European Chemicals Agency

Decision number: CCH-D-0000001422-85-05/F Helsinki, 30/11/2011

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

for Camphene, CAS 79-92-5 (EC Nr. 201-234-8), 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 **Camphene**, CAS 79-92-5 (EC Nr. 201-234-8), submitted by [redacted] (the "Registrant"), latest submission number [redacted], for 10-100 tonnes per year.

The compliance check was initiated on 28 September 2010.

On 17 January 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 15 February 2011 the Registrant provided to ECHA comments on the draft decision. Based on the information provided by the Registrant ECHA decided not to amend the draft decision because no update to the dossier had been received.

On 29 July 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 submitted proposals for amendment to the draft decision.

On 31 August 2011 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 within 30 days of the receipt of the notification. Based on the proposed amendments, ECHA decided to modify its draft decision.

The Registrant did not provide any comments on the proposed amendments.

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On 12 September 2011, the draft decision was referred to the Member State Committee.

After discussion in the Member State Committee meeting on 2-4 November 2011, the Member State Committee amended the modified draft decision and a unanimous agreement of the Member State Committee on the amended and modified draft decision was reached on 3 November 2011.

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:

    - Information related to substance identity, gas chromatogram, high pressure liquid chromatogram including integration data (Annex VI, 2.3.6.) or any other valid and appropriate method for camphene, low tricyclene.

2) Pursuant to Articles 41(1)(a), 41(3) and Annex VII of the REACH Regulation the Registrant shall submit the information using the test method as indicated below:

    - Growth inhibition study aquatic plants (algae preferred) (Annex VII, 9.1.2.; EU method C.3)
    - *In vitro* gene mutation study in mammalian cells (Annex VIII, 8.4.3.); EU method B.10.
    - Short-term toxicity testing on invertebrates (Annex VII, 9.1.1); EU method C.2.

3) Pursuant to Articles 41(1)(c), 41(3), 10(b) and 14 as well as Annex I of the REACH Regulation, the Registrant shall submit and update for the registered substance:
    - Exposure assessment (exposure scenarios and exposure estimation) and risk characterisation for all life cycle stages (including manufacturing)
    - Risk characterisation for flammability

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 **30/11/2012**.

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/or with Annexes I, III, VI, VII, VIII, 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

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VI, Section 2 lists information requirements that shall be sufficient to identify the registered substance.

A description of the quantitative analytical methods as required by Annex VI point 2.3.7 of the REACH Regulation has not been submitted for composition: "Camphene, lowtricyclene, solid" given in section 1.2 of the IUCLID dossier.

A description of the quantitative analytical methods and the results thereof for composition: "Camphene, lowtricyclene, solid" shall be provided. The submitted data need to include adequate quantification/integration results in order to prove the registered composition.

The Registrant is thus requested to update the dossier accordingly.

2) Missing information related to endpoints

Pursuant to Articles 10(a)(vi), 12(1)(a) and (b) of the REACH Regulation, a registration for a substance produced in quantities of 10 – 100 tonnes per year shall contain as a minimum the information specified in Annex VII and VIII of the REACH Regulation.

The technical dossier did not contain adequate information on the following endpoints:

- **A Growth inhibition study aquatic plants (algae preferred) is required by REACH Regulation Annex VII, 9.1.2.**
  The Registrant has provided two studies in the dossier on this endpoint. In both cases the Registrant claims that the concentration at the beginning of the test was [redacted] from nominal concentration due to low water solubility and high vapour pressure of the substance, no reference substance has been used and a concentration-effect relationship could not be established. Therefore the Registrant considered the studies not to be reliable and not fulfilling the validity criteria of the EU Method C.3.

- **An *in vitro* gene mutation study in mammalian cells is required by REACH Regulation Annex VIII, 8.4.3.**
  The Registrant has provided a study for 5-ethylidene-2-norbornene (CAS 16219-75-3) as a key study, but has submitted no *in vitro* gene mutation study conducted with the registered substance, i.e., the Registrant has therefore adapted the requirement in Annex VIII, 8.4.3. on the basis of Annex XI section 1.5., performing a read-across of the registered substance with 5-ethylidene-2-norbornene. The Registrant uses as the hypothesis for the analogue approach an assumption that the source substance 5-ethylidenebicyclo[2.2.1]hept-2-ene share the same organic functional group (cycloalkene), thus basing the read across on point 1 of Annex XI section 1.5.

  The hypothesis given by the Registrant for the analogue approach is not appropriate because none of the criteria given in Annex XI 1.5. are fulfilled. Camphene does not contain cycloalkene as a functional group as the Registrant claims, but rather a cycloalkane. The analogue approach to cycloalkene 5-ethylidene-2-norbornene is therefore rejected because the data currently provided is not considered sufficient to cover the requirement in Annex VIII 8.4.3. (*In vitro* gene mutation study).

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The Registrant is requested to update the dossier with an *in vitro* gene mutation study in mammalian cells using the registered substance. The study is to be conducted using EU method B.17.

- **A short-term toxicity study on invertebrates is required by REACH Regulation Annex VII, 9.1.1. Preferred species is *Daphnia*.**
  The Registrant has provided one study in the dossier on short term acute toxicity in invertebrates. According to the study summary in the dossier the test method was according to US EPA (1975) "Methods for acute toxicity tests with fish, macro invertebrates and amphibians". However, the registrant states that the study is unreliable because there was no evidence that test substance concentration had been maintained throughout the test period.

  The Registrant has submitted a justification for data waiving concerning the conduct of this study. The Registrant refers to the column 2 of REACH Annex VII, 9.1.1, which states that the study does not need to be conducted if adequate information for environmental classification and labelling is available.

  The Registrant bases his self-classification on an acute fish toxicity study which has an LC50 lower than 1 mg/l.

  Under Directive 67/548/EEC the substance is self-classified N; R50/53 "Dangerous for the environment; Very toxic to aquatic organisms, may cause long-term adverse effects in the aquatic environment".

  Under the CLP Regulation 1272/2008 the substance is self-classified "Hazardous to the Aquatic Environment, Acute Category 1 H400: Very toxic to aquatic life". For aquatic chronic toxicity the classification is "Aquatic Chronic 1 H410: Very toxic to aquatic life with long lasting effects", with an M-factor (chronic) 1. No M-factor has been derived for the acute effects. The Registrant has considered this as sufficient information for classification.

  While the hazard phrase of the classification for aquatic toxicity is already the maximum possible under the CLP regulation, a study with invertebrates may still have an impact on the M-factor (acute) which is essential information for the correct classification of mixtures. Moreover, toxicity information on a potentially more sensitive species (aquatic invertebrates) can also have implications on the risk assessment, that is, the derivation of PNEC.

  Therefore, the Registrant is requested to update the dossier with the result of an acute immobilisation study in Daphnia SP using the registered substance. The study is to be conducted using EU method C.2 which is equivalent to the OECD TG 202 (2004). Adaptation of the data requirement may be considered if a reliable QSAR-prediction within the applicability domain of a valid QSAR model in accordance with REACH Annex XI, 1.3 is submitted.

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3) Missing information related to Chemical Safety Report

- **Exposure assessment (generation of exposure scenarios and exposure estimation) and risk characterisation for all life cycle stages (including manufacturing) is required by the REACH Regulation, Articles 10(b) and 14(4) and Annex I Section 5.**

  The registered substance is self-classified by the Registrant as Flammable solid 2, Eye Irritant, Category 2 and Very toxic to aquatic life with long lasting effects (Aquatic Acute category 1) in accordance to Regulation (EC) No 1272/2008. From 1 December 2010, Article 14(4) of the REACH Regulation will include this classification.

  According to Articles 10(b) and 14(4) of the REACH Regulation, an exposure assessment and risk characterisation shall be included in the chemical safety assessment if the substance meets the criteria for classification as dangerous under Directive 67/548/EEC (from 1 December 2010, replaced by the criteria for the hazard classes and/or categories specified in Article 58(1) of Regulation (EC) No 1272/2008) or the PBT/vPvB criteria according to Annex XIII to the REACH Regulation.

  In addition, Annex I, Section 5 of the REACH Regulation requires the Registrant to generate exposure scenarios and exposure estimations for the registered substance. The exposure assessment shall consider all stages of the life-cycle of the substance resulting from the manufacture and identified uses and shall cover any exposures that may relate to the identified hazards.

  Deficiencies in the dossier

  The technical dossier (including the chemical safety report (CSR)) did not cover the manufacturing life cycle stage and the available information on exposure scenarios and exposure estimation were not detailed enough:

  a. In the CSR the manufacturing life cycle stage is not considered in exposure assessment. The Registrant has waived the exposure assessment because it functions as a Seveso II manufacturing facility. ECHA does not regard this information as relevant for not performing an exposure assessment for this lifecycle stage as the REACH Regulation does not contain a provision to waive the exposure assessment on the basis of Seveso II directive 96/82/EC. Therefore the Registrant is requested to generate exposure scenarios and provide exposure estimation together with risk characterisation for manufacturing life cycle stage and to update the CSR accordingly.

  b. The available exposure scenarios are not detailed enough, e.g., no tonnages are given for the exposure scenarios and no information on operational conditions/risk management measures in place has been provided in the CSR. Pursuant to Articles 10(b) and 14(4) as well as Annex I, Section 5.1.1. of the REACH Regulation, generated exposure scenarios shall cover in particular a description of the

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operational conditions and risk management measures applied to reduce or avoid direct and indirect exposure to humans and the different environmental compartments to the substance. Therefore, the Registrant is requested to update the developed exposure scenarios according to Annex I to REACH Regulation together with description of the operational conditions and risk management measures, for all developed scenarios and to update the CSR accordingly.

c. In the CSR, the assumptions for environmental exposure estimation are not justified. In cases where the default release values from environmental release categories (ERCs) has not been used for calculations, the Registrant needs to justify the use of alternative release values. Annex I Section 5.2.4. sets out the information that has to be taken into account when performing exposure estimation. The Registrant is accordingly requested to update exposure estimation together with risk characterisation calculations for all exposure scenarios according to Annex I to REACH Regulation and to update the CSR accordingly or provide a more robust justification for its current calculations.

- **Risk characterisation for flammability**

a. The Registrant has self-classified the substance as highly flammable. Pursuant to Articles 41(1)(a), 41(3), 14(1), 14(3), 14(4) and Annex I, of the REACH Regulation a risk characterisation for human health of the physico-chemical properties in the Chemical Safety Report (Article 14(4)(b) and Annex I, sections 2 and 6.3) has to be submitted if the substance is classified. However, no risk characterisation is conducted for this endpoint, i.e. the risk characterisation for human health of the physico-chemical properties. The Registrant is accordingly requested to upgrade the CSR for the endpoint flammability.

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 1907/2008 adapted to the technical progress by Commission Regulation (EC) No 761/2009 and use the applicable test methods to generate the information on the endpoints indicated above.

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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. The procedure is described in the Board of Appeal's "Preliminary instructions to Appellants" that can be found at the ECHA website. 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,

Director of Regulatory Affairs

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