~~Confidential~~

Helsinki, 30 July 2020

Addressee: [redacted]

Decision number: CCH-D-2114509894-40-01/F
Substance name: Cashew (Anacardium occidentale) nutshell oil, decarboxylated at high temperature (the 'Substance')
EC number: 232-355-4
CAS number: NS
Registration number: [redacted]
Submission number subject to follow-up evaluation: [redacted]
Submission date subject to follow-up evaluation: 1 April 2019

DECISION TAKEN UNDER ARTICLE 42(1) OF THE REACH REGULATION

By decision CCH-D-2114439571-49-01/F of 10 August 2018 ('the original decision') ECHA requested you to submit information by 19 November 2018 in an update of your registration dossier.

Based on Article 42(1) of Regulation (EC) No 1907/2006 (the 'REACH Regulation'), ECHA examined the information you submitted with the registration update specified in the header above, and concludes that

Your registration still does not comply with the following information requirement:

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

- **Name(s) in the IUPAC nomenclature or other international chemical name(s)**
- **manufacturing process description**

You are therefore still required to provide this information requested in the original decision.

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

The respective Member State competent authority (MSCA) and National enforcement authority (NEA) will be informed of this decision.[1] They may consider enforcement actions to secure the implementation of the original decision and exercise the powers reserved to them under Article 126 of Regulation No 1907/2006 (penalties for non-compliance) for the period during which the registration dossier was not compliant[2].

[1] Only the final decision will be sent to the National enforcement authority so they can consider enforcement actions.
[2] See paragraphs 61 and 114 of the judgment of 8 May of the General Court of the European Court of Justice in Case T-283/15 Esso Raffinage v. ECHA

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.

Approved[3] under the authority of Christel Schilliger-Musset, Director of Hazard Assessment

[3] 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

Under Article 10(a)(ii) of REACH, the technical dossier must contain information on the identity of the substance as specified in Annex VI, Section 2 to REACH. Under Annex VI, Section 2, the information provided has to be sufficient to enable the identification of the Substance.

Name or other identifier (Annex VI, Section 2.1.) of the Substance;

- **Name(s) in the IUPAC nomenclature or other international chemical name(s)**
- **manufacturing process description**

According to Annex VI, Section 2.1 of the REACH Regulation, the registration dossier must contain the name or other identifier of the Substance.

The naming of Unknown or Variable composition, Complex reaction products or Biological materials ('UVCB') substances must consist of two parts that must be representative for the substance: the chemical name and the more detailed description of the manufacturing process (Annex VI, Section 2.1; Guidance for identification and naming of substances under REACH (Version: 2.1, May 2017)- referred to as 'the Guidance').

In the compliance check decision, you were requested:

- To revise the chemical name assigned to the registered UVCB substance. The name shall describe the biological source and the relevant processing steps carried out for its manufacturing.
- To provide a description of the manufacturing process including the information on extraction and decarboxylation steps, as well as information on isolation and purification steps.

In the updated registration dossier subject to follow-up evaluation, you have provided the name "Cashew (Anacardium occidentale) nutshell oil, decarboxylated at high temperature" for the Substance.

The manufacturing process specified in section 1.2 of the IUCLID dossier describes a decarboxylation step by means of heating, and no further processing/isolation is included in the manufacturing process description provided.

You identified the registered substance as a UVCB. The provided name and manufacturing process describe the biological source and a process comprising a decarboxylation step. They do not describe any further [redacted] step for manufacturing the Substance.

The composition reported in section 1.2 of the IUCLID dossier includes various constituents of the "cardanol" type:

[redacted]

These are reported at typical cumulative concentrations corresponding to [redacted] (w/w). The reported composition [redacted].

The provided composition with [redacted] and [redacted] indicates, however, a refining step, such as the [redacted] step, for the following reasons:

- The decarboxylation step, by means of heating the substance, results in the formation of structures consisting of a [redacted]. Such structures are commonly named as [redacted] Heating the substance typically leads also to the formation of [redacted] in the composition.
- A common further processing step following the [redacted] is the distillation at reduced pressure. Such processing step is carried out for obtaining a composition having high concentration levels (ca 80%) of the above mentioned type of constituents [redacted] and having low concentration levels of [redacted] formed during the heating step.

Consequently, the composition provided is not consistent with the name and the manufacturing process description provided in the registration dossier and the provided name and manufacturing process are not representative for the Substance.

Therefore, you must:

- Clarify any further processing steps following the decarboxylation step in the manufacturing of the Substance.
- Confirm the name of Substance taking into account possible refinement steps.

  If the Substance is obtained by means of a decarboxylation and subsequent distillation step, it would be appropriately named as follows:

  "Cashew (Anacardium occidentale) Nutshell Extract, Decarboxylated, Distilled"

As for the reporting of the information in IUCLID:

- The chemical name should be specified in the "IUPAC name" field, in IUCLID section 1.1.
- The manufacturing process description should be reported in the "Description of composition" field, in section 1.2 of the IUCLID dossier.

Appendix 2: Procedural history

In accordance with Article 42(1) of the REACH Regulation, the Agency examined the information submitted by you in consequence of decision CCH-D-2114439571-49-01/F. The Agency considered that this information did not meet one or more of the requests contained in that decision. Therefore, a new decision-making process was initiated under Article 41 of the REACH Regulation.

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 of this decision was notified to the Member States Competent Authorities according to Article 51(1) of the REACH Regulation.

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

ECHA did not receive any comments within the 30-day notification period.

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

As no amendments were proposed, ECHA adopted the decision under Article 51(3) of REACH.

Appendix 3: Further information, observations and technical guidance

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

2. The Article 42(2) notification for the original decision is on hold until all information requested in the original decision has been received.