EUROPEAN CHEMICALS AGENCY

Decision number: CCH-D-0000004054-83-06/F Helsinki, 18 September 2014

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

For isopentyl acetate, CAS No 123-92-2 (EC No 204-662-3), 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 isopentyl acetate, CAS No 123-92-2 (EC No 204-662-3), submitted by [redacted] (Registrant). The scope of this compliance check is limited to the standard information requirement of Annex VIII, Section 9.2.2.1. of the REACH Regulation. ECHA stresses that it has not checked the information provided by the Registrant and other joint registrants 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 submitted after 6 March 2014, the date upon which ECHA notified its draft decision to the Competent Authorities of the Member States pursuant to Article 51(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 30 July 2013.

On 14 October 2013 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 12 November 2013, 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 6 March 2014 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 amendmends of the draft decision within 30 days of the receipt of the notification.

Subsequently, a proposal for amendment to the draft decision was submitted.

On 10 April 2014 ECHA notified the Registrant of the proposal for amendment to the draft decision and invited him pursuant to Article 51(5) of the REACH Regulation to provide comments on the proposal for amendment within 30 days of the receipt of the notification.

The ECHA Secretariat reviewed the proposal for amendment received and did not amend section II of the draft decision but modified section III of the draft decision.

On 22 April 2014 ECHA referred the draft decision to the Member State Committee.

By 12 May 2014 in accordance to Article 51(5), the Registrant provided comments on the proposal for amendment. In addition, the Registrant provided comments on the draft decision. The Member State Committee took the comments on the proposal for amendment of the Registrant into account.

A unanimous agreement of the Member State Committee on the draft decision was reached on 26 May 2014 in a written procedure launched on 15 May 2014. ECHA took the decision pursuant to Article 51(6) of the REACH Regulation.

II. Information required

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

> Hydrolysis as a function of pH (Annex VIII, 9.2.2.1.; test method: Hydrolysis as a function of pH, EU C.7/OECD 111).

Pursuant to Article 41(4) of the REACH Regulation, the Registrant shall submit the information in the form of an updated registration to ECHA by **25 March 2015.**

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 requirement. In accordance with Articles 10(a)(vii) and 12(1) of the REACH Regulation, any registration for a substance manufactured or imported in quantities of 10 tonnes or more per year per manufacturer/importer shall contain information on hydrolysis as a function of pH. This is a standard information requirement as laid down in Annex VIII, Section 9.2.2.1. of the REACH Regulation.

The technical dossier contains data for this standard information requirement, containing information obtained from a quantitative structure–activity relationship model ((Q)SAR) on hydrolysis at pH = 7 and pH = 8. According to the test method used, namely Method C.7 in Commission Regulation (EC) No 440/2008, "The hydrolysis test should be performed at pH values of 4, 7 and 9" (Section 1.8.3 of the method). As the information reported in the technical dossier do not contain all the values prescribed by the method, it is not adequate to fulfil the standard information requirement.

Further, the Registrant has sought to adapt the information requirement of Annex VIII, Section 9.2.2.1. of the REACH Regulation by means of providing results from a (Q)SAR model. In accordance with Annex XI, Section 1.3. of the REACH Regulation, the conditions for this adaptation are the following:

- results are derived from a (Q)SAR model whose scientific validity has been established,
- the substance falls within the applicability domain of the (Q)SAR model,
- results are adequate for the purpose of classification and labelling and/or risk assessment, and
- adequate and reliable documentation of the applied method is provided.

In the technical dossier, there is neither a justification of the scientific validity of the (Q)SAR model nor indications that the registered substance falls witin the applicability domain of a (Q)SAR model. Furthermore, no documentation of the applied method can be found. Accordingly, the submitted data cannot be adequate for the purpose of classifcation and labelling and/or risk assessment.

Therefore, the requirements for a general adaptation to the standard testing regime based on Annex XI, Section 1.3. of the REACH Regulation were not met and the registration dossier is not compliant with the information requirement of hydrolysis as a function of pH.

ECHA notes the Registrant's intention in his comments to update the dossier with other adequate ready biodegradability data on the same substance that would have become available. The data would indicate that isopentyl acetate is readily biodegradable. However, no such update has been received.

Therefore, the Registrant is requested to provide information on the hydrolysis as a function of pH using the appropriate test method and the registered substance and to submit the resulting information.

Guidance on how to report (Q)SAR studies is available in ECHA's Guidance on information requirements and chemical safety assessment, Chapter R.6, Section R.6.1 (pages 9–66, Version of May 2008) and in ECHA's Practical Guide 5: How to report (Q)SARs.

IV. Adequate identification of the composition of the tested material

ECHA stresses that the information submitted by the Registrant and other joint registrants 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 and that of joint Registrants to ensure that the joint registration covers one substance only and that the substance is correctly identified in accordance with Annex VI, Section 2 of the REACH Regulation.

In relation to the information required by the present decision, the sample of substance used for the new study must be suitable for use by all the joint registrants. Hence, the sample should have a composition that is within the specifications of the substance composition that are given by the joint registrants. It is the responsibility of all joint registrants who manufacture or import the same substance to agree on the appropriate composition of the test material and to document the necessary information on their substance composition.

In addition, it is important to ensure that the particular sample of substance tested in the new study 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 by each registrant. If the registration of the substance by any registrant covers different grades, the sample used for the new study must be suitable to assess these grades.

Finally 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.

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Director of Evaluation