Decision number: TPE-D-2114319122-65-01/F Helsinki, 30 March 2016

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

For tert-butyl α,α-dimethylbenzyl peroxide, EC No 222-389-8 (CAS No 3457-61-2), 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 registration dossier in accordance with Articles 10(a)(ix) and 12(1)(d) thereof for tert-butyl α,α-dimethylbenzyl peroxide, EC No 222-389-8 (CAS No 3457-61-2), submitted by [redacted] (Registrant).

- Viscosity (OECD 114)
- Long-term toxicity testing on aquatic invertebrates (OECD 211)
- 90-day oral toxicity study (OECD 408) in rats
- Developmental toxicity / teratogenicity study (OECD 414)

This decision is based on the registration 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 26 October 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 proposals for further examination pursuant to Article 40(1) on 11 April 2013.

ECHA held a third party consultation for the testing proposals from 15 July 2014 until 29 August 2014. ECHA also held a third party consultation for long-term toxicity testing on fish from 16 March 2015 until 30 April 2015. ECHA did not receive information from third parties.

On 19 August 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.

On 24 September 2015 ECHA received comments from the Registrant agreeing to ECHA's draft decision.

The ECHA Secretariat considered the Registrant's comments. The information is reflected in the Statement of Reasons (Section III) whereas no amendments to the information required (Section II) were made.

On 29 October 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 4 December 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.

By 4 January 2016, in accordance to Article 51(5), the Registrant provided comments on the proposal for amendment. The Member State Committee took the comments of the Registrant on the proposal for amendment into account.

A unanimous agreement of the Member State Committee on the draft decision was reached on 18 January 2016 in a written procedure launched on 8 January 2016.

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 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. Viscosity (Annex IX, Section 7.17.; test method OECD 114);
2. Sub-chronic toxicity study (90-day), oral route (Annex IX, Section 8.6.2.; test method: EU B.26/OECD 408) in rats;
3. Pre-natal developmental toxicity study (Annex IX, Section 8.7.2.; test method: EU B.31/OECD 414) in rats or rabbits, oral route;
4. Long-term toxicity testing on aquatic invertebrates (Annex IX, Section 9.1.5.; test method: *Daphnia magna* reproduction test, EU C.20/OECD 211).

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

5. Short-term toxicity testing on fish (Annex VIII, Section 9.1.3.; test method: Fish, Acute Toxicity Test, OECD 203);
6. Fish, early-life stage (FELS) toxicity test (Annex IX, Section 9.1.6.1.; test method: Fish, early-life stage toxicity test, OECD 210).

The sequence for information requests 4, 5 and 6 above is further outlined in section III of this decision.

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 requests in this decision, or to fulfil otherwise the information requirements 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 **6 April 2018** 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.

A. Tests required pursuant to Article 40(3)

1. Viscosity (Annex IX, Section 7.17.)

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.

"Viscosity" is a standard information requirement as laid down in Annex IX, Section 7.17. of the REACH Regulation. The information on this endpoint is not available for the registered substance subject to the present decision 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 viscosity.

ECHA considers the proposed test appropriate and testing should be performed with the registered substance.

In his comments, following the procedure set out in Article 50(1) of the REACH Regulation, the Registrant agreed to perform this test.

b) Outcome

Therefore, pursuant to Article 40(3)(a) of the REACH Regulation, the Registrant is requested to carry out the proposed test using the registered substance: Viscosity of liquids (test method: OECD 114).

2. 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) with the following justification: "*the substance has a low volatility-vapour pressure of 0.14 hPa at 40 °C) the oral route is considered as the most relevant route of exposure. In addition, although the substance has a skin irritation potential, there is no eye irritation potential and no effect was observed in stomach/forestomach following a 28-day exposure by oral route*".

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: the information provided in the technical dossier on the uses and human exposure do not contain spray application. Furthermore, the physicochemical properties of the substance as a liquid with low vapour pressure and being water soluble indicate oral testing as 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.

In his comments, following the procedure set out in Article 50(1) of the REACH Regulation, the Registrant agreed to perform this test.

b) 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, oral route (test method: EU B.26/OECD 408).

3. 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 in rats according to EU B.31/OECD 414 to be performed with the registered substance subject to the present decision.

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 proposed testing in rats. He proposed testing by the oral route. 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.

In his comments, following the procedure set out in Article 50(1) of the REACH Regulation, the Registrant agreed to perform this test.

b) 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, oral route (test method: EU B.31/OECD 414).

4., 5. and 6. Short-term toxicity testing on fish (Annex VIII, Section 9.1.3.), long-term toxicity testing on aquatic invertebrates (Annex IX, Section 9.1.5.) and Fish, early-life stage (FELS) toxicity test (Annex IX, Section 9.1.6.1.)

Pursuant to Article 40(3)(a) of the REACH Regulation, ECHA may require the Registrant to carry out the proposed test. In addition, pursuant to Article 40(3)(c) of the REACH Regulation, ECHA may require the Registrant to carry out one or more additional tests in case of non-compliance of the testing proposal with Annexes IX, X or XI of the REACH Regulation.

"Short-term toxicity testing on fish", "Long-term toxicity testing on aquatic invertebrates" and "Long-term toxicity testing on fish" are standard information requirement as laid down in Annex VIII, Section 9.1.3. and Annex IX, Sections 9.1.5. and 9.1.6. of the REACH Regulation respectively. Adequate information on those endpoints needs to be present in the technical dossier for the registered substance to meet those information requirements. The information on these endpoints 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 these endpoints.

ECHA *Guidance on information requirements and chemical safety assessment* (version 2.0, November 2014), Chapter R7b (Section R.7.8.5.3), concludes that the Chemical Safety Assessment (CSA) is to be based on all available toxicity information, and that the information used for the derivation of the predicted no effect concentration (PNEC) should at least cover species of three trophic levels: algae/aquatic plants, invertebrates (*Daphnia* preferred), and fish.

ECHA notes that no information on toxicity to fish is available in the registration dossier and, in the absence of information on toxicity to fish, it cannot be concluded if fish or invertebrates are shown to be substantially more sensitive (i.e. a difference of sensitivity by a factor of 10). Consequently, long-term studies might be required on both. In such case, according to the integrated testing strategy, the short-term toxicity study testing on fish is to be conducted first. If based on the results, either fish or aquatic invertebrates are shown to be substantially more sensitive than the respective other species, according to ECHA *Guidance on information requirements and chemical safety assessment* (version 2.0, November 2014), Chapter R7b (Section R.7.8.5 including Figure R.7.8-4), a long-term study on the more sensitive species is required. On the contrary, 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. 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. However, if a risk is indicated, long-term fish testing may need to be conducted.

The Registrant has submitted a testing proposal for testing the registered substance for long-term toxicity testing on aquatic invertebrates (*Daphnia magna* reproduction test, EU C.20/OECD 211) with the following justification: "*According to claimed uses of tert-butyl cumyl peroxide aquatic compartment exposure is likely. At the moment no data is available for characterizing tert-butyl cumyl peroxide long-term effects on organisms inhabiting aquatic compartment. Risk assessment demonstrated that there is a risk for those organisms using the PNEC derived based upon acute data, that's why a long-term test on aquatic invertebrates is proposed in order to refine the PNEC value.*" ECHA considers that the proposed study is appropriate to fulfil the information requirement of Annex IX, Section 9.1.5. of the REACH Regulation.

Regarding the proposed testing strategy on the aquatic toxicity endpoints, the Registrant considered that no toxicity study on fish is needed and justified this in its dossier as follows: "*Within REACH, the obligation to conduct tests with vertebrate animals should be considered as a last resort, only after exhausting all potential sources of information on the physical and (eco)toxicological properties of chemicals. Referring to the position paper "*[redacted]*" (attached to IUCLID), it can be conclude that algae and daphnids are the most sensitive species when tested with organic peroxides. As a consequence, no test on fish has been performed.*"

However, ECHA notes that the "[redacted]" document is not present in the IUCLID dossier for the current registration dossier and therefore ECHA has not been able to evaluate it. Consequently there is an information gap for those endpoints and it is necessary to provide information on fish toxicity.

ECHA considers that for the endpoint of long-term toxicity testing on fish pursuant to Annex IX, section 9.1.6., the FELS toxicity test according to OECD 210 is the most sensitive of the standard fish tests available as it covers several life stages of the fish from the newly fertilised egg, through hatch to early stages of growth and should therefore be used (see

ECHA *Guidance on information requirements and chemical safety assessment* (version 2.0, November 2014), Chapter R7b, Figure R.7.8-4 page 26). The test method OECD 210 is also the only suitable test currently available for examining the potential toxic effects of bioaccumulation (ECHA Guidance R7b, version 2.0, November 2014, p. 26). For these reasons, ECHA considers the FELS toxicity test using the test method OECD 210 as appropriate and suitable.

In his comments, following the procedure set out in Article 50(1) of the REACH Regulation, the Registrant agreed to perform these tests and to follow the integrated testing strategy. Thus, the Registrant expressed his will to perform first the short-term toxicity testing on fish and to determine the strategy for the long-term data, as indicated above, once the results for the short-term toxicity testing on fish are available.
ECHA notes to the Registrant that, according to ECHA Guidance on information requirements and chemical safety assessment (version 2.0, November 2014), Chapter R7b (Section R.7.8.5.), "*substantially more sensitive*" is associated with a factor of at least 10 in difference of sensitivity.

Therefore, pursuant to Article 40(3)(a) and (c)of the REACH Regulation, the Registrant is required to carry out the following studies using the registered substance subject to the present decision: Short-term toxicity testing on fish (Annex VIII, Section 9.1.3.; test method: Fish, Acute Toxicity Test, OECD 203) and, based on the results of that test: Long-term toxicity testing on aquatic invertebrates (Annex IX, 9.1.5.; test method: *Daphnia magna* reproduction test, EU C.20/OECD 211) and/or Fish, early-life stage (FELS) toxicity test (Annex IX, 9.1.6.1.; test method: Fish, early-life stage toxicity test, OECD 210).

Note for consideration by the Registrant

Pursuant to column 2 of Annex VIII, Section 9.1.3. the short-term toxicity testing on fish need not be conducted if a long-term study on fish is available. Thus the Registrant may choose to perform the long-term toxicity on fish (Annex IX, 9.1.6.1.; test method: Fish, early-life stage toxicity test, OECD 210) and long-term toxicity testing on aquatic invertebrates (Annex IX, 9.1.5.; test method: *Daphnia magna* reproduction test, EU C.20/ OECD 211) and waive the short-term toxicity on fish.

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[2] by Claudio Carlon, Head of Unit, Evaluation E2

[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.