Decision number: TPE-D-2114328552-53-01/F Helsinki, 22 April 2016

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

For 2-ethyl-2-[[(1-oxononyl)oxy]methyl]propane-1,3-diyl dinonan-1-oate, EC No 204-793-6 (CAS No 126-57-8), 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 as part of the registration dossier in accordance with Articles 10(a)(ix) and 12(1)(e) thereof for 2-ethyl-2-[[(1-oxononyl)oxy]methyl]propane-1,3-diyl dinonan-1-oate, EC No 204-793-6 (CAS No 126-57-8), submitted by [redacted] (Registrant).

- OECD Guideline 211 (*Daphnia magna* Reproduction Test)

This decision is based on the registration as submitted with submission number [redacted], for the tonnage band of 1000 tonnes or more per year.

This decision does not take into account any updates after 30 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 proposal for further examination pursuant to Article 40(1) on 24 February 2015.

ECHA held a third party consultation for long-term toxicity testing on fish from 17 April 2015 until 4 June 2015. ECHA did not receive information from third parties.

On 24 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 on the draft decision.

The ECHA Secretariat considered the Registrant's comments. The statement of reasons (Section III) was modified accordingly.

On 3 March 2016 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 test pursuant to Article 40(3)(a) and 13(4) of the REACH Regulation using the indicated test method and the registered substance subject to the present decision:

1. 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 tests pursuant to Article 40(3)(c) of the REACH Regulation using the indicated test methods and the registered substance subject to the present decision:

2. Long-term toxicity testing on fish (Annex IX, Section 9.1.6.1.; test method: Fish, early-life stage toxicity test, OECD 210).

Note for consideration by the Registrant:

The Registrant may adapt the testing requested above by providing the relevant information in accordance with the requirements of Annex IX 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 **2 May 2017** 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 proposal submitted by the Registrant for the registered substance.

A. Tests required pursuant to Article 40(3)

1. 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 testing for long-term toxicity testing on aquatic invertebrates *Daphnia magna* reproduction test, OECD 211 with the following justification: *"there are no aquatic toxicity tests available on TMP pelargonate. Annex VII and VIII prescribe the need to perform acute toxicity tests on organisms. However, based on the physico chemical properties of the substance (very low water solubility and high log Kow), acute toxicity testing is not deemed the most appropriate way of determining the intrinsic properties of the substance and chronic toxicity testing is considered more appropriate. For that reason, a testing proposal is submitted for long-term toxicity testing in invertebrates and based on that result the need for further testing in other organisms should be determined".*

ECHA considers that the proposed study is appropriate to fulfil the information requirement of Annex IX, Section 9.1.5 of the REACH Regulation.

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 subject to the present decision: 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

Due to the low solubility of the substance in water OECD Guidance Document on Aquatic Toxicity Testing of Difficult Substances and Mixtures, ENV/JM/MONO (2000)6 and ECHA Guidance, Chapter R7b, table R. 7.8-3 summarising aquatic toxicity testing of difficult substances should be consulted by the Registrant for choosing the design of the requested long-term ecotoxicity test and for calculation and expression of the result of this test.

2. Fish, early-life stage (FELS) toxicity test (Annex IX, Section 9.1.6.1.)

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.

Long-term toxicity testing on fish is a standard information requirement as laid down in Annex IX, Section 9.1.6., Column 1 of the REACH Regulation.

According to the *Guidance on information requirements and chemical safety assessment* (version 2.0, November 2014), Chapter R7b, Section R.7.8.5.3, 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) for water should at least cover species of three trophic levels: algae/aquatic plants, invertebrates (*Daphnia* preferred), and fish, irrespective of the term of the studies (whether short-term or long-term).

However, ECHA notes that no experimental results of short-term or long-term studies are available for aquatic toxicity tests in the registration dossier. In addition to the requested long-term test on *Daphnia*, information on toxicity to fish therefore have to be submitted in order to enable the derivation of the PNEC for water.

Long-term toxicity testing on fish is a standard information requirement of Annex IX Section 9.1.6. of the REACH Regulation. ECHA further notes that the reported water solubility for the registered substance is low (<0.08 mg/L) and that the Registrant himself indicates that "*based on the physico chemical properties of the substance (very low water solubility and high log Kow), acute toxicity testing is not deemed the most appropriate way of determining the intrinsic properties of the substance and chronic toxicity testing is considered more appropriate*". In the absence of any experimental results for aquatic toxicity, the Registrant has provided QSAR estimations using the ECOSAR model for short-term toxicity to *Daphnia*, short-term toxicity to fish and toxicity to algae. However, the Registrant acknowledges again that "*due to the intrinsic properties of the substance* [i.e. very low water solubility and high log Kow] *the predicted effect levels cannot be considered to be representing the actual toxicity levels*".

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), further specifies that if neither fish nor invertebrates are shown to be substantially more sensitive, long-term studies may be required on both. There is no indication in the dossier that the fish would be substantially more or less sensitive than aquatic invertebrates, therefore ECHA believes that long-term studies on both fish and *Daphnia* are required.

ECHA notes that the Registrant provided the following justification for waiving the requirement for a long-term toxicity study on fish: "*this dossier includes a testing proposal for a chronic toxicity study to aquatic invertebrates (OECD 211). Based on the results of this test, it will be decided if a long-term fish test is necessary*". However, ECHA considers that this statement of intention does not address any adaptation rule under the REACH Annexes, on which basis the standard information requirement could be waived.

ECHA considers that the Fish, Early-life Stage (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). 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). For these reasons, ECHA considers the FELS toxicity test using the test method OECD 210 to be appropriate and suitable.

In his comments, the Registrant agreed to perform the *Daphnia magna* reproduction test (OECD 211) on the registered substance but proposed to adapt the fish, early-life stage (FELS) toxicity test (OECD 210) by using read-across and QSAR adaptations. He further proposed to perform an *algae* growth inhibition test (OECD 201) on the registered substance claiming that *algae* was the most sensitive species.

ECHA acknowledges the Registrant's intention to perform a test on *algae* (OECD 201) in addition to the requested long-term test on *Daphnia* (OECD 211). ECHA however notes that the Registrant did not provide evidence to support his claim that *algae* is indeed the most sensitive species and therefore cannot conclude on whether such evidence may meet the standard information requirements on aquatic toxicity.

ECHA also took note of the Registrant's intention to adapt the fish, early-life stage (FELS) toxicity test (OECD 210) by using read-across and QSAR adaptations. ECHA points out that the Registrant will have to comply with the general rules detailed in Annex XI of the REACH Regulation for this adaptation to be acceptable.

Considering all the above, pursuant to Article 40(3)(c) of the REACH Regulation, the Registrant is required to carry out the additional study using the registered substance subject to the present decision: Fish, early-life stage (FELS) toxicity test (Annex IX, 9.1.6.1.; test method: Fish, early-life stage toxicity test, OECD 210).

Notes for consideration by the Registrant

The Registrant is advised to consult the ECHA Guidance on the standard information requirements and chemical safety assessment (version 2.0, November 2014), Chapters R.4, 5, 6, R.7b and R.7c. Where the Registrant decides to adapt the testing requested 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, ECHA advises to consult Practical Guides 4, 5 and 6. The guidance documents are available from the ECHA website.

Due to the low solubility of the substance in water OECD Guidance Document on Aquatic Toxicity Testing of Difficult Substances and Mixtures, ENV/JM/MONO (2000)6 and ECHA Guidance, Chapter R7b, table R. 7.8-3 summarising aquatic toxicity testing of difficult substances should be consulted by the Registrant for choosing the design of the requested long-term ecotoxicity test and for calculation and expression of the result of this test.

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 has not been checked for compliance with the substance identity requirements set out in Section 2 of Annex VI of the REACH Regulation.

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

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

[1] As this is an electronic document, it is not physically signed. This communication has been approved according to ECHA's internal decision-approval process.