ECHA
EUROPEAN CHEMICALS AGENCY

Decision number: TPE-D-2114308976-39-01/F Helsinki, 6 October 2015

DECISION ON TESTING PROPOSAL(S) SET OUT IN A REGISTRATION PURSUANT TO ARTICLE 40(3) OF REGULATION (EC) NO 1907/2006

For 6-tert-butyl-2,4-xylenol, CAS No 1879-09-0 (EC No 217-533-1), 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 40(1) of the REACH Regulation, ECHA has examined the following testing proposal submitted as part of the jointly submitted registration dossier in accordance with Articles 10(a)(ix) and 12(1)(d) thereof for 6-tert-butyl-2,4-xylenol, CAS No 1879-09-0 (EC No 217-533-1, submitted by [redacted] (Registrant).

- Long-term toxicity to fish (OECD 210)

This decision is based on the registration dossier as submitted with submission number [redacted], for the tonnage band 100 to 1000 tonnes per year. This decision does not take into account any updates after 8 April 2015, i.e. 30 calendar days after the end of the commenting period.

This decision does not imply that the information provided by the Registrant in his registration dossier is in compliance with the REACH requirements. The decision does not prevent ECHA from initiating a compliance check on the registration at a later stage.

ECHA received the registration dossier containing the above-mentioned testing proposal for further examination pursuant to Article 40(1) on 18 April 2013.

ECHA held a third party consultation for the testing proposal from 15 July 2014 until 29 August 2014. ECHA received information from third parties (see section III below).

On 30 January 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 9 March 2015 the Registrant did not provide any comments on the draft decision to ECHA.

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.

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

On 17 July 2015 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 the draft decision.

On 27 July 2015 ECHA referred the draft decision to the Member State Committee.

By 17 August 2015 the Registrant did not provide any comments on the proposal for amendment.

A unanimous agreement of the Member State Committee on the draft decision was reached on 31 August 2015 in a written procedure launched on 20 August 2015.

ECHA took the decision pursuant to Article 51(6) of the REACH Regulation.

II. Testing required

A. Tests required pursuant to Article 40(3)

The Registrant shall carry out the following proposed test pursuant to Article 40(3)(a) and 13(4) of the REACH Regulation using the indicated test method and the registered substance subject to the present decision:

1. Fish, early-life stage (FELS) toxicity test (Annex IX, Section 9.1.6.1.; test method: Fish, early-life stage toxicity test, OECD 210);

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.

B. Deadline for submitting the required information

Pursuant to Articles 40(4) and 22(2) of the REACH Regulation, the Registrant shall submit to ECHA by **13 October 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

The decision of ECHA is based on the examination of the testing proposal submitted by the Registrant for the registered substance and scientific information submitted by third parties.

A. Tests required pursuant to Article 40(3)

1. Fish, early-life stage (FELS) toxicity test (Annex IX, Section 9.1.6.1.)

a) Examination of the testing proposal

Pursuant to Article 40(3)(a) of the REACH Regulation, ECHA may require the Registrant to carry out the proposed test.

"Long-term toxicity testing on fish" is a standard information requirement as laid down in Annex IX, Section 9.1.6. of the REACH Regulation. The information on this endpoint is not available for the registered substance but needs to be present in the technical dossier to meet the information requirements. Consequently there is an information gap and it is necessary to provide information for this endpoint.

The Registrant has submitted a testing proposal for testing the registered substance for Fish, early-life stage toxicity test, OECD 210 with the following justification: *"Due to the lack of available detail in the Japanese translated report, and the results observed, it is considered appropriate to further investigate the effects of the substance in fish in a longer term study. A further study is therefore proposed.".* ECHA considers that the proposed study is appropriate to fulfil the information requirement of Annex IX, Section 9.1.6 of the REACH regulation.

ECHA notes that in the registration dossier a long-term study on aquatic invertebrates has already been submitted. The Registrant has considered that, in addition, a long-term study on fish is necessary.

According to ECHA *Guidance on information requirements and chemical safety assessment*, Chapter R7b, (Section R.7.8.5 including Figure R.7.8-4), if based on acute aquatic toxicity data neither fish nor invertebrates are shown to be substantially more sensitive, long-term studies may be required on both. While in the case of the registered substance, long-term test on fish is neither triggered by the substance profile (the substance is soluble) nor by the CSA (all RCRs <0.2), from the short-term toxicity studies on aquatic species available in the dossier it cannot be determined whether fish or aquatic invertebrates would be substantially more sensitive.
In such case, according to the integrated testing strategy, the *Daphnia* study is to be conducted first. If based on the results of the long-term *Daphnia* study and the application of a relevant assessment factor, no risks are observed (PEC/PNEC<1), no long-term fish testing may need to be conducted. It is worth noting that the the Registrant has already provided long-term toxicity results on Daphnia, but that the Registrant still considers that a long-term toxicity test on fish is necessary.

b) Consideration of the information received during third party consultation

ECHA received third party information concerning the testing proposal during the third party consultation. For the reasons explained further below the information provided by third parties on its own is not yet sufficient to fulfil this information requirement. However it might become relevant to fulfil this information requirement if further specifications are provided by the Registrant.

The third party information obtained during the public consultation for a testing proposal on long term fish toxicity contains an ECOSAR v1.11 calculation. Result values for both, the "phenols" and "neutral organics" classes, are provided. The third party entered manually

logKow, melting point and water solubility in the software, which correspond to the values in the registration dossier.

ECHA notes that the substance is a phenol and therefore the SAR for phenols is applicable. The SAR model for phenols has a defined endpoint, the algorithm is unambiguous, the domain of applicability is characterised in terms of structure and the parameters logKow and molecular weight. The R2 is given in the help file of the software as an indication for the performance for the data set used to build the SAR, which contains 13 substances and 35 data points.

The model could, in principle, be considered as scientifically valid and applied within a weight of evidence approach. However, the data set is small and the reliability of a prediction should be checked by comparing the performance of the model with close analogues prior to the model being applied.

Overall, the Registrant could be able to use the provided information towards fulfilling the information requirement for long term fish, especially within a weight of evidence approach, provided that sufficient consideration is given to the reliability of the prediction (by submitting an adequate QMRF and QPRF) and all the requirements in Section 1.2 of Annex XI of the REACH Regulation are fulfilled.

c) Outcome

Therefore, pursuant to Article 40(3)(a) of the REACH Regulation, the Registrant is required to carry out the proposed study using the registered substance subject to the present decision: Fish, early-life stage (FELS) toxicity test (Annex IX, 9.1.6.1.; test method: Fish, early-life stage toxicity test, OECD 210).

IV. Adequate identification of the composition of the tested material

The process of examination of testing proposals set out in Article 40 of the REACH Regulation aims at ensuring that the new study meet real information needs. Within this context, the Registrant's dossier was sufficient to confirm the identity of the substance to the extent necessary for examination of the testing proposal. The Registrant must note, however, that this information, or the information submitted by other registrants of the same substance, has not been checked for compliance with the substance identity requirements set out in Section 2 of Annex VI of the REACH Regulation.

In relation to the proposed test, 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 of the same substance to agree to the test proposed (as applicable to their tonnage level) 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 appeal shall be lodged within three months of receiving notification of this decision. Further information on the appeal procedure can be found on the 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 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.