ECHA
EUROPEAN CHEMICALS AGENCY

Decision number: CCH-D-0000002973-67-11/F Helsinki, 13 February 2014

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

For Terpineol (EC No 232-268-1), 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 Terpineol, (EC No 232-268-1), submitted by [redacted] (Registrant). The scope of this compliance check is limited to the standard information requirement of Annex IX, Section 8.6.2. 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 compliance check decision does not prevent ECHA from initiating further compliance checks on the present dossier at a later stage.

This decision is based on the registration 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 submitted after 1 August 2013, 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.

The compliance check was initiated on 6 March 2013.

On 31 May 2013 ECHA sent the draft decision to the Registrant and invited him to provide comments within 30 days of the receipt of the draft decision.

By 1 July 2013 the Registrant did not provide any comments on the draft decision to ECHA.

On 1 August 2013 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 submitted proposals for amendment to the draft decision.

On 6 September 2013 ECHA notified the Registrant of proposals for amendment to the draft decision and invited him pursuant to Article 51(5) of the REACH Regulation to provide comments on those proposals for amendment within 30 days of the receipt of the notification.

The ECHA Secreteriat reviewed the proposals for amendment received and decided not to amend the draft decision.

On 16 September 2013 ECHA referred the draft decision to the Member State Committee.

On 4 October 2013 the Registrant provided comments on the proposed amendments. The Member State Committee took the comments of the Registrant into account.

After discussion in the Member State Committee meeting on 4-8 November 2013, a unanimous agreement of the Member State Committee on the draft decision as modified at the meeting was reached on 6 November 2013. ECHA took the decision pursuant to Article 51(6) of the REACH Regulation.

II. Information required

Pursuant to Articles 41(1), 41(3), 10(a)(vii), 12(1)(e), 13 and Annex IX, of the REACH Regulation the Registrant shall submit the following information using the indicated test methods and the registered substance subject to the present decision:

- Sub-chronic toxicity study (90-day) in rats, inhalation route (Annex IX, 8.6.2.; test method: OECD 413).

Pursuant to Article 41(4) of the REACH Regulation the Registrant shall submit the information in the form of an updated registration to ECHA by **13 August 2015.**

At any time, the Registrant shall take into account that there may be an obligation to make every effort to agree on sharing of information and costs with other Registrants.

III. Statement of reasons

A sub-chronic toxicity study (90 day) is a standard information requirement as laid down in Annex IX, section 8.6.2. of the REACH Regulation. Adequate information on this endpoint needs to be present in the technical dossier for the registered substance to meet this information requirement.

In the technical dossier the Registrant provided information with which he sought to fulfil this standard information requirement. The provided information stems from a "Combined repeated dose toxicity study with the reproduction/developmental toxicity screening test" (test method: OECD 422). However, this study does not provide the information required by Annex IX, Section 8.6.2., because exposure duration is less than 90 days. The technical dossier neither contained a testing proposal nor an adaptation in accordance with column 2 of Annex IX, Section 8.6.2. or with the general rules of Annex XI for this standard information requirement.

As explained above, the information available on this endpoint for the registered substance in the technical dossier does not meet the information requirements. Consequently there is an information gap and it is necessary to provide information for this endpoint.

In light of the properties of the substance (liquid with low vapour pressure) and the information provided on the uses and human exposure (i.e., spray application with concentrations up to 25%) ECHA considers that testing by the inhalation route is most appropriate.

A Member State Competent Authority proposed to amend the decision by changing the route of administration for the sub-chronic toxicity study (90-days) from inhalation (test method OECD 413) to the oral route (test method EU B.26/ OECD 408), in absence of clear triggers for respiratory tract irritation and evidence of systemic toxicity following repeated oral dosing (test method OECD 422). The Registrant agreed with the proposal for amendment as he intends to further investigate this evidence using the same route of administration.

In the Meeting of the Member State Committee it was decided to request the study with inhalation route of administration. This is because the major concern for systemic toxicity, effects on male fertility, will be investigated further in a generation study by oral administration for which the Registrant made a testing proposal and for which the decision was referred to the Commission for further decision making. The available oral OECD 422 screening study can be used to set the doses for the generation study. Therefore, the concern for effects on male fertility will be addressed to a sufficient extent with the proposed test. However, the substance is used in spray applications at concentrations up to 25%. To investigate systemic effects, inhalation administration is considered the most appropriate route for the sub-chronic toxicity study (90-day) in this case.

According to the test method the rat is the preferred rodent species. ECHA considers this species as being appropriate.

Therefore, pursuant to Article 41(1) and (3) of the REACH Regulation, the Registrant is requested to submit information on sub-chronic toxicity (90-day) in rats, inhalation route (test method OECD 413) derived with the registered substance subject to the present decision.

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 relation to the information required by the present decision, the sample of substance used for the new study must be suitable for use by all the joint registrants. Hence, the sample should have a composition that is within the specifications of the substance composition that are given by the joint registrants. It is the responsibility of all joint registrants who manufacture or import the same substance to agree on the appropriate composition of the test material and to document the necessary information on their substance composition.

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://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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Director of Evaluation