

Decision number: TPE-D-0000002005-88-05/F

Helsinki, 18 July 2012

**DECISION ON A TESTING PROPOSAL SET OUT IN A REGISTRATION PURSUANT TO ARTICLE 40(3) OF REGULATION (EC) NO 1907/2006****For Bis( $\alpha,\alpha$ -dimethylbenzyl) peroxide, CAS No 80-43-3 (EC No 201-279-3), 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 testing proposals set out in the registration dossier for Bis( $\alpha,\alpha$ -dimethylbenzyl) peroxide, CAS No 80-43-3 (EC No 201-279-3) submitted by [REDACTED] (Registrant), latest submission number [REDACTED], for 1000 tonnes or more per year.

In accordance with Articles 10(a)(ix) and 12(1)(e) of the REACH Regulation, the Registrant submitted the following testing proposals as part of the registration dossier to fulfil the information requirements set out in Annexes IX and X:

- a) Sub-chronic repeated dose toxicity study (90-day) in rats, oral route, Annex IX, 8.6.2., test method: OECD 408;
- b) Pre-natal developmental toxicity study, Annexes IX and X, 8.7.2., test method: OECD 414 (no species/route of administration indicated).

The examination of the testing proposals was initiated on 23 November 2010.

ECHA opened a third party consultation for the testing proposals including testing on vertebrate animals that was held from 16 June 2011 until 1 August 2011. ECHA did not receive comments from third parties.

On 28 October 2011 ECHA notified the Registrant of its draft decision and invited him pursuant to Article 50(1) of the REACH Regulation to provide comments within 30 days of the receipt of the draft decision.

On 24 November 2011 the Registrant provided to ECHA comments on the draft decision. ECHA reviewed the further information received and amended the draft decision accordingly.

On 2 March 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 to the draft decision. ECHA has reviewed the proposal for amendment received and decided not to amend the draft decision.

On 4 April 2012 ECHA notified the Registrant of proposal for amendment to the draft decision and invited him pursuant to Article 51(5) of the REACH Regulation to provide

comments on that proposal for amendment within 30 days of the receipt of the notification. On 16 April 2012 ECHA referred the draft decision to the Member State Committee.

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 21 May 2012 in a written procedure launched on 10 May 2012.

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

## II. Testing required

Pursuant to Article 40(3)(a) of the REACH Regulation, the Registrant shall carry out the proposed tests with the registered substance subject to the present decision using the indicated test method:

- a) Sub-chronic toxicity study (90-day), in rats, oral route, Annex IX, 8.6.2., test method: EU B.26/OECD 408; and
- b) Pre-natal developmental toxicity study, in rats, oral route, Annexes IX and X, 8.7.2., test method: EU B.31/OECD 414.

The Registrant shall determine the appropriate order of the studies taking into account the possible outcome and considering the possibilities for adaptations of the standard information requirements according to column 1 or 2 provisions of the relevant Annexes of the REACH Regulation.

Pursuant to Articles 40(4) and 22 of the REACH Regulation, the Registrant shall submit to ECHA by **18 July 2014** an update of the registration dossier containing the information required by this decision.

Data from a second pre-natal developmental toxicity study on another species is a standard information requirement according to Annex X, 8.7.2. of the REACH Regulation. The Registrant should firstly take into account the outcome of the pre-natal developmental toxicity on a first species and all other relevant available data to determine if the conditions are met for adaptations according to Annex X, 8.7. column 2, or according to Annex XI. If the Registrant considers that testing is necessary to fulfil this information requirement, he should include in the update of his dossier a testing proposal for a pre-natal developmental toxicity study on a second species.

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.

## III. Statement of reasons

The decision of ECHA is based on the examination of the testing proposals of the Registrant for the registered substance.

- a) Sub-chronic toxicity study (90-day)

A sub-chronic toxicity study (90-day) is a standard information requirement under Annex IX, 8.6.2. of the REACH Regulation. ECHA notes that this standard information is not available in the present registration dossier, but a testing proposal concerning a sub-chronic toxicity study (90-day) has been made. In addition, the Registrant proposes to include

additional parameters on sexual organs. ECHA notes that examination of sexual organs is part of the OECD 408/EU B.26 test methods. Thus without any further explanation of the type of examinations and measurements on the sexual organs or their functioning, ECHA does not consider that the proposal is a modification of the current test method. However, the registrant is entitled to examine within the subchronic test any additional parameters relevant for reproductive toxicity he considers necessary.

According to the test method EU B.26/OECD 408 the rat is the preferred rodent species. ECHA considers this species as being appropriate. In the light of the physico-chemical properties of the substance and the information provided on the uses and human exposure, ECHA considers that testing by the oral route is appropriate.

Therefore, pursuant to Article 40(3)(a) of the REACH Regulation, the Registrant is requested to carry out with the registered substance the following test: 90-day repeated dose toxicity study in rats, oral route (test method: B.26/OECD 408), including parameters on sexual organs.

#### b) Pre-natal developmental toxicity study

Pre-natal developmental toxicity studies are part of the standard information requirements as laid down in Annexes IX and X, 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 generate the data for this endpoint.

The Registrant did not specify the species and route to be used 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 as a first species to be used.

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

When considering the need for a testing proposal for a prenatal developmental toxicity study in a second species, the Registrant should take into account the outcome of the pre-natal developmental toxicity study on the first species and all available data to determine if the conditions are met for adaptations according to Annex X, 8.7. column 2, or according to Annex XI; for example if the substance meets the criteria for classification as toxic for reproduction Category 1B: May damage the unborn child (H360D), and the available data are adequate to support a robust risk assessment, or alternatively, if Weight of Evidence assessment of all relevant available data provides scientific justification that the study in a second species is not needed.

The Registrant shall determine the appropriate order of the studies taking into account the possible outcomes and considering the possibilities for adaptations of the standard information requirements according to column 1 or 2 provisions of the relevant Annexes of the REACH Regulation. While the Registrant expressed consent to submit the proposed tests, ECHA agrees on the Registrant's proposal to extend the timeline to provide the requested information from 18 to 24 months starting from the date of the final decision.

#### IV. Adequate identification of the composition of the tested material

The process of evaluation of testing proposals set out in Article 40 of the REACH Regulation aims at ensuring that the generation of information is tailored to real information needs in order to prevent unnecessary testing. The information submitted in the registration dossier was sufficient to confirm the identity of the substance for the purpose of assessing the testing proposal. It is noted, 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 the joint registrants of the same substance to agree with the tests proposed in the testing proposal (as applicable to their tonnage level) and to document the necessary information on its composition. The substance identity information of the registered substance and of the sample tested must enable ECHA to confirm the relevance of the testing for the substance actually registered by each joint registrant. Finally, the studies must be shared by the joint registrants concerned.


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

ECHA always 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.

#### VI. 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](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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