EUROPEAN CHEMICALS AGENCY

Decision number: CCH-D-0000002068-76-06/F Helsinki, 4 July 2012

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

For Cashew, nutshell liq., CAS No 8007-24-7 (EC No 232-355-4), 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 the ECHA has performed a compliance check of the registration dossier for Cashew, nutshell liq., CAS 8007-24-7 (EC No 232-355-4), submitted by [redacted] (Registrant), latest submission number [redacted], for 1000 tonnes or more per year.

The compliance check was initiated on 3 November 2011.

On 2 December 2011 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 20 December 2011 ECHA received comments from the Registrant on ECHA's draft decision.

ECHA considered the Registrant's comments received and did not amend the draft decision.

On 25 May 2012 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.

This compliance check decision does not prevent ECHA to initiate further compliance checks on the present dossier at a later stage.

II. Information required

Pursuant to Articles 41(1)(a), 41(3) and 10(a)(ii) as well as Annex VI, section 2 of the REACH Regulation the Registrant shall submit for the registered substance:

a. Name or other identifiers of the substance (Annex VI, section 2.1.): Information which is suitable and necessary to allow ECHA to identify the name of the registered substance as specified under section III.a. below
b. Molecular and structural formula of the substance (Annex VI, section 2.2.), as indicated under section III.b. below;
c. The composition (Annex VI, 2.3.): any information which is suitable and necessary to allow ECHA to establish and verify the composition and the name of the registered substance, as specified under section III.c. below;
d. The spectral data (Annex VI, section 2.3.5.): infra-red (IR) and Ultra-violet (UV) spectra, as specified under section III.d. below.

Pursuant to Article 41(4) of the REACH Regulation the Registrant shall submit the information in the form of an updated IUCLID dossier to ECHA by **4 September 2012.**

III. Statement of reasons

Based on the examination of the technical dossier, ECHA concludes that the information therein, submitted by the Registrant for registration of the above mentioned substance for the purpose of registration within the applicable tonnage band of 1000 or more tonnes per year in accordance with Article 6 of the REACH Regulation, does not comply with the requirements of Articles 10 and with Annex VI thereof. Consequently, the Registrant is requested to submit the information mentioned above that is needed to bring the registration into compliance with the relevant information requirements.

Pursuant to Article 10(a)(ii) and Annex VI, section 2 of the REACH Regulation, the technical dossier of the registration shall include information on the identity of the substance. Annex VI, section 2 lists information requirements that shall be sufficient to identify the registered substance.

a. Name or other identifiers 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). The naming of UVCB substances shall consist of two parts: the chemical name and a more detailed description of the manufacturing process. ECHA observes that the Registrant provided a detailed description of the manufacturing process in IUCLID section 3.1 of the dossier. However, an appropriate chemical name has not been assigned to the substance, as required under Annex VI Section 2.1 of the REACH Regulation.

More specifically, the registrant indicated "Cashew, nutshell liq." as chemical name for the registered substance. ECHA points out that this chemical name is not an appropriate identifier. It does not take into account the fact that the registered substance is the result of the chemical processing, including the heat treatment and fractionation, applied to the cashew nutshell liquid starting material. In addition, the assigned CAS entry with CAS number 8007-24-7 and CAS name "Cashew, nutshell liq." does not specifically correspond to the registered substance. The registrant shall note this CAS entry includes the description "extractives and their physically modified derivatives" and does therefore not refer to any chemically modified derivative of cashew nutshell liquid such as the registered substance.

Accordingly, the Registrant is requested to revise the chemical name assigned to the registered UVCB substance. The name shall make reference to the biological source and the relevant processing steps carried out for its manufacturing. The registrant shall also remove

the CAS entry with CAS number 8007-24-7 from the CAS information associated the substance. The CAS entry may however be quoted in the dossier as related CAS information.

Regarding how to report the chemical name and related CAS information in IUCLID, further technical information is provided in paragraphs 2.1 and 2.2.2 of the "Data Submission Manual 18" available on the ECHA website[1]. The Registrant is also reminded that the description of the process for the manufacturing of UVCB substances should be specified in the Description field of the reference substance in IUCLID section 1.1.

b. Molecular and structural formula (Annex VI Section 2.2.)

The registrant did not systematically provide representative molecular and structural information for the registered substance, as required according to Annex VI, section 2.2.

More specifically, ECHA notes that the registrant assigned molecular and structural information corresponding to 3-[pentadeca-8,11,14-trien-1-yl]phenol. This structure is however for a well-defined substance which is *per se* not the same as the registered UVCB substance.

The Registrant is therefore requested to revise the molecular and structural information assigned to the registered substance.

As for the reporting of the molecular and structural information for the registered substance in the dossier, this information shall be included in the appropriate fields in IUCLID section 1.1.

c. The 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 corner stone of all the REACH obligations.

ECHA notes that the registration does not contain sufficient information for establishing the composition of the registered substance and therefore its identity, as required under Annex VI, Section 2.3 of the REACH Regulation.

More specifically, the identity of the constituents and groups of constituents reported in the composition is not consistent with those specified in the report from the chromatographic analysis of the registered substance which has been attached to the dossier:

- The first listed entry is a group of constituents which refers, according to the reported CAS, molecular and structural information, to cardanols presenting a C11 to C17 linear alkyl chain having 0, 1 or 2 unsaturation. However, the analytical report indicates that only a subset of this group of constituents has been identified. In addition, cardanols presenting 3 unsaturations have been reported in the analytical data but their presence has not been reflected in the composition. Furthermore, ECHA observes that the registrant specified "3-[(E)-pentadec-8-enyl]phenol" as chemical name for this group of constituents. This chemical name corresponds to a specific well-defined cardanol and is therefore as such not representative of the groups of constituents covered by this entry.

[1] http://echa.europa.eu/doc/reachit/dsm18/substance_id_report_iuclid_en.pdf

- The second listed entry is a specific cardol (5-pentadecylbenzene-1,3-diol) the presence of which is not indicated in the analytical report.
- The third entry corresponds to "2-methyl cardol" having a molecular formula matching only one of the two "2-methyl cardols" specified in the analytical report. The presence of the other "2-methyl cardol" has not been reported in the composition.
- The fourth listed entry is for a group of constituents presented as unidentified polymeric species. The identification and quantification of these constituents have not been described in the provided analytical data.
- The identity of the fifth and sixth group of constituents is unclear. The generic names given to these undefined groups make reference to phenols presenting a specific carbon number and a given number of unsaturations. However, the analytical report does not mention the identification and quantification of such unknown constituents.

In addition, ECHA observes that the concentration ranges reported for the different constituents and group of constituents are so overly broad that they do not represent the identity of the registered substance. ECHA points out that, according to the manufacturing process description, the registered UVCB substance corresponds to high purity cardanol obtained from the refinement by vacuum distillation of heat-treated cashew nutshell oil typically rich in cardanol (>60%). The Registrant nevertheless specified a lower concentration level for cardanol of [redacted]. In addition, the concentration values specified for "5-pentadecylbenzene-1,3-diol" and the polymeric species indicate that these constituents can also be predominant in the composition, their upper concentration being [redacted], respectively. It follows that the compositional information does not represent the registered substance and potentially covers several substances.

Following section 4.3 of the Guidance for identification and naming of substances under REACH,[2] the Registrant should 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 relevant for the classification and/or PBT assessment of the registered substance shall be identified and reported individually; and
- Unknown constituents shall be identified by a generic description of their chemical nature. The identification of these constituents must be provided in order to allow ECHA to establish the composition of the substance as manufactured and to use the compositional information as one identifier for the registered substance. This information must also allow ECHA to verify that the composition is consistent with the chemical name and description reported for the registered substance. The registrant must provide any information which is suitable and necessary to meet these objectives.

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

In line with the above, the Registrant is requested to revise the information on the identity and concentration of the constituents present in the composition. The Registrant shall provide any information which is suitable and necessary to allow ECHA to establish and verify the composition and the name of the registered substance.

Regarding how to report the composition in IUCLID, the following applies: The Registrant should specify the composition of the registered substance in IUCLID section 1.2. For each

[2] http://guidance.echa.europa.eu/docs/guidance_document/substance_id_en.pdf

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 indicated in the appropriate fields in IUCLID.

For the unknown 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 18 on the ECHA website mentioned above.

The registrant shall ensure that the compositional information is verifiable and therefore supported by a description of the analytical methods used for the identification of the constituents and groups of constituents required to be reported, in line with Annex VI, Section 2.3.7. In this respect ECHA points out that the provided analytical report describes a method for the relative quantification of selected constituents. A description of the method for the absolute quantification of the substance is required.

d. The spectral data (Annex VI, 2.3.5)

ECHA notes that the registration does not contain any IR and UV spectral data which is a standard requirement of Annex VI, Section 2.3.5. to support the identification of the registered substance.

ECHA points out that the missing spectral data as scientifically relevant to identify the registered substance. The IR spectrum displays characteristic vibration bands of the functionalities present in the structure of the constituents. The UV spectrum provides an analytical representation of the absorption, in the UV spectral region, of the chromophores in the substance.

The Registrant is therefore requested to submit UV and IR spectral data for the registered substance.

As for the reporting of the information in the dossier, the spectra should be attached in IUCLID section 1.4.

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.

[redacted]

Geert DANCET
Executive Director