EUROPEAN CHEMICALS AGENCY

Helsinki, 05/07/2012

Decision number: TPE-D-0000002187-74-05/F

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

For di-tert-butyl 3,3,5-trimethylcyclohexylidene diperoxide, CAS No. 6731-36-8 (EC No. 229-782-3), 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 di-tert-butyl 3,3,5-trimethylcyclohexylidene diperoxide, CAS No. 6731-36-8 (EC No. 229-782-3) submitted by [redacted] (Registrant), latest submission number [redacted]

In accordance with Articles 10(a)(ix) and 12(1)(d) 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:

- Viscosity for liquids (OECD 114)
- Pre-natal developmental toxicity study (OECD 414)
- *Daphnia magna* Reproduction Test (OECD 211/ EPA OPPTS 850.1300)
- Sediment toxicity (OECD 225 (*Lumbriculus variegatus*))

The examination of the testing proposals was initiated on 22 December 2010.

ECHA opened a third party consultation for the testing proposal including testing on vertebrate animals that was held from 1 July 2011 until 15 August 2011. ECHA did not receive information from third parties.

On 2 January 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.

On 31 January 2012 ECHA received comments from the Registrant. ECHA considered the Registrant's comments received and amended the draft decision.

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, Competent Authorities of the Member States submitted proposals for amendment to the draft decision. ECHA has reviewed the proposals for amendment received and decided not to amend the draft decision.

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

On 2 May 2012 April the Registrant provided comments on the proposed amendments. The Member State Committee took the comments of the Registrant into account.

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 following proposed tests using the indicated test methods and the registered substance:

- Viscosity (Annex IX, 7.17., test method: OECD 114)
- Pre-natal developmental toxicity study in rats, oral route (Annex IX, 8.7.2., test method: EU B.31/OECD 414)
- Long-term toxicity testing on aquatic invertebrates (Annex IX, 9.1.5., test method: EU C.20/OECD 211)
- Long-term toxicity to sediment organisms, (Annex X, 9.5.1., test method: OECD 225)

Pursuant to Articles 40(4) and 22 of the REACH Regulation, the Registrant shall submit to ECHA by **7 January 2014** an update of the registration dossier containing the information required by this decision.

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 proposal submitted by the Registrant for the registered substance.

1. Viscosity

Pursuant to Article 40(3)(a) of the REACH Regulation, ECHA may require the Registrant to carry out the proposed test.

Viscosity data 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 but needs to be presented in the technical dossier to meet the information requirements. Consequently there is an information gap and it is necessary to generate data for this endpoint.

Therefore, pursuant to Article 40(3)(a) of the REACH Regulation, the Registrant is required to carry out the proposed study: Viscosity (test method OECD 114) using the registered substance, 1,1-di(tert-butylperoxy)-3,3,5-trimethylcyclohexane.

2. Pre-natal developmental toxicity

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 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 required to carry out the proposed study: Pre-natal developmental toxicity study in rats, oral route (test method: EU B.31/OECD 414) using the registered substance, 1,1-di(tert-butylperoxy)-3,3,5-trimethylcyclohexane.

3. Long-term toxicity on invertebrates

Pursuant to Article 40(3)(a) of the REACH Regulation, ECHA may require the Registrant to carry out the proposed test.

A long term toxicity study on aquatic invertebrates is a standard information requirement as laid down in Annex IX, section 9.1.5. of the REACH Regulation if the chemical safety assessment according to Annex I indicates the need to investigate further the effects on aquatic organisms. 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 proposes in their technical dossier to conduct the test according to EPA OPPTS 850.1300 (Daphnid Chronic Toxicity Test) guideline, however in the CSR Registrant proposes to conduct the test according to OECD Guideline 211 (*Daphnia magna* Reproduction Test). The Registrants justification for the test is "The available study and the estimated ECOSAR on daphnids shows a E(L)C50 < 1 mg trigonox 29/L. A long-term toxicity to aquatic invertebrates is justified."

Therefore, pursuant to Article 40(3)(a) of the REACH Regulation the Registrant is required to carry out the proposed study: Long-Term toxicity to aquatic invertebrates (Test method EU C.20/OECD 211) using the registered substance, 1,1-di(tert-butylperoxy)-3,3,5-trimethylcyclohexane.

ECHA also notes, that taking into account the half-lives of the substance reported in the section 5.1.2 of IUCLID dossier the Registrant has to decide on the appropriate test design as specified in OECD Guidance document on aquatic toxicity testing of difficult substances

and mixtures and ECHA Guidance R.7.8 Aquatic toxicity. Specifically, the Registrant should consider the results of the definitive hydrolysis study currently ongoing as well as information on environmental exposure concentrations of the registered substance and its degradation products.

4. Long-term toxicity to sediment organisms

Pursuant to Article 40(3)(a) of the REACH Regulation, ECHA may require the Registrant to carry out the proposed test.

According to Article 12(1)(d) and section 9.5.1. of Annex X of the REACH Regulation, a long-term toxicity to sediment organisms is a standard information requirement for substances manufactured or imported in quantities of 1000 tonnes or more. Testing on long-term toxicity to sediment organisms shall be proposed if the results of the chemical safety assessment indicate the need to investigate further effects of the substance and/or relevant degradation products on sediment organisms.

The current registration dossier concerns a substance manufactured in quantities [redacted]. However, ECHA acknowledges that the Registrant may have a need to generate this information for its registration dossier before reaching the next tonnage band. Accordingly, ECHA has assessed this registration dossier with the understanding that the Registrant has made the testing proposal with a view to specifically generate the data for the purposes of meeting the information requirements of Annex X, section 9.5.1. of the REACH Regulation. Specifically, according to Guidance document R.7.8.7 organic carbon-water partition coefficient (Koc) ≥1000 can be used as a trigger value to decide on the need to perform the assessment of toxicity to sediment organisms. ECHA acknowledges that the reported value of the Koc of the registered substance is 133377, which might justify the need to perform the long-term toxicity to sediment organisms study.

Therefore, pursuant to Article 40(3)(a) of the REACH Regulation the Registrant is required to carry out the proposed study: Sediment-Water *Lumbriculus* Toxicity test using Spiked Sediment (Test method OECD 225) using the registered substance, 1,1-di(tert-butylperoxy)-3,3,5-trimethylcyclohexane.

5. Timeline to submit an updated IUCLID dossier

In his comments on 31 January 2012 the Registrant proposed to extend the submission deadline of an updated IUCLID dossier from 12 months to 24 months of the date of the decision. ECHA evaluated the justification for this extension request and acknowledges that the properties of the registered substance (organic peroxide Type B) justify the extension of the deadline by 6 months. Nevertheless the issues addressed in this decision do not request sequential testing which would necessitate an extension beyond 6 months. Therefore ECHA decided to extend the deadline from 12 months to 18 months from the date of the 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 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.

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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 reads:

> *"Ecotoxicological and toxicological tests and analyses shall be carried out in compliance with the principles of good laboratory practice provided for in Directive 2004/10/EC or other international standards recognised as being equivalent by the Commission or the Agency and with the provisions of Directive 86/609/EEC, if applicable."*

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.

National authorities monitoring good laboratory practice (GLP) maintain lists of test facilities indicating the relevant areas of expertise of each facility.

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. The notice of appeal will be deemed to be filed only when the appeal fee has been paid.

[redacted]

Geert Dancet
Executive Director