Helsinki, 10 August 2018

Addressee: [redacted]

Decision number: CCH-D-2114439545-44-01/F
Substance name: Fatty acids, tall-oil, reaction products with diethylenetriamine, maleic anhydride, tetraethylenepentamine and triethylenetetramine
EC number: 273-601-0
CAS number: 68990-47-6
Registration number: [redacted]
Submission number: [redacted]
Submission date: 08/02/2018
Registered tonnage band: [redacted]

DECISION ON A COMPLIANCE CHECK

Based on Article 41 of Regulation (EC) No 1907/2006 (the REACH Regulation), ECHA requests you to submit information on:

1. **Name or other identifier of the substance (Annex VI, Section 2.1.);**
   - **Manufacturing process**
2. **Composition of the substance (Annex VI, Section 2.3.);**
   - **Identity of the main constituent(s)**
3. **Description of the analytical methods (Annex VI, Section 2.3.7.);**
   - **Identification and quantification of the constituents**
   - **Peak table**

You have to submit the requested information in an updated registration dossier by **19 November 2018**.

The reasons of this decision are set out in Appendix 1. The procedural history is described in Appendix 2 and advice and further observations are provided in Appendix 3.

The scope of this compliance check decision is limited to the standard information requirements of Annex VI, Section 2 to the REACH Regulation.

EUROPEAN CHEMICALS AGENCY

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, has to 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 Jos Mossink, Head of Unit, Substance Identification and Data Sharing, C2.

[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.

Appendix 1: Reasons

In accordance with Article 10(a)(ii) of the REACH Regulation, the technical dossier must contain information on the identity of the substance as specified in Annex VI, Section 2 to the REACH Regulation. In accordance with Annex VI, Section 2 the information provided has to 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.

According to chapter 4.3 of the Guidance for identification and naming of substances under REACH and CLP (Version: 2.1, May 2017) - referred to as "the SID Guidance" thereinafter, the naming of Unknown or Variable composition, Complex reaction products or Biological materials (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.

The manufacturing process description typically consists of the following:

- identity and ratio of starting materials;
- a description of the relevant manufacturing steps in the order they occur (including information on the reaction steps/mechanisms);
- the relevant plant operating parameters applied to control the composition (e.g. temperatures/pressures; solvents; catalysis types...);
- extraction/isolation steps (if applicable);
- clean-up/purification steps (if applicable)

You have identified the registered substance as UVCB substance and you have provided a description of the manufacturing process in IUCLID section 1.2. According to the provided manufacturing process description, "[redacted]" is used as starting material with the following composition: [redacted]

Based on the analytical data, it is not possible to exclude the presence of cyclic and/or branched [redacted], such as [redacted] and [redacted], which are not separated due to their similar boiling point, and are therefore available on the market as a mixture of isomers. Therefore, even if the starting material has been identified with EC and CAS entries relative to linear structures, there is a likelihood that the starting material contains also cyclic and/or branched isomers.

Consequently, you are requested to clarify the identity of the starting material for what concerns the possible presence of branched and/or cyclic isomers, and their amount in the starting material.

This information shall be added to the manufacturing process description in the "Description" field in IUCLID 6 section 1.2.

In the comments to the draft decision according to Article 50(1) you have agreed with the requests in the draft decision. You provided in the comments further information on the starting material amines and a new analytical data report, attachment "[redacted]". ECHA notes that the information provided in the comments on the starting material, together with the new analytical report would appear to be in line with the request for "Name or other identifier of the substance".

Nevertheless, ECHA notes that such information, including the adequacy of the reported information, will be examined by ECHA only after the deadline set in the adopted decision has passed and all the substance identity information requested in this decision has been submitted in an updated registration dossier.

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

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 SID Guidance for UVCB substances 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.
- For each constituent and group of constituents, the typical, minimum and maximum concentration levels shall be specified.

In the registration dossier you have reported among the constituents one main entry identified with the same identifiers of the registered substance i.e. [redacted], with concentration range [redacted] %.

In addition, in the file "[redacted]" attached in IUCLID section 1.4 you provided a reaction scheme with the expected groups of constituents obtained by the manufacturing of the substance.

Moreover, the chromatographic analysis included in section 1.4 (attachment "[redacted]") reports more specific groups of constituents based on the amount of fatty acid units and the presence of maleic anhydride.

Therefore it appears possible to further subdivide the entry "[redacted]" into more defined groups of contituents, based for example on the number of fatty acids and the presence of maleic anhydride in the structures.

In addition, there is a concern linked to the large variability of the starting material "[redacted]", which could lead to different compositions covered within

the same registration. For example, when the starting material consists of [redacted], and consequently [redacted], the reaction products would be mainly derived from [redacted] as this is practically the only amine used as starting material. Whereas when the starting material amines would consist of [redacted], and consequently [redacted], the products would include broader distribution of different constituents (both in identity and in concentration ranges). The variation in the composition is not reflected the compositional information reported, because as explained above, this is a single entry identified as the registered substance.

Therefore, you are requested to subdivide the single entry "[redacted]" into groups of constituents, for example based on the amount of fatty acid units. In addition, the composition will need to take into account the variability deriving from the different ratios of [redacted] in the starting material, i.e. reporting different composition blocks when different ratios of starting materials are used. You shall also note that substances manufactured according to different manufacturing processes may indicate multiple substances and consequently the requirement for multiple registrations.

You 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. You shall also ensure that the composition is verifiable and therefore supported by a description of the analytical methods for the identification and quantification of the constituents required to be reported, as required under Annex VI, Section 2.3.7. If this is not possible only on the basis of analysing the substance due to the complexity of the substance, additional compositional information can be provided based on the composition of the starting materials and the description of the manufacturing process.

Regarding the composition, all constituents/groups of constituents are to be listed under "constituents" as the terms "main constituents" and "impurities" are not regarded as relevant for UVCB substances.

For the constituents/groups of 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 section 1.2 of IUCLID.

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 section 1.2 of IUCLID.

Further technical details on how to report the composition of UVCB substances in IUCLID are available in the Manual "How to prepare registration and PPORD dossiers" on the ECHA website.

In the comments to the draft decision according to Article 50(1) you have agreed with the requests in the draft decision. You provided in the comments further information on the

starting material amines and a new analytical data report, attachment "[redacted]".

ECHA considers that the subdividision of the composition in the registration dossier into the groups of constituents presented in the new analytical report (clusters) would appear to be in line with the request for "Composition of the substance".

Nevertheless, ECHA notes that such information, including the adequacy of the reported information, will be examined by ECHA only after the deadline set in the adopted decision has passed and all the substance identity information requested in this decision has been submitted in an updated registration dossier. It is furthermore noted by ECHA that for groups of constituents, 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, are to be reported in the appropriate fields in section 1.2 of IUCLID. In addition, the concentration ranges need to be in line with the substance as manufactured.

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

Among the analytical data attached in section 1.4, you have provided the high performance liquid chromatogram (HPLC), file named "[redacted]"
In this file you have reported a table with the list of groups of constituents, based on the fatty acid units, the presence of maleic acid (derived from the addition of maleic anhydride), and the type of amine present in the structures.

However the following is observed:

- The peak table of the [redacted] analysis does not include the concentrations for each of the groups of constituents identified;
- [redacted] is part of the substance name and also present in the description of the manufacturing process, however the [redacted] results do not report any constituent/group of constituent obtained from it.

Therefore, ECHA considers that the information obtained by the analytical data is not sufficient to confirm the identity and the composition of the registered substance and therefore to fulfil the information requirement.
You are requested to provide the description of the analytical methods and the corresponding results used for the identification and quantification of the composition that will need to be reported as described under point 2 of this present decision.

In particular the peak table shall include the area%, that is used to derive the concentration of the groups of constituents. In addition, the presence of [redacted] in the composition of the substance needs to be supported by the relevant analytical data.

As for the reporting in the registration dossier, the analytical data requested should be included in IUCLID section 1.4.
You need to ensure that the information given in the different sections of the dossier is consistent with each other.

In the comments to the draft decision according to Article 50(1) you have agreed with the requests in the draft decision. You provided in the comments further information on the starting material amines and a new analytical data report, attachment "[redacted]". The new analytical report includes the description of the methods used to determine the identity and composition of the substance, together with a peak table including the area percentage of each group of constituents (clusters). In addition, the presence of [redacted] has also been supported with the results.

ECHA considers that the information in the new analytical report in addition to the information in the comments would appear to be in line with the requests under point 3 (Description of the analytical methods).

Nevertheless, ECHA notes that such information, including the adequacy of the information, will be examined by ECHA only after the deadline set in the adopted decision has passed and all the substance identity information requested in this decision has been submitted in an updated registration dossier.

Appendix 2: Procedural history

For the purpose of the decision-making, this decision does not take into account any updates of your registration after the date when the draft decision was notified to you under Article 50(1) of the REACH Regulation.

An informal call with you was held on 13 December 2016, giving you the opportunity to revise substance identity issues. During the call you agreed to update your dossier addressing substance identity issues by 31 March 2017. The dossier was updated on the 8 February 2018, however the substance identiy issues were not fully addressed.

The compliance check was initiated on 1 March 2017.

The decision making followed the procedure of Articles 50 and 51 of the REACH Regulation, as described below:

ECHA notified you of the draft decision and invited you to provide comments.

In your comments you agreed to the draft decision. ECHA took your comments into account and did not amend the request(s).

ECHA notified the draft decision to the competent authorities of the Member States for proposals for amendment.

As no amendments were proposed, ECHA took the decision according to Article 51(3) of the REACH Regulation.

Appendix 3: Further information, observations and technical guidance

1. This compliance check decision does not prevent ECHA from initiating further compliance checks on the present registration at a later stage.

2. Failure to comply with the requests in this decision, or to otherwise fulfil the information requirements with a valid and documented adaptation, will result in a notification to the enforcement authorities of your Member State.