EUROPEAN CHEMICALS AGENCY

Decision number: CCH-D-2114308150-69-01/F Helsinki, 4 September 2015

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

For Reaction mass of (2S-cis)-tetrahydro-4-methyl-2-(2-methyl-1-propenyl)-2H-pyran and Tetrahydro-4-methyl-2-[...], List No 939-429-1, 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 for Reaction mass of (2S-cis)-tetrahydro-4-methyl-2-(2-methyl-1-propenyl)-2H-pyran and Tetrahydro-4-methyl-2-[...], List No 939-429-1, 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 100 to 1000 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.

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 23 May 2014.

On 16 April 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.

On 22 April 2015 ECHA received comments from the Registrant on the draft decision.

The ECHA Secretariat considered the Registrant's comments.

The information is reflected in the Statement of Reasons (Section III) whereas no amendments to the Information Required (Section II) were made.

On 23 July 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.), as specified under section III. (1) below; and
2. Name or other identifier of the substance (Annex VI, Section 2.1.), as specified under section III. (2) below.

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 **11 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.

C. 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.

(1) Composition of the substance (Annex VI Section 2.3.)

Annex VI, section 2.3. of the REACH Regulation requires that each registration dossier contains sufficient information for establishing the composition of the registered substance and therefore its identity.

ECHA notes that the Registrant identified the registered substance as a multi-constituent substance. In line with paragraph 4.2 of the Guidance for identification and naming of substances under REACH and CLP, referred to hereinafter as "the Guidance", multi-constituent substances are well-defined substances in which more than one constituent is present at a concentration >10% (w/w) and <80% (w/w), referred to hereinafter as "main constituent". Multi-constituents substances with other main constituents shall be regarded as different substances under REACH.

In line with of the Guidance, 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 ≥ 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.

ECHA notes that the composition reported in section 1.2 of the registration dossier specifies for three of the reported main constituents the following concentration levels as ranges:

Constituent	Concentration values
(2S-cis)-tetrahydro-4-methyl-2-(2-methyl-1-propenyl)-2H-pyran)	[redacted] %(w/w)
Tetrahydro-4-methyl-2-(2-methylpropen-1-yl)pyran (2R,4R)	[redacted] % (w/w)
(Tetrahydro-4-methyl-2-(2-methylpropen-1-yl)pyran (2S,4S)	[redacted] % (w/w)

The Registrant did not provide information on the typical concentration levels of the constituents present in the substance composition.

ECHA observes that the concentration ranges reported are wide and that the minimum concentration values reported indicate that the dossier covers also compositions presenting especially low content in the above-mentioned constituents. Therefore in principle, the composition information provided may cover substances having other main constituents.

In addition the missing information on the typical concentration levels prevents any further assessment to identify the actual composition of the substance.

It follows that the Registrant did not provide appropriate information on the composition of the registered substance.

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

Information on the typical concentration levels of the constituents required to be reported shall be provided. The Registrant shall state the lower and upper concentration levels more precisely to ensure that it is accurate and reflects the composition of the substance actually manufactured. The Registrant shall revise the information given on the composition of the registered substance to ensure that it is consistent with its chemical name and identifiers.

Regarding how to report the composition in IUCLID, the Registrant shall report the minimum, maximum and typical concentration, in the appropriate fields in IUCLID section 1.2.

The Registrant shall delete from the registration any information (including analytical data) referring to different substances than the substance which is the subject of this registration.

In his comments on the draft decision the Registrant agreed to update the dossier as requested. ECHA has not amended the draft decision.

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

Annex VI, section 2.1. of the REACH Regulation requires that each registration dossier includes appropriate chemical name and other identifiers such as EC and CAS entries when available.

ECHA notes that the Registrant provided the chemical name "Reaction mass of (2S-cis)-tetrahydro-4-methyl-2-(2-methyl-1-propenyl)-2H-pyran and Tetrahydro-4-methyl-2-(2-methylpropen-1-yl)pyran (2R,4R) and Tetrahydro-4-methyl-2-(2-methylpropen-1-yl)pyran (2S,4S) and (2R-cis)-tetrahydro-4-methyl-2-(2-methyl-1-propenyl)-2H-pyran" for identifying the registered substance.

Such name refers to a multi-constituent substance consisting of the four isomers of Tetrahydro-4-methyl-2-(2-methylprop-1-enyl)pyran and for which the following EC identifier and associated CAS identifier are available:

- EC No. 240-457-5, Tetrahydro-4-methyl-2-(2-methylprop-1-enyl)pyran
- CAS No. 16409-43-1, 2*H*-Pyran, tetrahydro-4-methyl-2-(2-methyl-1-propen-1-yl)-

ECHA notes also that in the analytical report ([redacted]) attached in section 1.4 of the IUCLID dossier, the Registrant reported CAS 16409-43-1 as corresponding to a "Mixture of all four isomers". However, the Registrant reported neither the above CAS identifier nor the above EC identifier in section 1.1 of the IUCLID dossier.

Considering that the Registrant did not provide a consistent set of available identifiers for the registered substance ECHA concludes that the given information for identifying the registered substance is not appropriate.

The Registrant is accordingly requested to clarify the identity of the registered substance by providing a consistent set of identifiers, including chemical name and appropriate EC and CAS identifiers.

If the registered substance corresponds to: Reaction mass of (2S-cis)-tetrahydro-4-methyl-2-(2-methyl-1-propenyl)-2H-pyran and Tetrahydro-4-methyl-2-(2-methylpropen-1-yl)pyran (2R,4R) and Tetrahydro-4-methyl-2-(2-methylpropen-1-yl)pyran (2S,4S) and (2R-cis)-tetrahydro-4-methyl-2-(2-methyl-1-propenyl)-2H-pyran; the Registrant shall report the corresponding CAS information : CAS 16409-43-1, 2*H*-Pyran, tetrahydro-4-methyl-2-(2-methyl-1-propen-1-yl)- in section 1.1 of the IUCLID dossier.

If the registered substance does not correspond to such name, the Registrant shall provide an appropriate CAS identifier if available. If the registered substance corresponds to a well-defined substance, a chemical name shall be derived in accordance with section 4.2 of the Guidance. The Registrant shall note that mono-constituent substances are named after the main constituent. For multi-constituent substances main constituents typically $\geq$ 10% contribute to the name.
If the manufacturing process applied results in a high varibility of the composition of the registered substance, e.g. the composition shows broad concentration ranges, ECHA considers appropriate identifying the substance as of Unknown or Variable composition, Complex reaction products or Biological materials (UVCB).

The Registrant shall derive a chemical name accordingly. Section 4.3 of the Guidance includes the naming convention set for UVCB substances. In this case, the Registrant shall also provide a description of the manufacturing process.
The description shall include clear information on the identity and ratio of the starting materials, any manufacturing step, specifications of nature of any catalyst used and the process parameters that are determinant for the composition of the registered substance, any relevant isolation and purification step. The information shall include sufficient details to understand the reasons for the variability of the composition.

In relation to the description of the manufacturing process provided in section 3.1 of the IUCLID dossier, as a note to the Registrant ECHA observes that the starting material "[redacted]" specified in the descritpion is the same substance that the Registrant has registered.

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. A description of the manufacturing process shall be indicated under the "Description" field in IUCLID section 1.1. if appropriate. A correct CAS number and CAS name shall be reported under the "CAS information" header in IUCLID section 1.1.

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.

In case when the EC identifier does not fully correspond to the registered substance, the Registrant shall not remove or modify at this stage this EC entry for technical reasons, the registration being linked to that EC entry in REACH-IT. To ensure unambiguous identification of the registered substance, the Registrant shall however indicate, in the "Remarks" field of the reference substance in IUCLID section 1.1, the following: "The List entry 939-429-1 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 should also specify, in the same "Remarks" field, any available and appropriate EC number for the substance.

The Registrant should note that ECHA has established processes, subject to certain conditions, enabling registrants to adapt the EC identifier of an existing registration, while maintaining the regulatory rights already conferred to the substance concerned. Should the Registrant consider that the EC identifier provided in his dossier should be adapted to cover a different substance or if it actually covers several other substances, he is thus encouraged to contact ECHA for a possible adaptation of the registration.

Finally, the Registrant shall ensure that appropriate and consistent identifiers are used throughout the registration whenever reference to the specific substance which is the subject of this registration is made.

In his comments on the draft decision the Registrant agreed to update the dossier as requested. ECHA has not amended the draft decision.

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 Guilhem de Seze, 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.