EUROPEAN CHEMICALS AGENCY

Decision number: CCH-D-2114307091-66-01/F Helsinki, 9 September 2015

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

For 2-(2-(4-methyl-3-cyclohexen-1-yl)propyl)cyclopentanone, CAS No 95962-14-4 (EC No 404-240-0), 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 2-(2-(4-methyl-3-cyclohexen-1-yl)propyl)cyclopentanone, CAS No 95962-14-4 (EC No 404-240-0), submitted by [redacted] (Registrant).

The scope of this compliance check decision is limited to the standard information requirements of Annex VI, Section 2 of the REACH Regulation.

This decision is based on the registration as submitted with submission number [redacted], for the tonnage band of 1 to 10 tonnes per year. This decision does not take into account any updates after the deadline for updating (15 March 2015) communicated to the Registrant by ECHA on 6 February 2015.

The Registrant notified the substance pursuant to the national legislation implementing Directive 67/548/EEC relating to the classification, packaging and labelling of dangerous substances (as amended) by submitting a notification to the Competent Authority of the [redacted] in accordance with Article 7 of Directive 67/548/EEC. The notification number allocated was [redacted]. Article 24(1) of the REACH Regulation provides that the notification is regarded as a registration and ECHA has assigned a registration number.

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 6 October 2014.

On 14 November 2014 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 22 December the Registrant did not provide any comments on the draft decision.

On 11 June 2015 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 for amendment of the draft decision within 30 days of the receipt of the notification.

As no proposal for amendment was submitted, ECHA took the decision pursuant to Article 51(3) of the REACH Regulation.

II. Information required

A. Information in the technical dossier related to the identity of the substance

Pursuant to Articles 41(1), 41(3), 10(a)(ii) and Annex VI, Section 2 of the REACH Regulation the Registrant shall submit the following information for the registered substance subject to the present decision:

1. Composition of the substance (Annex VI, Section 2.3.);
2. Information on optical activity and typical ratio of (stereo) isomers (if applicable and appropriate) (Annex VI, Section 2.2.2.);
3. The description of the analytical methods or the appropriate bibliographical references for the identification of the substance (Annex VI, 2.3.7.).

B. Deadline for submitting the required information

Pursuant to Articles 41(4) and 22(2) of the REACH Regulation the Registrant shall submit to ECHA by **16 December 2015** an update of the registration dossier containing the information required by this decision.

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 requirements.

A. Information in the technical dossier related to the identity of the substance

Pursuant to Article 10(a)(ii) of the REACH Regulation, the technical dossier shall contain information on the identity of the substance as specified in Annex VI, Section 2 of the REACH Regulation. In accordance with Annex VI, Section 2 the information provided shall be sufficient to enable the identification of the registered substance. Provision of adequate information on the identification of the registered substance, and in particular on the composition (including information on the ratio of stereoisomers), was already a requirement under Directive 67/548/EEC as amended by Directive 92/32/EEC.

1. Composition of the substance

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 cornerstone of all the REACH obligations.

ECHA notes that the registration does not contain information that is sufficient for establishing the complete composition of the registered substance, as required under Annex VI, Section 2.3. of the REACH Regulation. More specifically, ECHA notes that the minimum concentration value ([redacted]%) specified for the group of consituents reported in Section 1.2 of the IUCLID file indicates that up to [redacted]% (w/w) of the composition of the registered substance is not accounted for. The Registrant did not report the presence of any impurity in the composition. ECHA can therefore not verify that all individual impurities required to be identified have been reported in the composition of the registered substance.

The Registrant is accordingly requested to complete the above information on the composition of the registered substance provided in the registration dossier for ECHA to have a complete chemical representation of what the substance consists of.

Regarding how to report the composition of the registered substance in IUCLID, the following applies: the Registrant shall report individually any 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 Section 1.2 of the IUCLID dossier.

2. Information on optical activity and typical ratio of (stereo) isomers;

The name and identifiers provided for the registered substance correspond to a substance containing three stereogenic centers covering eight different stereoisomers. However, ECHA notes that the Registrant did not provide any information on the ratio of stereoisomers present in the composition of the substance, as required under Annex VI, Section 2.2.2. of the REACH Regulation. More specifically, ECHA observes that the the group of constituents corresponding to 2-(2-(4-methyl-3-cyclohexen-1-yl)propyl)cyclopentanone reported in the composition of the registered substance presents stereogenic centers. ECHA considers that information on the ratio of (stereo) isomers is necessary to allow unambiguous identification of the registered substance . Nevertheless this information is missing from the registration.

The Registrant is therefore requested to specify the identity and typical ratio of the different stereoisomers of 2-(2-(4-Methyl-3-cyclohexen-1-yl)propyl)cyclopentanone.

Regarding how to report the information on the ratio of stereoisomers in IUCLID, the following applies: The Registrant shall report the chemical name and the corresponding typical ratio of the different stereoisomers present in the registered substance in the Remarks field under the reference substance assigned in IUCLID section 1.2 of the registration dossier.

The Registrant shall ensure that the IUPAC name and the molecular and structural information assigned in IUCLID section 1.1 for the registered substance are consistent with the identity of the main stereoisomers present in the composition. The Registrant shall also ensure that the information on the stereochemistry is verifiable and therefore supported by a description of the analytical methods used for the quantification, as required under Annex VI section 2.3.7. of the REACH Regulation.

3. The description of the analytical methods

The technical dossier does not contain any details on the analytical methods used for the identification and quantification of the different stereoisomers present in the composition of the registered substance, as required pursuant to Annex VI, Section 2.3.7 of the REACH Regulation.

The Registrant is therefore requested to provide the necessary description of the analytical methods for the identification of the registered substance. The information shall be sufficient for the methods to be reproduced and shall therefore include complete details of the experimental protocol followed, the calculation made and the results obtained.

ECHA would like to underline that, if the complexity of the composition of the substance hinders the appropriate identification and quantification of such constituents, considerations on the starting materials and manufacturing process applied can be used for predicting the

composition and deriving the requested information.This information should be attached in IUCLID section 1.4 of the registration dossier.

The Registrant shall provide any information that is suitable and appropriate to meet the above-mentioned objectives.

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://www.echa.europa.eu/regulations/appeals. The notice of appeal will be deemed to be filed only when the appeal fee has been paid.

Authorised[1] by Claudio Carlon, Head of Unit, Evaluation

[1] As this is an electronic document, it is not physically signed. This communication has been approved according to ECHA's internal decision-approval process.