EUROPEAN CHEMICALS AGENCY

Helsinki, 25 June 2019

Addressee: [redacted]

Decision number: CCH-D-2114471001-66-01/F
Substance name: Diisopropylbenzene
EC number: 246-835-6
CAS number: 25321-09-9
Registration number: [redacted]
Submission number: [redacted]
Submission date: 26/03/2013
Registered tonnage band: 100-1000

DECISION ON A COMPLIANCE CHECK

Based on Article 41 of Regulation (EC) No 1907/2006 (the REACH Regulation), ECHA requests you to submit information on:

1. **Bioaccumulation in aquatic species (Annex IX, Section 9.3.2.; test method: Bioaccumulation in fish: aqueous and dietary exposure, OECD TG 305, [aqueous exposure] with the registered substance;**

You have to submit the requested information in an updated registration dossier by **2 April 2020**. You shall also update the chemical safety report, where relevant.

The reasons of this decision are set out in Appendix 1. The procedural history is described in Appendix 2 and advice and further observations are provided in Appendix 3.

Appeal

This decision can be appealed to the Board of Appeal of ECHA within three months of its notification. An appeal, together with the grounds thereof, has to be submitted to ECHA in writing. An appeal has suspensive effect and is subject to a fee. Further details are described under: http://echa.europa.eu/regulations/appeals.

Authorised[1] by **Claudio Carlon**, Head of Unit, Hazard Assessment

[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.

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Appendix 1: Reasons

1. Bioaccumulation in aquatic species (Annex IX, Section 9.3.2.)

In accordance with Articles 10(a) and 12(1) of the REACH Regulation, a technical dossier registered at 100 to 1000 tonnes per year must contain, as a minimum, the information specified in Annexes VII to IX to the REACH Regulation. The information to be generated for the dossier must fulfil the criteria in Article 13(4) of the same regulation.

Pursuant to Article 10(a)(vii) of the REACH Regulation, the information set out in Annex VII to XI must be provided in the form of a robust study summary. Article 3(28) defines a robust study summary as a detailed summary of the objectives, methods, results and conclusions of a full study report providing sufficient information to make an independent assessment of the study minimising the need to consult the full study report. Guidance on the preparation of the robust study summaries is provided in the Practical Guide on "How to report robust study summaries".

A Bioaccumulation in aquatic species study is a standard information requirement as laid down in Annex IX, Section 9.3.2. 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.

You have provided three endpoint study records to meet the standard information requirement of Annex IX, Section 9.3.2., namely:

- Ogata (1984). In this study you provide information from a study using goldfish as test organism, a log BCF=2.11 (BCF=129) is reported for m-diisopropylbenzene.
- Fh-ITEM (2008). In this QSAR study you provide the bioconcentration factors (BCF) of m- and p-diisopropylbenzene as calculated using EPIWIN v3.20, BCFWIN v2.17 taking into account the calculated log Kow=4.9. The calculation yielded a BCF=1194 for both isomers.
- CERI (1983). You have provided a study record for a OECD 305E Bioaccumulation: flow-through fish test conducted on the registered substance.

For the study by Ogata (1984) you assign a klimisch reliability score of 4 stating that this is an insufficiently documented study using goldfish as test organism. Annex XI, section 1.1.1 of the REACh Regulation sets out the conditions under which data can be considered equivalent to data generated by the corresponding tests methods referred to in article 13(3). ECHA agrees that the study is not sufficiently documented and hence the adequacy of the study cannot be assessed against the information requirement.

On the QSAR study, the results provide evidence of some bioaccumulation potential. Annex XI, section 1.3 of the REACh Regulation sets out the conditions under which results from QSARs may be used instead of testing. One such condition is that the results are adequate for the purpose of classification and labelling and/or risk assessment. ECHA considers that in this case the QSAR results alone are not adequate for risk assessment because the experimental data from the 1983 CERI study indicates a higher bioaccumulation potential than that indicated by the QSAR study and so the experimental data gives rise to greater concern. The results of the CERI study are sufficient to disqualify the results of the QSAR study. However, as there are critical missing elements in the reporting of the experimental CERI study, as described below, further information is needed to complete the PBT assessment.

ECHA Guidance on How to report robust study summaries, Practical Guide 3 (version 2.0 November 2012) and the ECHA Guidance on Information Requirements and Chemical Safety Assessment Chapter R.11: PBT/vPvB assessment (version 3.0, June 2017) further explain what information needs to be provided in a robust study summary.

Contrary to Article 3(28) of the REACH Regulation and what is described in the above mentioned guidances, the documentation of this CERI study is insufficient and does not allow an independent assessment of the adequacy of the study, its results and its use for hazard and PBT assessment.

In particular, the following elements are missing from your study summary: Fish lipid content, information on fish weight and growth during the conduct of the study, numbers of test fish, duration of the uptake and depuration phases, information on the analytical method and its sensitivity, information on sampling and information on temperature variation.

ECHA Guidance on Information Requirements and Chemical Safety Assessment Chapter R.11: PBT/vPvB assessment (version 3.0, June 2017) explains that for bioaccumulative substances the kinetics of bioaccumulation are slow and growth dilution may have a major impact on the bioconcentration factor (BCF). BCF K_{gL} (The lipid normalised, growth corrected kinetic bioconcentration factor) is preferred for PBT substances due to i) the slow kinetics possibly leading to non-equilibrium within the timeframe of the experimental bioaccumulation test, and especially ii) the correction for growth dilution, which is not included in the steady state BCF. The lipid normalised, growth corrected kinetic bioconcentration factor (BCF K_{gL}) is normalised to a fish with a 5% lipid content and corrected for growth during the study period as described in Annex 5 of the OECD TG 305.

ECHA notes that information on the fish lipid content and growth is critical to inform the PBT assessment given that the results of the study indicate that there is bioaccumulation potential with BCF values ranging from 546 to 3210 at 2 µg/L m-diisopropylbenzene and 512 to 2960 at 2 µg/L for p-diisopropylbenzene. ECHA understands that missing information mentioned above to complete the robust study summary is not likely to be available for this 1983 study. As noted in ECHA Guidance on Information Requirements and Chemical Safety Assessment Chapter R.11: PBT/vPvB assessment (version 3.0, June 2017) *"for older fish bioaccumulation studies, information on growth may not be available. In this case, an assessment of the likely significance of growth on the results should be made to determine what weight should be given to the study in the Weight-of-Evidence assessment."* However, you have not provided information on this in your dossier. Accordingly, ECHA considers that this study cannot fulfil the information requirement as it is not sufficient for PBT and risk assessments.

ECHA has considered all of the provided information in the context of a weight of evidence adaptation in accordance with Annex XI, section 1.2 and concludes that there is insufficient weight of evidence from the available sources of information which would allow a conclusion that the substance is not bioaccumulative. As explained above there is a concern for bioaccumulation from the CERI experimental study and the substance meets the B criterion. However, without the missing information on growth and lipid content it is not possible to conclude whether the substance would also meet the vB citerion.

As explained above, the information provided 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.

According to ECHA Guidance on information requirements and chemical safety assessment, Chapter R.7c (version 3.0, June 2017) bioaccumulation in fish: aqueous and dietary exposure (test method EU C.13. / OECD TG 305) is the preferred test to cover the standard information requirement of Annex IX, Section 9.3.2. ECHA Guidance defines further that results obtained from a test with aqueous exposure can be used directly for comparison with the B and vB criteria of Annex XIII of REACH Regulation and can be used for hazard classification and risk assessment. Comparing the results of a dietary study with the REACH Annex XIII B and vB criteria is more complex and has higher uncertainty. Therefore, the aqueous route of exposure is the preferred route and shall be used whenever technically feasible.

ECHA notes that the aqueous route of exposure is feasible given that the available OECD 305 (CERI) study from 1983 was conducted via this route.

Therefore, pursuant to Article 41(1) and (3) of the REACH Regulation, you are requested to submit the following information derived with the registered substance subject to the present decision

Bioaccumulation in fish: aqueous exposure bioconcentration fish test (test method: OECD TG 305-I)

In case you have access to the missing information as listed above to complete the robust study summary, you can also fulfill the information requirement by providing this missing information.

Notes for your consideration

ECHA notes that there are registrations for p-Diisopropylbenzene (EC 202-826-9) and also for m-Diisopropylbenzene (EC 202-773-1, also known as 1,3-diisopropylbenzene). Please be informed that a decision requesting an OECD 305 study has also been sent to the registrant for m-Diisopropylbenzene (EC 202-773-1). ECHA notes that the OECD 305 (CERI) study from 1983 was conducted on a mixture of meta and para isomers of diisopropylbenzene and that it was possible to determine BCF values for each isomer in that study. Accordingly, the registrants of the above mentioned substances can also consider to perform a single OECD 305 study on Diisopropylbenzene EC 246-835-6 (which contains both m-Diisopropylbenzene and p-Diisopropylbenzene as major consituents) to fulfil this information requirement for all of the above substances. According to Article 25 of REACH Regulation testing on vertebrate animal shall be undertaken only as a last resort. Therefore, in case the registrant for m-Diisopropylbenzene (EC 202-773-1) decides to perform the test on Diisopropylbenzene EC 246-835-6 you should discuss with the Registrants of that substance and agree on who will perform the test and how best to fulfil the information gaps for both registations.

In your comments on the draft decision you explained that you discussed with the Registrant of m-Diisopropylbenzene (EC 202-773-1) how best to fulfil the information gaps for both registrations and agreed to perform an OECD 305, bioaccumulation in fish test. You indicate that the test will be performed with aqueous exposure and on the test substance diisopropylbenzene, mixture of isomers (25321-09-9; 246-835-6).

ECHA considers this to be appropriate to address the information gap.

Appendix 2: Procedural history

For the purpose of the decision-making, this decision does not take into account any updates of your registration after the date when the draft decision was notified to you under Article 50(1) of the REACH Regulation.

The compliance check was initiated on 15 October 2018.

The decision making followed the procedure of Articles 50 and 51 of the REACH Regulation, as described below:

ECHA notified you of the draft decision and invited you to provide comments.

In your comments you agreed to the draft decision. ECHA took your comments into account and did not amend the request.

ECHA notified the draft decision to the competent authorities of the Member States for proposals for amendment.

As no amendments were proposed, ECHA took the decision according to Article 51(3) of the REACH Regulation.

Appendix 3: Further information, observations and technical guidance

1. The substance subject to the present decision is provisionally listed in the Community rolling action plan (CoRAP) for the start of substance evaluation in 2020.

2. This compliance check decision does not prevent ECHA from initiating further compliance checks on the present registration at a later stage.

3. Failure to comply with the requests in this decision will result in a notification to the enforcement authorities of your Member State.

4. In relation to the information required by the present decision, the sample of the substance used for the new tests must be suitable for use by all the joint registrants. Hence, the sample should have a composition that is suitable to fulfil the information requirement for the range of substance compositions manufactured or imported 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 the substance tested in the new tests 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 or imported by each registrant.

   If the registration of the substance by any registrant covers different grades, the sample used for the new tests must be suitable to assess these grades. Finally there must be adequate information on substance identity for the sample tested and the grades registered to enable the relevance of the tests to be assessed.