1 of the IUCLID dossier are representative of the UVCB substance as described by the manufacturing process. In particular, the naming of the starting materials used in the process and to be quoted in the name of the registered substance shall also follow the naming conventions specified in the. The Registrant shall note that the registration is currently linked to chemical identifiers (including the list number 614-452-7) referring to reaction products of fatty acids, C18-unsatd. dimers with polyethylenepolymines. Should the substance intended to be covered by this registration refer to a different substance, the Registrant can however not remove or modify at this stage identifiers such as the list number for technical reasons, the registration being linked to that number in REACH-IT. To ensure unambiguous identification of the registered substance, the Registrant shall however indicate, in the "Remarks" field of the reference substance in IUCLID section 1.1, the

following: "The list number 614-452-7 currently assigned does not specifically correspond to the registered substance. This identifier cannot be modified or deleted at this stage in the present registration update for technical reasons". The Registrant shall also specify, in the same "Remarks" field, any available and appropriate EC number for the substance. Registrant shall note that ECHA has established a process, subject to certain conditions, enabling registrants to adapt an existing registration, while maintaining the regulatory rights already conferred to the substance concerned.

The Registrant shall ensure that the correct 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 agreed to clarify the identity of the starting materials, to provide more details of the manufacturing steps and to delete the CAS entry from the CAS information for the registered substance. Also, the Registrant agreed to specify the current CAS entry as "related CAS information" for the registered substance. The information to be provided by the Registrant will only be assessed on the basis of an updated dossier.

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

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, the Registrant shall 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 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.

For each constituent or group of constituent, the typical, minimum and maximum concentrations shall be specified.

ECHA notes that the Registrant reported the presence of 2 groups of constituents in the composition of the registered substance:

[redacted]

[redacted]

The constituents resulting from the chemical transformations are, thus, essentially reported under one main generic group (the first listed group of constituents). For this group, the Registrant provided a very generic structural formula describing the different types of structures that may be obtained as a result of the reactions. These structures include "[redacted]" and [redacted] that are formed in a subsequent reaction. However, the general structure for [redacted] is not appropriate as it does not display an amide functionality but instead an amine chemically bound to a carboxylate). In addition, no further information was specified on the identity and concentration level of the "[redacted]" constituents actually present in the substance. ECHA underlines that, as already mentioned in section III.A.1. (ii) hereinabove, the Registrant explained that the manufacturing process conditions determine the extent to which the transformations will lead to the formation of [redacted]. The relative concentration levels in [redacted] would thus be expected to be controlled and therefore known.

ECHA therefore considers that the composition currently provided does not allow ECHA to identify sufficiently precisely the composition of the substance.

The Registrant is accordingly requested to specify the identity and typical, upper and lower concentration level of the constituents and groups of constituents required to be reported. Concerning the reporting of the unknown constituents, the Registrant shall note that, for substances such as the registered substance, a subdivision of these unknown constituents according to the number of '[redacted] building blocks is necessary for this purpose as a baseline. The relative content in [redacted] should also be specified.

ECHA notes that in the event the Registrant covers different grades of the registered substance in the present registration dossier, he shall report separately the compositional information of each grade. This means that if the substance covered by the present registration has two (or more) different compositions, then these must be presented separately. 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 each 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, 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 – 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.

The Registrant shall ensure that the reported composition is consistent with the description of the process used for the manufacturing of the registered substance, including the identity of the starting materials used. The Registrant shall also ensure that the composition is verifiable and therefore supported by a description of the analytical methods for the quantification of the constituents required to be reported, as required under Annex VI, section 2.3.7.

In the comments to the draft decision, the Registrant agreed to clarify the substance composition and to provide to ECHA structural representation of the substance's constituents. The Registrant also explained that, due to the nature and complexity of the reaction mixture, the quantification will be based on estimation of the analytical results (HPLC and GPC) since separation of the different adducts is not possible with available techniques as confirmed by LC-MS. The Registrant also indicated his intention to describe the constituents according to their molecular weight distribution providing semi-quantitative information.

Irrespective of whether the newly provided information may be sufficient to meet the information requirement addressed in the decision, ECHA can already point out the following: the information in the comments would seem to be in line with the expectations in the draft decision. The Registrant shall ensure that any eventual analytical limitations in establishing the composition of the registered substance is reported transparently in the updated registration dossier. The scientific rationale behind such limitations shall be attached in section 1.4 of the IUCLID dossier. The information to be provided by the Registrant will only be assessed on the basis of an updated dossier.

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

ECHA observes that the Registrant did not provide sufficient and appropriate description of the analytical methods used for the identification and quantification of the constituents and groups of constituents required to be reported in the composition of the registered substance, as requested according to Annex VI section 2.3.7.

The Registrant provided a description of High Performance Liquid Chromatography (HPLC-ELSD allowing the determination of the overall content in unreacted [redacted] as well as the content in adducts with "[redacted]". This information does however not provide any indication of the identity of the actual adducts present in the analysed sample. The Registrant also submitted a description of a Gel Permeation Chromatographic (GPC) analysis. The results from the analysis do nevertheless not allow the resolution of the types of chemical structures present in the composition. The Registrant furthermore included a description of a LC-MS (ESI) analysis. The Registrant however indicated that "*LC-MS could not be used to identify major adducts in Euretek 540*".

ECHA therefore concludes that the Registrant did not provide sufficient description of the analytical methods used for the identification and quantification of the constituents and groups of constituents required to be reported in the composition of the registered substance.

The Registrant is accordingly requested to provide a description of the analytical methods used for the identification and quantification of the constituents and groups of constituents required to be reported in the composition of the registered substance. 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. The

Registrant should note that ECHA will consider any method that is suitable to verify the composition, including any indirect method involving chemical derivatisation of the substance or any analysis involving also considerations on the starting materials and the manufacturing process.

As for the reporting of the data in the registration dossier, the information shall 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 agreed to review section 1.2 of the composition and to align it with the analytical data in section 1.4. Also, the method and the interpretation part will be expanded to include typical structures, calculations and results to help the reviewer determine how such results have been obtained. As for the description of the reactants, this has been provided in the first part of the analytical report. 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

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 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.