~~CONFIDENTIAL~~

European Chemicals Agency

Decision number: CCH-D-0000001766-67-03/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 Resin acids and Rosin acids, esters with pentaerythritol, 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 **Resin acids and Rosin acids, esters with pentaerythritol (CAS No 8050-26-8, EC No 232-479-9)** 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 7 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. High-pressure liquid chromatogram or gas chromatogram (Annex VI, 2.3.6) as specified under section III. 1)(b) below and
   c. 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)(c) 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 **Resin acids and Rosin acids, esters with pentaerythritol** (CAS No 8050-26-8, EC No 232-479-9) 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 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 Registrant shall 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) High-pressure liquid chromatogram, gas chromatogram (Annex VI, 2.3.6)

ECHA recognized that a high-pressure liquid chromatogram or gas chromatogram for identifying the composition of the substance is not provided in the registration

dossier, as required by Annex VI, Section 2.3.6. Instead of that a gel permeation chromatogram (GPC) is provided. However this analytical method does not provide sufficient information on the detailed composition of the substance as it gives only low resolution information on the presence of constituents with different molecular weight. Considering the found molecular masses a more detailed analysis on the identity of individual constituents and their concentrations possibly complemented by GPC for higher molecular species- seems possible and necessary for the substance identification.

Therefore, ECHA concludes the provided information is not sufficient to identify the composition of the substance.

Accordingly, in line with Annex VI, 2.3.6, the Registrant is requested to submit a gas chromatogram or a high pressure liquid chromatogram. The chromatogram is requested to be recorded in such way that the individual constituents are separated, identified and quantified. Similar constituents might be grouped if it is not possible to identify individual constituents.

As for the reporting of the chromatogram in the registration dossier, the chromatogram should be attached in IUCLID section 1.4.
Furthermore the results should be used to report the composition of the registered substance in IUCLID section 1.2.

(c) 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.

The quantitative analysis of the GPC (Gel Permeation Chromatography) data applied by the registrant is not described adequately. The choice of cut-off times/masses for the assignment of different ester species has not been explained. In case the GPC method will be replaced, the alternative method including the quantitative analysis of the raw data shall also be described in sufficient detail to be able to reproduce the method and verify the correctness of the results.

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.

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 present 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