~~CONFIDENTIAL~~

European Chemicals Agency

Decision number: CCH-D-0000001755-70-03/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, 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 (CAS No 8050-09-7; EC No 232-475-7)**, 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 1 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

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 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. 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)(b) below and
c. 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. 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.

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, 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) 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 relevant individual constituents or groups of constituents have not been identified and reported in section 1.2 of the substance dataset. Therefore, the substance identity, including the chemical name, could not have been verified.

The provided chemical name and identifiers **Rosin (EC number 232-475-7, CAS number 8050-09-7),** are not by themselves enough to identify the substance and its composition with sufficient precision. The Registrant should report the chemical name of the registered substance in the IUPAC name field of IUCLID section 1.1.

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** (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.

Based on composition of the registered substance 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) 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.

(c) The 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 measured peak areas and calculation methods are not provided. Furthermore the provided assignment of the observed peaks to constituents is not complete.

Therefore the indicated results of the chromatographic analysis are not sufficient to support the identification of the substance.

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.

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,

[redacted]

Jukka Malm
Director of Regulatory Affairs