EUROPEAN CHEMICALS AGENCY

Decision number: CCH-D-0000002614-77-03/F Helsinki, 15 November 2012

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

For Tall oil, CAS No 8002-26-4 (EC No 232-304-6), 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 dossier for Tall oil, CAS No 8002-26-4 (EC No 232-304-6) submitted by [redacted] (Registrant).

This decision is based on the registration dossier as submitted with submission number [redacted], for the tonnage band of 1000 tonnes or more per year. This decision does not take into account any updates after 19 July 2012, the date upon which ECHA notified its draft decision to the Competent Authorities of the Member States pursuant to Article 51(1) of the REACH Regulation.

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

The compliance check was initiated on 27 June 2011.

On 15 June 2012 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 16 July 2012 ECHA received comments from the Registrant agreeing to ECHA's draft decision.

On 19 July 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.

II. Information required

1) 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. The name or other identifier (Annex VI, 2.1): Information which is suitable and necessary to allow ECHA to identify the name of the registered substance as specified under section III.1)(a) below;
   b. 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.1)(b) below;
   c. The spectral data (Annex VI, 2.3.5.): nuclear magnetic resonance, such as a ^{1}H-NMR or as an alternative to the NMR spectrum, a mass spectroscopic analysis as specified under section III.1)(c) below;
   d. The description of the analytical methods (Annex VI, 2.3.7.): description of the analytical methods, or the appropriate bibliographical references, to identify the registered substance, including its composition as specified under section III.1)(e) below.

2) Pursuant to Articles 41(1)(a) and (b), 41(3), 10(a)(vi) and (ix), 12(1)(e), 13 and Annexes IX to XI of the REACH Regulation, the Registrant shall submit:

   a. An adequate justification detailing and documenting why information on the substance crude tall oil (EC No 232-304-6, CAS 8002-26-4) would fulfil the information requirements of Annex IX and X, for the registered substance Tall oil, as further described under section III.2) 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 **15 February 2013**.

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 in accordance with Article 6 of the REACH Regulation, does not comply with the requirements of Articles 10, 12 and 13 and with Annexes VI, X and XI 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.

1) Missing information related to substance identity

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 identifier (Annex VI, 2.1):

The name and other identifiers are used to identify the substance in an unambiguous manner and are therefore essential parts 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 name or other identifiers of the registered substance and therefore its identity, as required under Annex VI, Section 2.3 of the REACH Regulation. The EC and CAS entry used (EC number 232-304-6, Tall oil; CAS number 8002-26-4,) are not by themselves enough to identify the substance with sufficient precision. As the substance is a UVCB substance (substances of Unknown, or Variable Composition, or of Biological origin) the manufacturing process needs to be described in more detail as this information is considered essential for identifying the substance and should be provided as part of the name.

Following section 4.3 of the Guidance for identification and naming of substances under REACH and CLP (Version 1.2, March 2012), the Registrant should 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:

- Chemical composition alone is not sufficient for substance identification, but the substance should be identified by its name, its origin or source and most relevant steps taken during processing.
- The process should be described precisely enough to enable the substance to be identified unambiguously and should include information on the identity of the starting materials, the relevant process steps involved and associated process parameters (including the identity of any substance/solvent involved in an extraction process, the cut-off range of any fractioning step, the operating parameters used (temperature, pressure), the identity and ratio of any reactant used).

The provided process description is not adequate as it does neither include all the parameters listed above nor the exact specification of the starting materials. Therefore the Registrant should provide all relevant process parameters and describe the tall oil used as starting materials in more detail by specifying either:

- the origin (including genus and species of the plant source(s) as specific as possible and the manufacturing process to derive the used tall oil) or
- by providing information on the qualitative (chemical name and structural formula) and quantitative (% (w/w)) composition of the tall oil used including the concentration ranges observed.

In line with the above, the Registrant is requested to provide specific information which is suitable and necessary to allow ECHA to establish the name and other identifiers of the registered substance.

Regarding how to report the name and other identifiers of the registered substance in IUCLID, the following applies:

- - The Registrant should report the chemical (generic) name of the registered substance in the IUPAC name filed of IUCLID section 1.1 and give detailed description of the starting material and of the manufacturing process in writing in the description field.

(b) Composition of the registered substance (Annex VI, 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 report in sufficient detail the composition of the registered substance and therefore its identity, as required under Annex VI, Section 2.3 of

the REACH Regulation. More specifically, not all the relevant individual constituents or groups of constituents have been reported in section 1.2 of the substance dataset.

Following section 4.3 of the Guidance for identification and naming of substances under REACH and CLP (Version 1.2, March 2012), the Registrant should 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 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. The identification of these other 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 reported for the registered substance. The registrant must provide any information which is suitable and necessary to meet these objectives.

In line with the above, the Registrant is requested to 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 of the registered substance in IUCLID, the following applies: The Registrant should report the 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, Version 1.0/2010.

(c) The spectral data (Annex VI, 2.3.5.):

ECHA points out that the registration does not contain a nuclear magnetic resonance spectrum which is required according to Annex VI, Section 2.3.5 of the REACH Regulation to support the indicated substance identity. The Registrant has not provided any justifications for not providing this information.

This spectral data is a standard requirement of Annex VI, Section 2.3.5. necessary for the identification of the registered substance. A nuclear magnetic resonance (NMR) spectrum, such as a ^{1}H-NMR, may not necessarily enable the structure of single

constituents to be established, due to the complexity of the UVCB substance, but it provides at least complementary information on the presence/absence of certain constituents.

Therefore, the Registrant is requested to submit an NMR spectrum, such as a ^{1}H-NMR. As an alternative to the NMR spectrum, a meaningful mass spectroscopic analysis of the registered substance can be provided.

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

(d) The description of the analytical methods (Annex VI, 2.3.7.):

ECHA notes that the experimental conditions for recording the IR spectrum have not been provided. This information is required according to Annex VI, Section 2.3.7 of the REACH Regulation. The information shall be sufficient for each method to be reproduced and shall include details of the experimental protocol followed, the calculation used and the result obtained.

Therefore, the Registrant is requested to submit the complete description of the analytical methods used.
As for the reporting of the description of the analytical method in the registration dossier, the description should be reported in IUCLID section 1.4.

2) Missing information concerning the use of read-across approach

ECHA notes that the toxicological data of some endpoints (sensitization, repeat dose sub-acute oral toxicity study and in vitro mutagenicity) have been obtained from studies performed using the registered substance. For other endpoints, the data provided in the IUCLID (and CSR) dossiers were obtained using read-across from the substance Crude Tall Oil. In the dossier, the registrant states that "Distilled Tall Oil is produced by fractionating Crude Tall Oil", "Distilled Tall Oil is an amber to dark brown liquid ... Crude Tall Oil is a dark brown to dark amber viscous mixture" and "historically, the term Tall Oil refers to distilled Tall Oil and crude Tall Oil, both substances have previously shared the same CAS (8002-26-4) and EINECS (232-304-6) numbers."

In the CSR, the section 1.4 Justification for Read-across reads: "Distilled Tall Oil (DTO) is produced from the fractional distillation of the precursor substance – Crude Tall Oil (CTO). Both substances have very similar constituents of fatty acids, resin acids, neutrals and polymeric compounds, but with different percentage composition. There is a strong overlap between CTO and DTO in terms of the chemical constituents present, and hence, to an extent and where justified, available data for CTO may be read across to DTO where data gaps exist. DTO does not contain any constituents that are absent from CTO, but read across from DTO to CTO should not normally be considered because CTO does contain some constituents that are not present in DTO."

ECHA considers that no sufficient comparison between the registered substance and the read-across substance with regard to physical-chemical, ecotoxicological and toxicological properties of the registered substance and the read-across substances were included in the registration dossier.

Article 13(1) and Annex IX and X, third introductory paragraph, require the Registrant to clearly state reasons for adapting the standard information according to the rules in Annex

XI. More specifically, Annex XI, section 1.5. provides that substances whose physicochemical, toxicological and ecotoxicological properties are likely to be similar or follow a regular pattern as a result of structural similarity may be considered in a read-across approach. Application of the read-across approach requires that physicochemical properties, human health effects and environmental effects or environmental fate may be predicted from data for reference substance(s) by interpolation to other substances in the read-across approach.

The similarities, may, according to Annex XI, section 1.5., be based on:
(1) common functional group;
(2) the common precursors and/or the likelihood of common breakdown products via physical or biological processes, which result in structurally similar chemicals; or
(3) a constant pattern in the changing of the potency of the properties across the category.

Annex XI, section 1.5. requires that the results (i) are adequate for the purpose of classification and labelling and/or risk assessment, (ii) have adequate coverage of the key parameters and cover an exposure duration addressed in the corresponding test method referred to in Article 13(3) and (iii) that the documentation of the applied method is adequate and reliable.

ECHA points out that the read-across justification presented in the registration dossier specifies neither the composition of the registered and of the read-across substances, nor which information on the physicochemical properties, and human health effects and environmental effects is available.

While some relevant information on the similarity of substances, and on the common precursors as required under Annex XI, section 1.5. were provided, based on that information it is not possible for ECHA to consider if the legal provisions of Annex XI needed for a read-across approach are met. Therefore, the requirements of Annex XI, section 1.5. in conjunction with Article 13(1) and Annex X, third introductory paragraph, of the REACH Regulation are deemed not to be met.

Taking into account the substance identity information requested under point 1), the Registrant is thus requested to submit a justification detailing why the data obtained using the read-across substances would fulfil the information requirements for the registered substance in line with Annex XI, section 1.5.

Moreover, information on the production processes that could further justify the read-across approach is to be provided. This issue is reported in paragraphs 6.2.5 and 6.2.6 of the Guidance on information requirements and chemical safety assessment, Chapter R.6: QSARs and grouping of chemicals (version1.0, May 2008) and in a Practical Guide 6: How to report read-across and categories (24 March 2010) that can be found on the ECHA web page.

This above-mentioned information on physicochemical properties, human health effects and environmental effects that are used to justify the read-across approach should also be reported in the IUCLID registration dossier in a form of robust study summaries or study summaries.

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.

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