EUROPEAN CHEMICALS AGENCY

Decision number: CCH-D-2114306459-47-01/F Helsinki, 27 July 2015

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

For 1,4-Dioxane-2,5-dione, 3,6-dimethyl-, (3R,6R)-, CAS No 13076-17-0 (EC No 603-436-5), 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 1,4-Dioxane-2,5-dione, 3,6-dimethyl-, (3R,6R)-, CAS No 13076-17-0 (EC No 603-436-5), submitted by [redacted] (Registrant).
The scope of this compliance check decision is limited to the standard information requirement of Annex VII, Section 7.8. of the REACH Regulation. ECHA stresses that it has not checked the information provided by the Registrant for compliance with requirements regarding the identification of the substance (Section 2 of Annex VI).

This decision is based on the registration as submitted with submission number [redacted], for the tonnage band of 1000 tonnes or more per year. This decision does not take into account any updates after the date (20 March 2015) 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 12 December 2014.

On 20 March 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 24 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 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

Pursuant to Articles 41(1), 41(3), 10(a)(vi), 12(1)(e), 13 and Annex VII of the REACH Regulation the Registrant shall submit the following information using the indicated test method and the registered substance subject to the present decision:

- Partition coefficient n-octanol/water (Annex VII, Section 7.8.; using an appropriate test method).

Note for consideration by the Registrant:

The Registrant may adapt the testing requested above according to the specific rules outlined in Annexes VI to X and/or according to the general rules contained in Annex XI of the REACH Regulation. In order to ensure compliance with the respective information requirement, any such adaptation will need to have a scientific justification, referring to and conforming with the appropriate rules in the respective Annex, and an adequate and reliable documentation.

Failure to comply with the request(s) in this decision, or to fulfil otherwise the information requirement(s) with a valid and documented adaptation, will result in a notification to the Enforcement Authorities of the Member States.

A. 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 **3 February 2016** an update of the registration dossier containing the information required by this decision[, including, where relevant, an update of the Chemical Safety Report].

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.

Pursuant to Articles 10(a)(vi) and/or (vii), 12(1)(e) of the REACH Regulation, a technical dossier for a substance manufactured or imported by the Registrant in quantities of 1000 tonnes or more per year shall contain as a minimum the information specified in Annex VII of the REACH Regulation.

"Partition coefficient n-octanol/water" is a standard information requirement as laid down in Annex VII, Section 7.8. of the REACH Regulation. Adequate information on this endpoint needs to be present in the technical dossier for the registered substance to meet this information requirement.

The technical dossier contains data for this standard information requirement, which according to the information provided by the Registrant meets Klimisch criterion 4 only and is therefore not reliable. The Klimisch criterion is a system to assess the reliability of data as laid out in the Guidance on information requirements and chemical safety assessment Chapter R.4: Evaluation of available information, Section R.4.2. (Version of December 2011).
ECHA concludes that the Registrant has not provided any reliable data and has therefore not fulfilled the standard information requirement of Section 7.8. of Annex VII of the REACH Regulation. He has neither made an adaptation to the standard information requirement.

As explained above, the information available on this endpoint for the registered substance in the technical dossier does not meet the information requirement. Consequently there is an information gap and it is necessary to provide information for this endpoint.

In the comments to the draft decision, the Registrant agreed with the information requirement in the draft decision. In addition, he indicated his intention to address the information requirement in an update of the registration dossier by 31 August 2015 (This date is the specified deadline of a decision issued to the Registrant on 23 February 2015 on the same registration dossier).

The Registrant outlined in the comments to the draft decision how he could address the information requirement by stating that *"for the substance in question the registrant is already obliged to submit a dossier update due to the final decision number CCH-D-21 14292041-59-01/F (issued 23 February 2015), addressing the endpoints "vapour pressure", Annex VII, Section 7.5, and "hydrolysis", Annex VIII, Section 9.2.2.1. A corresponding dossier update will be submitted by the specified deadline (31 August 2015) at the latest. The registrant intends to make use of the possibilities of adaptation of data requirements as provided by the REACH Regulation and as explicitly advised in the aforementioned final decision of 23 February 2015. Adaptation of information requirements is also feasible in the case of the partition coefficient, subject to the current draft decision: A fully documented QSAR calculation is considered to be suitable for fulfilling this information requirement. Therefore, instead of submitting several dossier updates due to several ECHA-decisions in sequence we propose to include updated information on the partition coefficient already in the upcoming dossier update, needed as a result of final decision number CCH-D-21 14292041-59-01/F. The current draft decision could then be considered as obsolete"*.

ECHA notes that as stated above in section II under "Note for consideration by the Registrant", the Registrant may adapt the testing requested above according to the general rules contained in Annex XI of the REACH Regulation.

The Registrant is reminded that this decision does not take into account any updates submitted after 20 March 2015. All the new information in the later update(s) of the registration dossier will however be assessed for compliance with the REACH requirements in the follow-up evaluation, for this decision, pursuant to Article 42 of the REACH Regulation.

Therefore, pursuant to Article 41(1) and (3) of the REACH Regulation, the Registrant is requested to submit the following information derived with the registered substance subject to the present decision: Partition coefficient n-octanol/water. Guidance for determining appropriate test methods for the partition coefficient n octanol/water is available in the ECHA Guidance on information requirements and chemical safety assessment (version 2.2., August 2013), Chapter R.7a, Section R.7.1.8.3.

IV. Adequate identification of the composition of the tested material

ECHA stresses that the information submitted for identifying the substance has not been checked for compliance with the substance identity requirements set out in Section 2 of Annex VI of the REACH Regulation. The Registrant is reminded of his responsibility to ensure that his registration covers one substance only and that the substance is correctly identified in accordance with Annex VI, Section 2 of the REACH Regulation.

In carrying out the study required by the present decision it is important to ensure that the particular sample of substance tested is appropriate to assess the properties of the registered substance, taking into account any variation in the composition of the technical grade of the substance as actually manufactured. If the registration of the substance covers different grades, the sample used for the new study must be suitable to assess these.

Furthermore, there must be adequate information on substance identity for the sample tested and the grade(s) registered to enable the relevance of the study to be assessed.

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. 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 Ofelia Bercaru, 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.