~~CONFIDENTIAL~~

European Chemicals Agency

Decision number: CCH-D-0000001765-69-03/F Helsinki, 04/11/2011

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

For Rosin, hydrogenated, 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 **Rosin, hydrogenated (CAS No 65997-06-0; EC No 266-041-3),** submitted by [redacted], (Registrant), latest submission number [redacted], for 1000 tonnes or more per year.

The compliance check was initiated on 17 June 2011.

On 11 July 2011 ECHA notified the Registrant of its draft decision and invited him pursuant to Article 50(1) of the REACH Regulation to provide comments within 30 days of the receipt of the draft decision.

On 3 August 2011 the Registrant provided to ECHA comments on the draft decision.

ECHA reviewed the further information received and amended the draft decision accordingly.

On 2 September 2011 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. 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

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. 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)(a) below;
   b. Description of the analytical methods or the appropriate bibliographical references for the identification of the substance (Annex VI, 2.3.7) as specified under section III. 1) (b) 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. Identity of the substance intended to be tested in the proposed pre-natal developmental toxicity study. The information to be provided shall, in addition to the CAS and EC numbers already provided, include the chemical name or any other identifier of the substance to be tested and its composition, as described under section III.1)(a) below for the registered substance.

3) 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 **Rosin** (CAS No 8050-09-7, EC No 232-475-7) substance proposed to be tested would fulfil the information requirement of pre-natal developmental toxicity study of Annex IX and X, section 8.7.2. for the registered substance, as further described under section III.3) 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 **31 January 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 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, IX to 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) 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 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 provided chemical name and identifiers **Rosin, hydrogenated** (CAS No 65997-06-0; EC No 266-041-3) are not by themselves enough to identify the substance and its composition with sufficient precision. Furthermore, the Registrant should report the chemical (generic) name of the registered substance in the IUPAC name field and the CAS name in the respective field of IUCLID section 1.1. In particular the terms resin acids and rosin acids are generic terms and do not indicate which type of acids are included in the substance. The qualitative and quantitative composition of these acids might vary depending on the biological and/or geographical origin and their processing. The composition of the registered substance has not been analysed on the level of individual constituents and the relevant individual constituents or groups of constituents have not been identified and reported in IUCLID section 1.2. In addition, the information provided in IUCLID section 1.4 is not sufficient to derive a meaningful composition of the substance.

Following section 4.3 of the Guidance for identification and naming of substances under REACH http://guidance.echa.europa.eu/docs/guidance_document/substance_id_en.pdf, the Registrant should note that for UVCB substances 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.

The Registrant is requested to provide information which is suitable and necessary to allow ECHA to verify the composition and the name of the registered substance.

Based on composition of the registered substance composition and the relevant analytical data the Registrant is requested to reconsider the substance name and other identifiers and revise them, if necessary.

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 18 on the ECHA website at:
http://echa.europa.eu/doc/reachit/dsm18/substance_id_report_iuclid_en.pdf.

(b) Description of the analytical methods or the appropriate bibliographical references for the identification of the substance (Annex VI, 2.3.7)

ECHA observes that the registration does not contain sufficient details of the analytical methods used to identify the composition of the substance, as required by Annex VI, Section 2.3.7 of the REACH Regulation.

Accordingly, in line with Annex VI, 2.3.7, the Registrant is requested to submit the description of the missing analytical methods, or the appropriate bibliographical references, to identify the registered substance, including its composition and results of the method used. The information shall be sufficient for each method to be reproduced and shall therefore include details of the experimental protocol followed, the calculation used and the result obtained.

Although the operating conditions to record the chromatogram are provided in sufficient detail, the evaluation of the chromatogram cannot be followed as no allocation of detected peaks to the constituents is provided. Furthermore, the conversion from % (area/area) to % (weight/weight) cannot be followed as no peak table which includes the detected areas and no calculation are attached in the dossier. Therefore, the provided results of the chromatographic analysis cannot be followed.

The Registrant is requested to provide a peak table with the allocation of the detected peaks and their corresponding % (area/area) and calculations, which explain the indicated results.

Regarding how to report this information in the IUCLID, the following applies: The Registrant should attach information on the analytical methods or the appropriate bibliographical references used for the identification and quantification of the substance and its composition in IUCLID section 1.4.

2) Missing information concerning the endpoint concerned

ECHA notes that the Registrant intends to cover the information requirement of the pre-natal developmental toxicity study (a standard information requirement of Annexes IX and X, 8.7.2.) by performing a test according to OECD guideline 414. The Registrant proposes to perform this test with **Rosin** (CAS No 8050-09-7, EC No 232-475-7), which is an UVCB substance. The Registrant does not specify the composition of this

substance, which does not allow ECHA to sufficiently verify the identity of the substance.

If the Registrant suggests carrying out the proposed test required by Annexes IX and X with a substance other than the registered substance, Article 13(1) and Annexes 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. This includes that similarity between the registered substance and the substance to be tested needs to be established by the Registrant.

ECHA concludes that as the composition of the substance to be tested was not sufficiently provided in the registration dossier, the similarity of the substance to be tested and the registered substance could not to be considered, and the requirements of Annex XI, section 1.5., as explained below, in conjunction with Article 13(1) and Annexes IX and X, third introductory paragraph, of the REACH Regulation are not met.

The Registrant is accordingly requested to submit adequate information concerning the composition of the substance to be tested. The information to be provided shall include an appropriate chemical name or any other identifier of the constituents of the substance to be tested and composition as described under point 1 (a) for the registered substance.

Regarding how to report the identity of the test substance in IUCLID, the following applies: The Registrant should report the name or any other identifier of the substance in the "test material identity" field of the endpoint study record. The constituents or group of constituents required to be specified shall be identified by a chemical name. The concentration of these constituents in the substance to be tested shall also be reported. The information on the composition should be reported in either the "details on test material" or "confidential details on test material" field of the endpoint study record.

3) Missing information concerning the use of read-across / grouping approach

The technical dossier submitted by the Registrant contains a general statement for using a grouping approach for rosins, including the registered substance. The group of rosins is said to consist of different categories. The Registrant suggests that the substance to be tested for pre-natal developmental toxicity (Annexes IX and X, 8.7.2.) is **Rosin** (CAS No 8050-09-7, EC No 232-475-7), which reportedly is a member of the category of **Rosin, hydrogenated rosin and their salts.** Also the registered substance is reportedly from this category.

The category justification provided by the Registrant is generic and consists of a list of different substances said to be members of the category of rosin, hydrogenated rosin and their salts. While there is some similarity between the precursors of different rosins, the Registrant did not provide sufficient information on the chemical similarity between the registered substance and the substance to be tested. Furthermore, no information was provided on the break-down products or metabolites of the registered substance. Some information was provided on the repeated dose toxicity and reproductive toxicity of the substance to be tested, while no such information was provided on the registered substance.

No sufficient comparison between the registered substance and the substance to be tested with regard to physical-chemical, ecotoxicological and toxicological properties of the registered substance and the substance to be tested were included in the registration dossier. Furthermore, no comparison between the other category members and these two substances was provided to further justify the read-across within the category. It is not clear from the registration dossier on which grounds, listed in Annex XI, section 1.5., governing grouping of substances and read-across this grouping approach is based on.

Article 13(1) and Annexes 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 as a group, or 'category' of substances. Application of the group 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 group (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.

The Registrant indicated in its dossier that the registered substance and the substances to be tested belong to the same category. However, ECHA points out that the read-across / category justification presented in the dossier does not specify the composition of the substance to be tested. In addition, the registration dossier does not specify which information is available on the physicochemical properties, human health effects and environmental effects of these substances. The relevance of any read-across / category approach cannot be confirmed without this information.

Furthermore, the information under IUCLID section 7.8 and the document attached in IUCLID section 13 of the dossier provide a list of substances which are members of the category of the registered substance. This list is inconsistent with the lists provided by other registrants of the reportedly same category.

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 group or category of substances 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) and the information on the substance to be tested requested under point 2), the Registrant is thus requested to submit a justification detailing why the proposed test on the specified substance would fulfil the information requirement for pre-natal developmental toxicity of Annex IX, section 8.7.2. for the registered substance in line with Annex XI, section 1.5. This applies if the substance specified under point 2) above is not the registered substance.

To justify the above mentioned read-across, further information on the grouping approach must also include the identity of the substances that are members of the category of the registered and test substance, including their composition. Furthermore, it is to be clearly and fully indicated for which substances test data exists on the physicochemical properties, human health effects and environmental effects. Moreover, information on the production processes that could further justify the grouping approach, is to be provided. This issue is reported in paragraphs 6.2.5 and 6.2.6 of the Guidance on QSARs and grouping of chemicals
http://guidance.echa.europa.eu/docs/guidance_document/information_requirements_r6_en.pdf?vers=20_08_08
and in a Practical Guide: "How to report read-across and categories" that can be found on the ECHA web page
http://echa.europa.eu/doc/publications/practical_guides/pg_report_readacross_categ.pdf.

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

IV. General requirements for the generation of information and Good Laboratory Practice

ECHA always reminds Registrants of the requirements of Article 13(4) of the REACH Regulation that reads:

> "Ecotoxicological and toxicological tests and analyses shall be carried out in compliance with the principles of good laboratory practice provided for in Directive 2004/10/EC or other international standards recognised as being equivalent by the Commission or the Agency and with the provisions of Directive 86/609/EEC, if applicable."

According to Article 13(3) of the REACH Regulation, tests that are required to generate information on intrinsic properties of substances shall be conducted in accordance with the test methods laid down in a Commission Regulation or in accordance with other international test methods recognised by the Commission or the European Chemicals Agency as being appropriate. Thus, the Registrant shall refer to Commission Regulation (EC) No 440/2008 laying down test methods pursuant to Regulation (EC) No 1907/2006, as adapted to technical progress, and use the applicable test methods to generate the information on the endpoints indicated above.

National authorities monitoring good laboratory practice (GLP) maintain lists of test facilities indicating the relevant areas of expertise of each facility.

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://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.

Done at Helsinki,

Jukka Malm
Director of Regulatory Affairs