EUROPEAN CHEMICALS AGENCY

Helsinki, 10 August 2018

Addressee: [redacted]

Decision number: CCH-D-2114439571-49-01/F
Substance name: Cashew, nutshell liq.
EC number: 232-355-4
CAS number: 8007-24-7
Registration number: [redacted]
Submission number: [redacted]
Submission date: 04/03/2014
Registered tonnage band: 100-1000

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.) of the registered substance;**

   - EC and CAS identifiers

   - chemical name

   - process description

You have to submit the requested information in an updated registration dossier by **19 November 2018**. You also have to update the chemical safety report, where relevant.

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.

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.

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

ECHA notes that you have not provided appropriate information on the name and other identifiers for the registered substance, as required according to Annex VI Section 2.1. of the REACH Regulation.

EC and CAS identifiers, the chemical name, as well as the other identifiers submitted, must describe precisely and consistently the identity of the registered substance.

You identified the registered substance as a substance as of Unknown or Variable composition, Complex reaction products or Biological materials (UVCB). In line with the Guidance for identification and naming of substances under REACH (Version: 2.1, May 2017)- referred to as "the Guidance" hereinafter- the naming of UVCB substances shall consist of two parts: the chemical name and the more detailed description of the manufacturing process.

You assigned the EC entry with EC number 232-355-4, EC name "Cashew, nutshell liq.", EC description: "Extractives and their physically modified derivatives. Anacardium occidentale, Anacardiaceae" to the registered substance.

This entry refers to a UVCB substance obtained by a manufacturing process involving an extraction and a physical modification. Such entry does not refer to any chemically modified derivative of cashew nutshell liquid.

The following can be noted in relation to the other identifiers provided in the registration dossier:

- You reported the name "Cashew, nutshell liq" as chemical name. Such name generically describes a liquid produced from cashew nutshell and does not describe any specific processing.

- You assigned CAS number 8007-24-7 and CAS name: "Cashew nutshell liquid" to the registered substance. This CAS entry includes the definition: "Extractives and their physically modified derivatives. Anacardium occidentale, Anacardiaceae." for the substance. This entry describes the same substance as the EC entry provided.

- Section 1.1 of the IUCLID dossier includes the description "[redacted]."
  The description given defines a substance that is the result of a chemical modification leading to [redacted] of the starting material [redacted].

As indicated above:

The EC and CAS entries define "extractives and their physically modified derivatives" and therefore do not refer to any chemically modified derivative of cashew nutshell liquid.

The chemical name provided does not refer to any specific processing.

Therefore the above-mentioned description reporting a chemical modification is not consistent with the EC and CAS entries and chemical name provided for the registered substance.

In addition, you did not provide any further description of the manufacturing process of the registered substance.
You described the source used as starting material, however a precise description of the extraction and [redacted] steps, as well as information on isolation and purification steps is missing from the registration dossier.

Accordingly you are requested to provide the following information describing the **manufacturing process**, as specified in chapter 4.3 of the Guidance :

- the identity and ratio of the relevant starting materials used,
- a description of the most relevant steps taken during manufacturing affecting the composition and therefore the identity of the substance and the associated process parameters applied to those steps, including information on the solvent used for the extraction and parameters related to the [redacted] step.
- details and conditions applied for any isolation and purification steps

You are also 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.

The modified name must be based on the following considerations:

1. a substance that is the result of the [redacted] from cashew (*Anacardium occidentale*) nutshell would be appropriately named as:

   cashew (*Anacardium occidentale*) nutshell extract, [redacted]

2. a substance that is obtained by a further [redacted] as described above (1) would be appropriately named as:

   cashew (*Anacardium occidentale*) nutshell extract, [redacted]

3. a substance that corresponds to the [redacted] as described above (1 and 2) would be appropriately named as:

   cashew (*Anacardium occidentale*) nutshell extract, [redacted] residue.

You must also ensure that the **CAS entry** reported is appropriate for describing the registered substance. This means that the CAS entry needs to unambiguously describe the registered substance, e.g. is representative of the source and relevant processing steps that are determining the composition of the registered substance.

If the registered substance is the result of a chemical modification of the starting material [redacted], you shall remove the CAS entry with CAS number 8007-24-7 from

the CAS information associated with the substance. The CAS entry may however be quoted in the dossier as related CAS information.

In case the current **EC identifier** is not appropriate to describe the registered substance, for technical reasons you should not remove or modify this EC entry when submitting the updated dossier, as the registration is linked to that EC entry in REACH-IT.

To ensure unambiguous identification of the registered substance, you should however indicate, in the "Remarks" field of the reference substance in IUCLID section 1.1, the following: "The EC number 232-355-4 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". You should also specify, in the same "Remarks" field, any available and appropriate EC number for the substance.

You should note that ECHA has established a process, subject to certain conditions, enabling registrants to adapt the EC identifier of an existing registration, while maintaining the regulatory rights already conferred to the substance concerned.

Pending the resolution of the non-compliances addressed in the present decision, any possible adaptation of the identifier can only become effective once ECHA is in a position to establish unambiguously the identity of the substance intended to be covered by you with this registration.

Should the information submitted by you as a result of the present decision enable ECHA to identify the substance unambiguously and result in a need to modify the identifier of the substance, the process of adapting the identifier will be considered relevant. In that case, ECHA will inform you in due time as to when and how the identifier adaptation process shall be initiated.

In any case, you should note that the application of the process of adapting the identifier does not affect your obligation to fulfil the requirements specified in this decision.

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.
- Any available CAS information should be reported under the CAS information header of the reference substance in IUCLID section 1.1. The CAS entry with CAS number 8007-24-7 can be reported under the "Other identifiers" field in section 1.1 of the IUCLID dossier.
- 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

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.

The compliance check was initiated on 26 February 2018.

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.

ECHA did not receive any comments by the end of the commenting period.

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.