

Decision number: CCH-D-0000002401-88-03/F

Helsinki, 4 July 2012

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

**For Terpineol, CAS No 8000-41-7 (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 dossier for Terpineol, CAS No 8000-41-7 (EC No 232-268-1) submitted by [REDACTED] (Registrant), latest submission number [REDACTED], for the tonnage band of 1000 tonnes or more per year.

The compliance check was initiated on 29 February 2012.

On 21 March 2012 ECHA sent the draft decision to the Registrant and invited him to provide comments within 30 days of the receipt of the draft decision.

On 20 April 2012 ECHA received comments from the Registrant agreeing to ECHA's draft decision.

ECHA considered the Registrant's comments received and did not amend the draft decision.

On 25 May 2012 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.

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. Name of the substance (Annex VI, 2.1.) as specified under section III.(a) below;
  - b. Composition of the substance (Annex VI, 2.3.) as specified under section III.(b) 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 **4 September 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 for the purpose of registration within the applicable tonnage band of over 1000 tonnes per year in accordance with Article 6 and 11(2) of the REACH Regulation, does not comply with the requirements of Article 41(1)(a) and with Annex VI 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.

#### 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) Name of the substance (Annex VI, 2.1.)

ECHA notes that the Registrant identified the registered substance as a multi-constituent substance. In line with the Guidance for identification and naming of substances under REACH and CLP<sup>1</sup>, multi-constituent substances are well-defined substances in which more than one constituent is present at a concentration  $\geq 10\%$  (w/w) and  $< 80\%$  (w/w) (referred to thereafter as "main constituent"). A multi-constituent substance is named as the reaction mass of the main constituents. ECHA observes that the Registrant did not provide appropriate information on the name of the substance, as required under Annex VI Section 2.1 of the REACH Regulation.

More specifically, the Registrant assigned the EC and CAS entries for "Terpineol" to the registered substance. ECHA notes that terpineol is available in six different isomers, including (+)- $\alpha$ -terpineol, (-)- $\alpha$ -terpineol, cis- $\beta$ -terpineol, trans- $\beta$ -terpineol,  $\gamma$ -terpineol and  $\delta$ -terpineol. The multi-constituent substance identified as "terpineol" refers under REACH to a well-defined substance for which all 6 possible isomers are the main constituents. However, ECHA observes that the Registrant assigned a chemical name and molecular and structural information referring to "2-(4-methylcyclohex-3-en-1-yl)propan-2-ol", i.e.  $\alpha$ -terpineol, to the substance. The multi-constituent substance  $\alpha$ -terpineol corresponds under REACH to a well-defined substance for which only (+)- $\alpha$ -terpineol and (-)- $\alpha$ -terpineol are the main constituents.

In addition, ECHA observes that the compositional information reported in the dossier indicates that terpineols other than (+)- $\alpha$ -terpineol and (-)- $\alpha$ -terpineol are also present as main constituents while  $\delta$ -terpineol is never a main constituent. It follows that the registration dossier includes contradictory information on the identity of the terpineol isomers which are the main constituents of the registered substance.

ECHA points out that, in accordance with the criteria for substance sameness specified in paragraph 5 of the Guidance for identification and naming of substances under REACH and CLP<sup>2</sup>, multi-constituents substances with different main constituents shall be regarded as

<sup>1</sup> <http://echa.europa.eu/web/guest/guidance-documents/guidance-on-the-different-methods-under-reach>

different substances under REACH. ECHA therefore concludes that the provided EC/CAS entries, chemical name and the composition specified in the dossier refer to different substances.

The Registrant is accordingly requested to provide a chemical name corresponding to the specific terpeneol-based multi-constituent substance covered in this registration. The chemical name shall follow the generic format "Reaction mass of [names of the main constituents]". The Registrant shall also specify any available and appropriate CAS number and CAS name reflecting the identity of the main constituents of the substance. The Registrant shall delete from the registration any information referring to different substances than the multi-constituent substance which is the subject of this registration.

As for the reporting of the information in IUCLID, the chemical name shall be indicated in the "IUPAC name" field in IUCLID section 1.1. The CAS number and CAS name shall be reported under the "CAS information" header in IUCLID section 1.1. The Registrant is requested not to remove or modify at this stage the EC entry currently assigned to this registration for technical reasons, the registration being linked to that EC entry in REACH-IT.

The Registrant shall ensure that the molecular and structural information specified in IUCLID section 1.1 and the composition indicated in IUCLID section 1.2 are consistent with the chemical name and CAS number and CAS name assigned to the registered substance.

(b) Composition of the substance (Annex VI Section 2.3. of the REACH Regulation)

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 and appropriate 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, ECHA notes that the Registrant did not provide information on the concentration of each individual isomer present in the composition of the registered substance. In particular, the concentration of the (+)- $\alpha$ -terpineol, (-)- $\alpha$ -terpineol, cis- $\beta$ -terpineol and trans- $\beta$ -terpineol isomers has not been specified. The Registrant provided instead cumulated concentration values for  $\alpha$ -terpineols and  $\beta$ -terpineols. It follows that the identity of the main constituents present in the composition of the registered substance can not be established. Similarly, the Registrant has not specified information on the identity and concentration of several of the individual stereoisomers within the impurities required to be reported, including "4-(isopropyl)-1-methylcyclohex-3-en-1-ol", "p-menth-1-en-4-ol", "3,3-dimethyl-8,9-dinorbornan-2-ol", "1-methyl-4-[1-methyl-1-(1-methylethoxy)ethyl]-cyclohexene" and "p-menthane-1,8-diol". ECHA therefore concludes that the composition of the registered substance has not been provided to the required level of detail.

In addition, ECHA notes that the Registrant has not specified any information on the typical concentration values of the constituents required to be reported. Without this information, a representation of the composition of the registered substance can not be established. Furthermore, ECHA observes that the Registrant indicated especially wide concentration ranges for some of the constituents. In particular, the cumulated concentration range of the  $\beta$ -terpineols (which cover cis- $\beta$ -terpineol and trans- $\beta$ -terpineol) varies from [REDACTED].

Such concentration range indicates that the reported composition covers at least both a well-defined multi-constituent substance which does not include any of the  $\beta$ -terpineol isomers as well as a substance including at least one of the  $\beta$ -terpineol isomers as main constituent. In line with the substance sameness criteria highlighted in section III.(a) in this communication for multi-constituent substances, ECHA concludes that the compositional information does not specifically refer to the substance which is the subject of this registration but covers several substances.

In line with paragraph 4.3 of the Guidance for identification and naming of substances under REACH and CLP, the following applies to all multi-constituent substances, including the registered substance:

- All main constituents shall be identified and reported individually; and
- All the impurities present at  $\geq 1$  % shall be identified and reported individually; and
- All the impurities relevant for the classification and/or PBT assessment shall be identified and reported individually.

For each constituent, including the main constituents and any impurity, the typical, minimum and maximum concentration level shall be specified.

The Registrant is accordingly requested to complete and correct the above information on the composition of the registered substance provided in the registration dossier, for ECHA to have a precise chemical representation of what the specific multi-constituent substance, which is the subject of this registration, consists of.

Regarding how to report the composition in IUCLID, the following applies: The Registrant shall report individually each main constituent and impurity required to be identified and specify at least one of the following identifiers: chemical name, CAS number, EC number and/or molecular formula, as well as the minimum, maximum and typical concentration, in the appropriate fields in IUCLID section 1.2.

The Registrant shall ensure that the compositional information is verifiable and therefore supported by a description of the analytical methods used for the identification and quantification of each constituent required to be reported, as specified under Annex VI section 2.3.7. of the REACH Regulation. The description shall be sufficient for the methods to be reproduced and shall therefore include details of the experimental protocol followed, any calculation made and the results obtained.

#### 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](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.



Geert DANCET  
Executive Director