ECHA
EUROPEAN CHEMICALS AGENCY

Decision number: TPE-D-2114308971-49-01/F Helsinki, 5 October 2015

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

For 2-(2H-benzotriazol-2-yl)-4,6-bis(1-methyl-1-phenylethyl)phenol, CAS No 70321-86-7 (EC No 274-570-6), 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 registration dossier in accordance with Articles 10(a)(ix) and 12(1)(d) thereof for 2-(2H-benzotriazol-2-yl)-4,6-bis(1-methyl-1-phenylethyl)phenol, CAS No 70321-86-7 (EC No 274-570-6, submitted by [redacted] (Registrant).

- Testing proposal: bioaccumulation: aquatic/sediment (OECD 305)

This decision is based on the registration dossier 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 submitted after the deadline for updating (18 March 2015) communicated to the Registrant by ECHA on 9 February 2015.

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 10 April 2013.

ECHA held a third party consultation for the testing proposal from 15 July 2014 until 29 August 2014. ECHA did not receive information from third parties.

On 6 November 2014 ECHA sent the draft decision to the Registrant and invited him to provide comments within 30 days of the receipt of the draft decision. That draft decision was based on submission number [redacted].

On 2 December 2014 the Registrant updated his registration dossier with the submission number [redacted].

On 11 December 2014 ECHA received comments from the Registrant on the draft decision.

The ECHA Secretariat considered the Registrant's comments and update.
On basis of this information, only the deadline in Section II was amended. The Statement of Reasons (Section III) was changed accordingly.

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 amended 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:

> Bioaccumulation in aquatic species (Annex IX, Section 9.3.2.; test method Bioaccumulation in Fish: Aqueous or Dietary Exposure Bioaccumulation Fish Test, OECD 305).

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 **12 July 2017** 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.

A. Tests required pursuant to Article 40(3)

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

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.

"Bioaccumulation in aquatic species, preferably fish" is a standard information requirement as laid down in Annex IX, Section 9.3.2. 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 a bioaccumulation in aquatic species (Bioaccumulation in Fish: Aqueous and Dietary Exposure, OECD 305) with the following justification: *"The bioaccumulation potential of the substance was assessed in a weight of evidence approach using several QSAR calculations as well as one experimental study. The only available experimental result is a BCF study conducted for the Japanese authorities in 1980. The study was conducted according to OECD guideline 305. For test substance preparation a solubilizer was used. The tested concentrations of the substance were 0.1 and 1 mg/L, respectively. Because the tested concentrations are far above the actual water solubility of the substance (< 0.005 mg/L) and the additional use of a solubilizer in substance preparation the study cannot be regarded as valid. Therefore, it was not taken into account in the present weight-of-evidence approach..... In summary, in a weight-of-evidence approach balancing different QSAR estimations an accumulation of the compound in organisms is expected. However, due to the informative value of the QSARs it is not expected that the compound is above the "B" cut-off criterion of 2000.....To further clarify the bioaccumulation potential of the substance, a bioaccumulation study according to OECD guideline 305 is proposed".* ECHA considers that the proposed study is appropriate to fulfil the information requirement of Annex IX, Section 9.3.2. of the REACH regulation.

ECHA has considered the available information submitted in the technical dossier and agrees with the Registrant that the available information does not meet the conditions set out in Annex XI, Section 1.2. of the REACH Regulation i.e. the results obtained from the bioaccumulation screening do not allow an assumption/conclusion that the registered substance subject to the present decision has or has not bioaccumulation potential in aquatic species. Hence, the available data are not adequate for the purpose of classification and labelling and/or risk assessment.

In the testing proposal the Registrant has not specified whether the aqueous or dietary exposure route is to be used in the proposed OECD 305 bioaccumulation study. In their comments, however, the Registrant has expressed a preference for the aqueous exposure route using radiolabelled testing material. ECHA notes that for the selection of the appropriate exposure route for the test, the Registrant is advised to consult the OECD 305

Test Guideline and the ECHA *Guidance on information requirements and chemical safety assessment* (version 1.1., November 2012), Chapter R7c, (Section R.7.10.3) and to determine the most appropriate route of exposure accordingly.

The Registrant is reminded that this decision does not take into account any updates submitted after 18 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 pursuant to Article 42 of the REACH Regulation.

b) 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: Bioaccumulation in aquatic species, preferably fish (Annex IX, 9.3.2.; test method: Bioaccumulation in Fish: Aqueous or Dietary Exposure Bioaccumulation Fish Test, OECD 305).

Before conducting testing, the Registrant is advised to consult the ECHA Guidance on information requirements and chemical safety assessment (version 2.0, November 2014), Chapter R.11. PBT/vPvB assessment, in particular to first conclude on whether the registered substance is not persistent and not very persistent or whether it may fulfil Annex XIII of the REACH Regulation criteria of being persistent or very persistent and to consult the PBT assessment for Weight-of-Evidence determination and the integrated testing strategy for bioaccumulation assessment.

In addition, the Registrant is advised to consult the ECHA Guidance on the information requirements and chemical safety assessment (version 2.0, November 2014), Chapters R.4, 5, 6, R.7b and R.7c. Where the Registrant decides to adapt the testing requested 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, ECHA refers him to the advice provided in practical Guides 4, 5 and 6.

B. Deadline for submitting the required information

In the draft decision communicated to the Registrant the time indicated to provide the requested information was 9 months from the date of adoption of the decision. In his comments on the draft decision, the Registrant requested an extension of the timeline to 24 months. He sought to justify this request by providing evidence of the additional time needed for the preparation of the radiolabelled material (6 months) and for the execution of the test (12 months). The Registrant further provided a statement from the testing facility indicating that the 12 months estimated for execution of the test may only be applicable at present and that future increase in workload of the testing facility may extend such timing to 18 months. ECHA agrees with the additional time requested by the Registrant for the preparation of the testing material (6 months). ECHA also accepts the evidence provided by the Registrant that currently the study could be finalised within 12 months of commissioning. Nevertheless, ECHA does not agree with the forecast of the testing facility that workload may increase by the time the decision becomes final, since such statement is speculative and not supported by evidence. Therefore, ECHA has only partially granted the request and set the deadline to 21 months. This new deadline takes into consideration the time needed for preparation of the material (6 months), execution of the study (12 months) and inclusion of the new information in the technical dossier (3 months)

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 has not been checked for compliance with the substance identity requirements set out in Section 2 of Annex VI of the REACH Regulation.

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. If the registration of the substance covers different grades, the sample used for the new study must be suitable to assess these.

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

[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.