Decision number: CCH-D-2114306447-52-01/F Helsinki, 30 July 2015

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

For Fatty acids, tall-oil, reaction products with diethylenetriamine, maleic anhydride, tetraethylenepentamine and triethylenetetramine, CAS No 68990-47-6 (EC No 273-601-0), 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 for Fatty acids, tall-oil, reaction products with diethylenetriamine, maleic anhydride, tetraethylenepentamine and triethylenetetramine, CAS No 68990-47-6 (EC No 273-601-0), submitted by [redacted] (Registrant).

The scope of this compliance check decision is limited to the standard information requirements of Annex VIII, Section 9.3.1. and Annex IX, Section 9.3.3. of the REACH Regulation. ECHA stresses that it has not checked the information provided by the Registrant and other joint registrants for compliance with requirements regarding the identification of the substance (Section 2 of Annex VI).

This decision is based on the registration as submitted with submission number [redacted], for the tonnage band of [redacted] per year. This decision does not take into account any updates after 29 January 2015, i.e. the date when the draft decision was notified to the Registrant under Article 50(1) of the REACH Regulation.

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

The compliance check was initiated on 28 May 2014.

On 29 January 2015 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 9 March 2015 ECHA received comments from the Registrant on the draft decision.

The ECHA Secretariat considered the Registrant's comments. The information is reflected in the Statement of Reasons (Section III) whereas no amendments to the Information Required (Section II) were made.

On 11 June 2015 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 for amendment of the draft decision within 30 days of the receipt of the notification.

As no proposal for amendment was submitted, ECHA took the decision pursuant to Article 51(3) of the REACH Regulation.

II. Information required

A. Information in the technical dossier derived from the application of Annexes VII to XI

Pursuant to Articles 41(1)(a), 41(3), 10(a)(vi), 12(1)([redacted]), 13 and Annexes VIII and IX of the REACH Regulation, the Registrant shall submit the following information using an appropriate test method and the registered substance subject to the present decision:

- Adsorption/desorption (Annex VIII, section 9.3.1., and Annex IX, section 9.3.3.)

Guidance for determining appropriate test methods for Adsorption/desorption is available in the ECHA Guidance on information requirements and chemical safety assessment (version 3.0, August 2014), Chapter R.7a, Section R.7.1.15.

Note for consideration by the Registrant:

The Registrant may adapt the testing requested above according to the specific rules outlined in Annexes VI to X and/or according to the general rules contained in Annex XI of the REACH Regulation. In order to ensure compliance with the respective information requirement, any such adaptation will need to have a scientific justification, referring to and conforming with the appropriate rules in the respective Annex, and an adequate and reliable documentation.

Failure to comply with the request(s) in this decision, or to fulfil otherwise the information requirement(s) with a valid and documented adaptation, will result in a notification to the Enforcement Authorities of the Member States.

B. Deadline for submitting the required information

Pursuant to Articles 41(4) and 22(2) of the REACH Regulation the Registrant shall submit to ECHA by **8 February 2016** an update of the registration dossier containing the information required by this decision, including, where relevant, an update of the Chemical Safety Report.

III. Statement of reasons

Pursuant to Article 41(3) of the REACH Regulation, ECHA may require the Registrant to submit any information needed to bring the registration into compliance with the relevant information requirements.

A. Information in the technical dossier derived from the application of Annexes VII to XI

Pursuant to Articles 10(a)(vi) and/or (vii), 12(1)([redacted]) of the REACH Regulation, a technical dossier for a substance manufactured or imported by the Registrant in quantities of [redacted]

[redacted] per year shall contain as a minimum the information specified in Annexes VII to X of the REACH Regulation.

"Adsorption/desorption screening" and "Further information on adsorption/desorption depending on the results of the study required in Annex VIII" are standard information requirements laid down in Annex VIII (Section 9.3.1.) and Annex IX (Section 9.3.3.), respectively, of the REACH Regulation.

The technical dossier does not contain the relevant data to fulfil the above information requirements. In the technical dossier, the Registrant stated that "the study was not performed due to lack of a suitable analytical method to be applied during the analytical phase". The statement provided by the Registrant is interpreted by ECHA as an attempt to adapt the information requirements pursuant to Annex XI, Section 2 of the REACH Regulation ("Testing is technically not possible").

Annex XI, Section 2 of the REACH Regulation stipulates that testing for a specific endpoint may be omitted if it is technically not possible to conduct the study as a consequence of the properties of the substance. However, the guidance given in the test methods referred to in Article 13(3) of the REACH Regulation shall always be respected.

ECHA notes that for this endpoint there are available appropriate test methods, such as OECD TG 121, which can commonly be applied also to multiconstituent and UVCB substances. The Registrant has in his dossier used high-pressure liquid chromatography as an analytical method to determine the water solubility of the registered substance. ECHA does not see a reason why, for instance, OECD 121 would not be a suitable method for estimating the adsorption/desorption coefficient as well. Consequently, the justification provided by the Registrant to adapt the standard information requirement is not considered appropriate nor corresponding to the available adaptation possibilities in column 2 of the relevant Annexes VIII and IX, nor Annex XI.

In his comments on the draft decision, the Registrant indicated that the possibility to conduct Adsorption/desorption tests for UVCB substances was not clear at the time when the dossier was prepared and that it was only for that reason that the waiver was originally proposed.

Therefore, pursuant to Article 41(1) and (3) of the REACH Regulation, the Registrant is requested to submit information on Adsorption/desorption derived with an appropriate test method and the registered substance.

IV. Adequate identification of the composition of the tested material

ECHA stresses that the information submitted by the Registrant and other joint registrants for identifying the substance has not been checked for compliance with the substance identity requirements set out in Section 2 of Annex VI of the REACH Regulation. The Registrant is reminded of his responsibility and that of joint Registrants to ensure that the joint registration covers one substance only and that the substance is correctly identified in accordance with Annex VI, Section 2 of the REACH Regulation.

In addition, it is important to ensure that the particular sample of substance tested in the new study is appropriate to assess the properties of the registered substance, taking into account any variation in the composition of the technical grade of the substance as actually manufactured by each registrant. If the registration of the substance by any registrant

covers different grades, the sample used for the new study must be suitable to assess these grades.

Finally there must be adequate information on substance identity for the sample tested and the grade(s) registered to enable the relevance of the study to be assessed.

V. 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://www.echa.europa.eu/regulations/appeals. The notice of appeal will be deemed to be filed only when the appeal fee has been paid.

Authorised[1] by Leena Ylä-Mononen Director of Evaluation

[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.