Decision number: TPE-D-2114297290-47-01/F Helsinki, 23 March 2015

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

For 1,1,3,3-tetramethylbutyl 2-ethylperoxyhexanoate, CAS No 22288-43-3 (EC No 244-894-2), 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 1,1,3,3-tetramethylbutyl 2-ethylperoxyhexanoate, CAS No 22288-43-3 (EC No 244-894-2), submitted by [redacted] (Registrant).

- Viscosity of liquids (OECD 114);
- *Daphnia magna* Reproduction Test (OECD 211);
- Prenatal developmental toxicity study study (OECD 414) in rats, oral route.

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 15 January 2015, the date upon which ECHA notified its draft decision to the Competent Authorities of the Member States pursuant to Article 51(1) 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 from initiating a compliance check on the registration at a later stage.

On 23 May 2013, pursuant to Article 40(1) of the REACH Regulation, ECHA initiated the examination of the testing proposals set out by the Registrant in the registration dossier for the substance mentioned above.

ECHA held a third party consultation for the testing proposals from 3 March 2014 until 17 April 2014. ECHA did not receive information from third parties.

On 30 June 2014 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 7 July 2014 ECHA received comments from the Registrant agreeing to ECHA's draft decision regarding the requested tests as per Section II.A; however, asking for extention of the deadline to provide the requested information.

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 15 January 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) of the REACH Regulation using the indicated test methods and the registered substance subject to the present decision:

- Viscosity (Annex IX, Section 7.17.; test method OECD 114);
- Long-term toxicity testing on aquatic invertebrates (Annex IX, Section 9.1.5.; test method: *Daphnia magna* reproduction test, EU C.20/OECD 211).
- Pre-natal developmental toxicity study (Annex IX, Section 8.7.2.; test method: EU B.31/OECD 414) in rats or rabbits, 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 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 **30 March 2016** an update of the registration dossier containing the information required by this decision, including, where relevant, an update of the Chemical Safety Report.

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)

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 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 Viscosity of liquids.

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

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. Long-term toxicity testing on aquatic invertebrates (Annex IX, Section 9.1.5.)

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

"Long-term toxicity testing on aquatic invertebrates" is a standard information requirement as laid down in Annex IX, Section 9.1.5. 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 long-term toxicity study on aquatic invertebrates *Daphnia magna* reproduction test, OECD 211 with the following justification avialable in CSR: '*A chronic Daphnia test is proposed (OECD 211), since the substance is highly insoluble and no acute toxicity was observed up to the water solubility limit.* ' ECHA considers that the proposed study is appropriate to fulfil the information requirement of Annex IX, Section 9.1.5 of the REACH Regulation.

According to ECHA *Guidance on information requirements and chemical safety assessment* (version 1.2., November 2012), Chapter R7b (Section R.7.8.5 including Figure R.7.8-4), 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 *Daphnia* and fish.

ECHA notes that the Registrant has provided adaptation to the related endpoint 'short-term toxicity to fish' with the following justification: '*Based on the Organic Peroxides consortium's position paper "*[redacted]*), see also attachment in IUCLID section 13) fish are generally considered the least sensitive of the 3 trophic levels, thus no acute toxicity is expected for fish'.*

However, ECHA considers that, while comparing data of other alkyl-substituted peroxy esters, it is likely that the registered substance will not exhibit short-term aquatic toxicity as the substance has a low water solubility. Based on the available short term toxicity data on

other alkyl-substituted peroxy esters and on the fact that the substance is poorly water soluble, neither fish nor *Daphnia* can be regarded as substancially more sensitive (i.e. 10 times of more) than the other for alkyl-substituted peroxy esters.

Therefore, pursuant to Article 40(3)(a) of the REACH Regulation, the Registrant is required to carry out the proposed study using the registered substance: Long-term toxicity testing on aquatic invertebrates (Annex IX, 9.1.5.; test method: *Daphnia magna* reproduction test, EU C.20/OECD 211)

Notes for consideration by the Registrant

ECHA notes that the Registrant has provided a waiver for a long-term toxicity study on fish with the following justification: '*Based on the Organic Peroxides consortium's position paper "*[redacted]*), see also attachment in IUCLID section 13) fish are generally considered the least sensitive of the 3 trophic levels, thus the performance of a long term test will have no added value to the risk assessment process.'*

As explained above, ECHA considers that there is no convincing evidence available in the dossier that the fish would be substantially less sensitive than aquatic invertebrates and consequently, there are information gaps for both the short-term toxicity testing on fish and long-term toxicity testing on fish. Therefore, ECHA considers that it is necessary to provide information for these endpoints in the registration dossier. In addition, ECHA considers that as the short term toxicty data to fish would not be conclusive due to the low solubilty of the registered substance the Registrant should consider performing only the long-term toxicity study with fish.

Based on the considerations above, the Registrant shall consider the need for submitting testing proposal for long-term toxicity testing with fish.

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

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 with the following justification: '*OECD 414 in the rat is proposed via the oral route (per Endpoint Specific Guidance Chaper 7 pg 370: Since most acute, repeated-dose and toxicokinetic studies are conventionally conductd in the rat, it is advisable that the first developmental toxicity study should also be conducted in this species).*'

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.

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).

III.B Deadline for submitting the required information

In the draft decision communicated to the Registrant the time indicated to provide the requested information was 12 months from the date of adoption of the decision. In his comments on the draft decision of 7 July 2014, the Registrant requested an extension of the timeline to 18 or preferably 24 months. He sought to justify this request by '*the difficulties that can be encountered with organic peroxides and the timing that we have experienced with Tier 1 OECD 408/414 organic peroxide studies',* but has not substantiated it with any specific information (what types of difficulties were encountered in performing the above studies on organic peroxides and which are expected in performing the requested studies, and why those difficulties would justify a need for either 6 or 12 months more in performing the tests).

Therefore ECHA secretariat considers that there is no substance-specific reason to deviate from standard deadline given for the requested tests that would be 12 months. Therefore, ECHA has not modified the deadline of the decision.

IV. Adequate identification of the composition of the tested material

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. If the registration of the substance covers different grades, the sample used for the new studies must be suitable to assess these.

Furthermore, 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. 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).

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

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