EUROPEAN CHEMICALS AGENCY

Decision number: CCH-D-2114324394-53-01/F Helsinki, 20 April 2016

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

For A mixture of: 4-(2,2,3-trimethylcyclopent-3-en-1-yl)-1-methyl-2-oxabicyclo[2.2.2]octane; 1-(2,2,3-trimethylcyclopent-3-en-1-yl)-5-methyl-6-oxabicyclo[3.2.1]octane; spiro[...], EC No 422-040-1 (CAS No 426218-78-2), 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 A mixture of: 4-(2,2,3-trimethylcyclopent-3-en-1-yl)-1-methyl-2-oxabicyclo[2.2.2]octane; 1-(2,2,3-trimethylcyclopent-3-en-1-yl)-5-methyl-6-oxabicyclo[3.2.1]octane; spiro[...], EC No 422-040-1 (CAS No 426218-78-2), submitted by [redacted] (Registrant).

This decision is based on the registration as submitted with submission number [redacted], for the tonnage band of 10 to 100 tonnes per year.

This decision does not take into account any updates after the date when the draft decision was notified to the Registrant under Article 50(1) of the REACH Regulation.

The substance subject to the present decision is provisionally listed in the Community rolling action plan (CoRAP) for start of substance evaluation in 2016.

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 21 August 2015.

On 11 September 2015 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 19 October 2015 the Registrant did not provide any comments on the draft decision to ECHA.

The Registrant updated his registration after the expiry of the deadline for updating mentioned above, and therefore too late in the decision making process for being considered. If still relevant, the dossier update will be considered by ECHA in line with its follow up process after the deadline established in the present decision has passed.

On 21 January 2016 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:

Name or other identifier of the substance (Annex VI, Section 2.1.)

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 **27 July 2016** 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.

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.

Name or other identifier of the substance (Annex VI, Section 2.1.)

"Name or other identifier of the substance" is an information requirement as laid down in Annex VI, Section 2.1. of the REACH Regulation. The name and other identifiers are used to identify the substance in an unambiguous manner and are therefore fundamental for substance identification.

The Registrant identified the substance with the EC entry 422-040-1. The EC name (*A mixture of: 4-(2,2,3-trimethylcyclopent-3-en-1-yl)-1-methyl-2-oxabicyclo[2.2.2]octane; 1-(2,2,3-trimethylcyclopent-3-en-1-yl)-5-methyl-6-oxabicyclo[3.2.1]octane; spiro[cyclohex-3-en-1-yl-[(4,5,6,6a-tetrahydro-3,6',6',6'a-tetramethyl)-1,3'(3'aH)-[2H]cyclopenta[b]furan]; spiro[cyclohex-3-en-1-yl-[4,5,6,6a-tetrahydro-4,6',6',6'a-tetramethyl)-1,3'(3'aH)-[2H]cyclopenta[b]]furan]*) associated to this entry covers the following group of isomers as main constituents:

[redacted]

The Registrant also provided a IUPAC name ([redacted] covering the following main constituents:

[redacted]

ECHA notes that the IUPAC name reflects the main constituents that are reported in the technical registration dossier for the composition of the substance.

ECHA also notes that the Registrant provided a document [redacted] justifying the differences between the EC and IUPAC name. Based on that document and on the other information provided in the dossier ECHA observes that:

- The Registrant claims and supports with gas chromatogram (GC) data that the substance has remained unchanged and still contains the same constituents in similar proportions as during the time of the original notification (98-11-0152) under Directive 67/548/EEC.

- The Registrant states that the assignment of structures to certain constituents has changed due to progress in analytical techniques. Specifically the group "isomer III" reported in the EC name as constituents 3 and 4 has been found to contain also constituents of different structure now reported as impurities [redacted] in the registration dossier. Of the constituents reported in the EC name as constituents 3 one isomer is now reported as constituent 2 in the IUPAC name whereas its enantiomer is considered as impurity [redacted] in the registration dossier. The constituents 4 in the EC name are not part of the composition in the registration dossier.

- The constituent "isomer II" reported in the EC name as constituent 2 has been reported as separate enantiomers in the IUPAC name of the registration dossier (constituents 1 and 3).

- The Registrant does not claim that the structure of the constituent reported in the EC name as constituent 1 has changed but still this substance is neither described by any of the main constituents mentioned in the IUPAC name nor by any of the reported impurities. (note that a related constituent is reported as constituent 4 in the IUPAC name)

- The constituent reported in the IUPAC name as constituent 4 is not described in the EC name. In the document ("[redacted]") this constituent is identified with a name and structural formula that are consistent with the name reported in the IUPAC field. However, the constituent is at the same time identified as one of the isomers covered by the CAS number (142169-46-8) which corresponds to constituent 1 (group of isomers) in the EC name, which has a different identity from the reported name and structural formula. Moreover in the document ([redacted], the annotated chromatograms are labelled with structural formula corresponding to the same group of constituents covered by the reported CAS number. Additionally, from the manufacturing process description provided in section 3.1 of the IUCLID file, this constituent would not be expected to be a product of the described reaction. More specifically, the locations of [redacted] and [redacted] substituents would not be possible to obtain starting from the reported starting materials.

The EC name provided at this stage is not appropriate to describe the substance as it covers one constituent now considered to be an impurity (the 1R isomer of constituent 3 in the EC name) and two groups of isomers (constituents 1 and 4in the EC name) that apparently are not present in the composition of the substance. Additionally, the provided EC name does not cover one of the main constituents reported in the composition (constituent 4 in the IUPAC name). Furthermore, the identity of the constituent 4 described in the IUPAC name is not clear, as its identity through the dossier is not consistent.

The Registrant is therefore requested to clarify the identity of the substance, to clarify the inconsistencies related to constituent 4 in the IUPAC name and to revise accordingly the EC and IUPAC name. Special attention should be given to the correctness of the reported constituents, the completeness of the justification how EC name and IUPAC name given in the current registration dossier correspond to each other and the consistent identification of constituents throughout the dossier.

The Registrant shall ensure that the information reported is consistent throughout the dossier.

For technical reasons the Registrant is requested at this stage, not to remove or revise the EC name in the updated dossier. To revise the EC name the Registrant shall indicate, in the "Remarks" field of the reference substance in IUCLID section 1.1, the following: "The EC name "*A mixture of: 4-(2,2,3-trimethylcyclopent-3-en-1-yl)-1-methyl-2-oxabicyclo[2.2.2]octane; 1-(2,2,3-trimethylcyclopent-3-en-1-yl)-5-methyl-6-oxabicyclo[3.2.1]octane; spiro[cyclohex-3-en-1-yl-[(4,5,6,6a-tetrahydro-3,6',6',6'a-tetramethyl)-1,3'(3'aH)-[2H]cyclopenta[b]furan]; spiro[cyclohex-3-en-1-yl-[4,5,6,6a-tetrahydro-4,6',6',6'a-tetramethyl)-1,3'(3'aH)-[2H]cyclopenta[b]]furan]*" currently assigned does not specifically correspond to the registered substance. This identifier cannot be modified or deleted at this stage in the present registration update for technical reasons". The Registrant shall also specify, in the same "Remarks" field, any available and appropriate name for the substance (e.g IUPAC name) and a reference to the justification document attached to the dossier.

Further technical details on how to report the identifiers of well-defined substances in IUCLID are available in paragraph 2 of the Data Submission Manual – Part 18: How to report the substance identity in IUCLID 5 for registration under REACH (version: 2.0, July 2012) on the ECHA website.

Any document to justify the correspondence between EC name and IUPAC name shall be attached to section 1.4 ("Analytical information") of the registration dossier.

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[2] by Ofelia Bercaru, Head of Unit, Evaluation E3

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