EUROPEAN CHEMICALS AGENCY

Decision number: TPE-D-0000002581-78-04/F Helsinki, 2 November 2012

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

For a mixture of: α-3-(3-(2H-benzotriazol-2-yl)-5-tert-butyl-4-hydroxyphenyl) propionyl-ω-hydroxypoly(oxyethylene); α-3-(3-(2H-benzotriazol-2-yl)-5-tert-butyl-4-hydroxyphenyl)propionyl-ω-3-(3-(2H-benzotriazol-2-yl)-5-tert-butyl-4-hydroxyphenyl)propionyloxypoly(oxyethylene), EC No 400-830-7, 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 in accordance with Articles 10(a)(ix) and 12 (1)(e) thereof for α-3-(3-(2H-benzotriazol-2-yl)-5-tert-butyl-4-hydroxyphenyl)propionyl-ω-hydroxypoly(oxyethylene); α-3-(3-(2H-benzotriazol-2-yl)-5-tert-butyl-4-hydroxyphenyl)propionyl-ω-3-(3-(2H-benzotriazol-2-yl)-5-tert-butyl-4-hydroxyphenyl)propionyloxypoly(oxyethylene), EC No 400-830-7, by [redacted] (Registrant), latest submission number [redacted], for the tonnage band of 1000 tonnes or more per year:

- Pre-natal developmental toxicity study, in rabbits, oral route, OECD Guideline 414, with the registered substance.

The examination of the testing proposal was initiated upon the date when receipt of the complete registration dossier was confirmed on 28 October 2011.

ECHA held a third party consultation for the testing proposal from 16 December 2011 until 30 January 2012. ECHA did receive information from third parties (see section III below).

On 24 April 2012 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 24 May 2012 the Registrant did not provide any comments on the draft decision to ECHA.

On 14 June 2012 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 to amend the draft decision within 30 days of the receipt of the notification. Subsequently, one Competent Authority of a Member State submitted a proposal for amendment of the draft decision.

ECHA reviewed the proposal for amendment received and decided not to amend the draft decision.

On 18 July 2012 ECHA notified the Registrant of the proposal for amendment to the draft decision and invited him pursuant to Article 51(1) of the REACH Regulation to provide comments on the proposal for amendment within 30 days of the receipt of the notification.

On 30 July ECHA referred the draft decision to the Member State Committee.

The Registrant did not provide any comments on the proposed amendment.

After discussion in the Member State Committee meeting on 19-21 September 2012, a unanimous agreement of the Member State Committee on the draft decision as modified at the meeting was reached on 20 September 2012. ECHA took the decision pursuant to Article 51(6) of the REACH Regulation.

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 to initiate a compliance check on the present dossier at a later stage.

II. Testing required

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

- Pre-natal developmental toxicity study in rabbits, oral route (Annex X, 8.7.2.; test method: EU B.31/OECD 414).

Pursuant to Articles 40(4) and 22 of the REACH Regulation, the Registrant shall submit to ECHA by **4 November 2013** an update of the registration dossier containing the information required by this decision.

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.

Pre-natal developmental toxicity study

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. According to section 8.7.2 of Annex X subject to the Annex IX, 8.7.2 column 2 requirements of the REACH Regulation, a further pre-natal developmental toxicity study performed in a second species is required to fulfil the standard information requirements. The information available on this endpoint for the registered substance in the technical dossier does not meet these information requirements. Consequently there is an information gap and it is necessary to generate the data for this endpoint.

ECHA reminds the Registrant that Column 2, Section 8.7 of Annex X of the REACH Regulation allows a Registrant to adapt the standard information requirement for a pre-natal developmental toxicity study if a substance is known to cause developmental toxicity meeting the criteria for toxic to reproduction category 1A or 1B: May damage the unborn child (H360D) and the available toxicity data are adequate to support a robust risk assessment. More specifically, the Registrant should consider whether the results of a pre-natal developmental toxicity study, one generation reproduction toxicity study and a range finding study, as provided in the registration dossier, are sufficient to meet the criteria for classification of the registered substance as toxic to reproduction, Repr. 1B.

If the conditions of the above adaptation are met and full justification is provided by the Registrant in the dossier, in accordance with Column 2, Section 8.7 of Annex X, then the developmental toxicity study would not be needed.

However, the version of the registration dossier examined by ECHA to arrive at its decision does not contain such an adaptation. Therefore, there is currently a data gap which needs to be filled.

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.

The third party states that the dossier contains a reliable pre-natal developmental toxicity study conducted with rats, and concludes that since data for this endpoint already exists, no further testing is needed. ECHA notes that the developmental toxicity potential of the registered substance can not be judged based on the result of the existing pre-natal developmental toxicity study, and therefore ECHA concludes that it is necessary to generate additional data for this endpoint.

c) Outcome

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

At any time, the Registrant shall take into account that there may be an obligation to make every effort to agree on sharing of information and costs with other Registrants.

IV. General requirements for the generation of information and Good Laboratory Practice

ECHA reminds registrants of the requirements of Article 13(4) of the REACH Regulation that ecotoxicological and toxicological tests and analyses shall be carried out in compliance with the principles of good laboratory practice (GLP). National authorities monitoring GLP maintain lists of test facilities indicating the relevant areas of expertise of each facility.

According to Article 13(3) of the REACH Regulation, tests that are required to generate information on intrinsic properties of substances shall be conducted in accordance with the test methods laid down in a Commission Regulation or in accordance with other international test methods recognised by the Commission or the European Chemicals Agency as being appropriate. Thus, the Registrant shall refer to Commission Regulation (EC) No 440/2008 laying down test methods pursuant to Regulation (EC) No 1907/2006 as adapted to technical progress or to other international test methods recognised as being

appropriate and use the applicable test methods to generate the information on the endpoints indicated above.

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://echa.europa.eu/appeals/app_procedure_en.asp. The notice of appeal will be deemed to be filed only when the appeal fee has been paid.

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Jukka Malm
Director of Regulatory Affairs