EUROPEAN CHEMICALS AGENCY

~~CONFIDENTIAL~~

Decision number: CCH-D-0000003896-60-03/F Helsinki, 28 May 2014

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

For (R)-p-mentha-1,8-diene, CAS No 5989-27-5 (EC No 227-813-5), 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 (R)-p-mentha-1,8-diene, CAS No 5989-27-5 (EC No 227-813-5), submitted by [redacted] (Registrant). The scope of this compliance check is limited to the standard information requirement of Annex VI, Sections 4.1 and 4.2 relating to classification and labelling for aquatic hazard. ECHA stresses that it has not checked the information provided by the Registrant and other joint registrants for compliance with the requirements regarding the identification of the substance (Section 2 of Annex VI) or those of Annexes VII to IX relating to aquatic toxicity.

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 31 October 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.

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 17 June 2013.

On 25 July 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 26 August 2013 the Registrant did not provide any comments on the draft decision to ECHA.

On 31 October 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 did not propose amendments to the draft decision and ECHA took the decision pursuant to Article 51(3) of the REACH Regulation.

II. Information required

Pursuant to Articles 41(1)(a), 41(3), 10(a)(iv) and Annex VI, sections 4.1. and 4.2. of the REACH Regulation in conjunction with Article 4(3) and Annex VI, Part 3 of Regulation (EC) No 1272/2008 on classification, labelling and packaging of substances and mixtures (CLP Regulation) the Registrant shall submit the following information for the registered substance subject to the present decision:

- the hazard classification of the registered substance for Aquatic Acute Hazard Category 1, as well as the resulting hazard statement 'H400: Very toxic to aquatic life'.

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 **4 September 2014.**

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 requirement. The scope of the present decision is limited to classification and labelling for aquatic toxicity (Annex VI, Sections 4.1 and 4.2 of the REACH Regulation).

Pursuant to Article 10(a)(iv) and Annex VI, section 4 of the REACH Regulation, the technical dossier of the registration shall include information on the classification and labelling of the substance. Annex VI, section 4.1 clarifies that the hazard classification of the substance shall result from the application of Title I and II of the CLP Regulation. According to Article 4(3) (in Title I) of the CLP Regulation, if a substance is subject to harmonised classification and labelling in accordance with Title V of the CLP Regulation through an entry in Part 3 of Annex VI, that endpoint of that substance shall be classified in accordance with that entry.

Furthermore, the technical dossier must include the resulting hazard label for the substance in line with Title III of the CLP Regulation (Annex VI, section 4.2 of the REACH Regulation).

In the present case, ECHA notes the following:

Part 3 of Annex VI to the CLP Regulation contains a harmonised classification and labelling for the registered substance. According to this entry, the substance shall be classified as Aquatic Acute Hazard Category 1 and Aquatic Chronic Hazard Category 1. The resulting hazard statements are 'H400: Very toxic to aquatic life' and '410: Very toxic to aquatic life with long lasting effects'.

The Registrant has indicated in his registration dossier that the substance is classified as Aquatic Chronic Hazard Category 1 and indicated the hazard statement 'H410: Very toxic to aquatic life with long lasting effects'. However, the Registrant has not included the classification as Aquatic Acute Hazard Category 1 nor the hazard statement H400: Very toxic to aquatic life, required by the CLP Regulation in his registration dossier.

Therefore, the Registrant is requested to submit the above missing hazard classification for aquatic toxicity and the resulting hazard statement of the registered substance which is required by Part 3 of Annex VI to the CLP Regulation.

IV. 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.

[redacted]

Leena Yla-Mononen
Director of Evaluation