Decision number: TPE-D-2114306744-52-01/F Helsinki, 30 July 2015

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

For 2-tert-butylphenol, CAS RN 88-18-6 (EC No 201-807-2), 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 proposals submitted as part of the jointly submitted registration dossier in accordance with Articles 10(a)(ix) and 12(1)(d) thereof for 2-tert-butylphenol, CAS RN 88-18-6 (EC No 201-807-2), submitted by [redacted] (Registrant).

- 90-day oral toxicity study (OECD 408)
- Developmental toxicity / teratogenicity study (OECD 414), in the rat

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 after 8 April 2015, i.e. 30 calendar days after the end of the commenting period under Article 50(1) of the REACH Regulation.

This decision does not imply that the information provided by the Registrant in their 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 held a third party consultation for the testing proposals from 14 August 2014 until 28 September 2014. ECHA received information from third parties (see section III below).

On 29 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, ECHA did not receive comments from the Registrant on the draft decision.

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. Testing required

A. Tests required pursuant to Article 40(3)

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

1. Sub-chronic toxicity study (90-day), by oral route (Annex IX, Section 8.6.2.; test method: EU B.26/OECD 408) in rats;
2. Pre-natal developmental toxicity study (Annex IX, Section 8.7.2.; test method: EU B.31/OECD 414) in rats or rabbits, by oral route.

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 **7 August 2017** an update of the registration dossier containing the information required by this decision, including, where relevant, an update of the Chemical Safety Report. The timeline has been set to allow for sequential testing as appropriate.

III. Statement of reasons

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

A. Tests required pursuant to Article 40(3)

1. Sub-chronic toxicity study (90-day) (Annex IX, Section 8.6.2.)

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.

A sub-chronic toxicity study (90 day) is a standard information requirement as laid down in Annex IX, Section 8.6.2. 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 a sub-chronic toxicity study (90 day) in rats via the oral route (EU B.26/OECD 408).

ECHA considers that the proposed study via the oral route is appropriate to fulfil the information requirement of Annex IX, Section 8.6.2. of the REACH Regulation because the proposed route is the most appropriate route of administration having regard to the likely route of human exposure due to the following reasons.

In light of the physico-chemical properties of the substance (liquid with low vapour pressure classified as corrosive to the skin and/or damaging to the eyes, water soluble) and the information provided on the uses and human exposure (i.e. no uses with spray application), ECHA considers that testing by the oral route is most appropriate.

The Registrant proposed testing in rats. According to the test method EU B.26/OECD 408, the rat is the preferred species. ECHA considers this species as being appropriate and testing should be performed with the rat.

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 is not sufficient to fulfil this information requirement.

A third party has proposed a read-across approach for ECHA to take into account before further tests on vertebrate animals are required, stating that: *"We refer to existing data of nonylphenol and an oral 90-day sub-chronic toxicity study which will be conducted with 2,6-di-tert-butylphenol according to a draft decision of the Agency. From a sub-chronic toxicity study with nonylphenol a NOAEL of 50 mg/kg bw/d was derived based on a small decrease in bodyweight and food consumption at 150 mg/kg bw/d. This information may be used for the registration of 2-tert-butanol in a read-across approach."*

ECHA has taken the information provided into account and concludes that, although it might be scientifically valid, it is insufficient in demonstrating that the conditions of Annex XI, Section 1.5 of the REACH regulations are met. More specifically, the third party did not submit scientifically valid information and studies that address the substance and hazard endpoint (pursuant to Article 40(2)). Also, the proposed read-across approach is not sufficiently justified to conclude whether the registered substance may exert the particular intrinsic property.

ECHA notes that it is the Registrant's responsibility to consider and justify any adaptation of the information requirements in accordance with the relevant conditions as established in Annex XI, Section 1.5. Therefore, the Registrant should assess whether they can justify a read-across as suggested by the third party. If the information requirement can be met by way of adaptation, they should include the adaptation argument with all necessary documentation according to Annex XI, Section 1.5. in the registration dossier. This would require the registrant to demonstrate that the results used under this approach are adequate for the purpose of classification and labelling and/or risk assessment, have adequeate and reliable coverage of the key parameters, cover a comparable exposure duration and that adequate and reliable documentation is provided.

c) Outcome

Therefore, pursuant to Article 40(3)(a) of the REACH Regulation, the Registrant is requested to carry out the proposed study with the registered substance subject to the present

decision: Sub-chronic toxicity study (90-day) in rats, by oral route (test method: EU B.26/OECD 408).

2. Pre-natal developmental toxicity study (Annex IX, Section 8.7.2.)

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.

A pre-natal developmental toxicity study for a first species is a standard information requirement as laid down in Annex IX, Section 8.7.2. 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 a pre-natal developmental toxicity study according to EU B.31/OECD 414.

ECHA considers that the proposed study is appropriate to fulfil the information requirement of Annex IX, Section 8.7.2. of the REACH Regulation.

The Registrant did not specify the species to be used for testing and did not specify the route for testing. According to the test method EU B.31/OECD 414, the rat is the preferred rodent species, the rabbit the preferred non-rodent species and the test substance is usually administered orally. ECHA considers these default parameters appropriate and testing should be performed by the oral route with the rat or the rabbit as a first species to be used.

The Registrant failed to specify the substance to be tested. ECHA requests that testing should be performed on the registered substance.

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 is not sufficient to fulfil this information requirement.

A third party has proposed that: *"We refer to the option of read-across to nonylphenol and 2,6-di-tert-butyl phenol. In a similar manner the registrant of 4-tert-butanol proposed read-across to nonylphenol. In an OECD Test Guideline 414-compliant study, maternal toxicity but no developmental effects of nonylphenol were noted up to the maximum dose of 300 mg/kg bw/d administered by oral gavage. From the results of a reproduction developmental toxicity screening test with 2,6-di-tert-butyl phenol, a NOAEL of 150 mg/kg bw/d for maternal and developmental toxicity was derived based on clinical signs of the dams and reduced viability and weight gain of the pups at the dose level 750 mg/kg bw/d. The read-across information suggests that 2-tert-butylphenol would not have to be classified for developmental toxicity effects."*

ECHA has taken the information provided into account and concludes that, although it might be scientifically valid, it is insufficient in demonstrating that the conditions of Annex XI, Section 1.5 of the REACH regulations are met. More specifically, the third party did not submit scientifically valid information and studies that address the substance and hazard endpoint (pursuant to Article 40(2)). Also, the proposed read-across approach is not

sufficiently justified to conclude whether the registered substance may exert the particular intrinsic property.

ECHA notes that it is the Registrant's responsibility to consider and justify any adaptation of the information requirements in accordance with the relevant conditions as established in Annex XI, Section 1.5. Therefore, the Registrant should assess whether they can justify a read-across as suggested by the third party. If the information requirement can be met by way of adaptation, they should include the adaptation argument with all necessary documentation according to Annex XI, Section 1.5. in the registration dossier. This would require the registrant to demonstrate that the results used under this approach are adequate for the purpose of classification and labelling and/or risk assessment, have adequeate and reliable coverage of the key parameters, cover a comparable exposure duration and that adequate and reliable documentation is provided.

c) Outcome

Therefore, pursuant to Article 40(3)(a) of the REACH Regulation, the Registrant is requested to carry out the proposed study with the registered substance subject to the present decision: Pre-natal developmental toxicity study in rats or rabbits, by oral route (test method: EU B.31/OECD 414).

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 studies 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 tests, the sample of substance used for the new studies 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 tests 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 studies 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 studies 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 studies 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 Leena Ylä-Mononen, Director of 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.