

Decision number: TPE-D-2114306660-60-01/F

Helsinki, 30 July 2015

DECISION ON TESTING PROPOSALS SET OUT IN A REGISTRATION PURSUANT TO ARTICLE 40(3) OF REGULATION (EC) NO 1907/2006**For undec-10-enoic acid, CAS No 112-38-9 (EC No 203-965-8), 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 proposals submitted as part of the registration dossier in accordance with Articles 10(a)(ix) and 12(1)(e) thereof for undec-10-enoic acid, CAS No 112-38-9 (EC No 203-965-8), submitted by [REDACTED] (Registrant).

- Long-term toxicity testing on fish (OECD 210 Fish, Early-Life Stage Toxicity Test)
- Long-term toxicity testing on terrestrial macroorganisms (OECD 222 (Earthworm Reproduction Test (Eisenia fetida/Eisenia andrei)))

This decision is based on the registration dossier 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 25 April 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 updated registration dossier containing the above-mentioned testing proposals for further examination pursuant to Article 40(1) on 25 August 2014.

ECHA held a third party consultation for the testing proposal from 16 October 2014 until 1 December 2014. ECHA did not receive information from third parties.

On 17 February 2015, ECHA sent the draft decision to the Registrant and invited him to provide comments within the 30 days of the receipt of the draft decision.

On 23 March 2015 ECHA received comments from the Registrant on the draft decision.

The ECHA Secretariat considered the Registrant's comments. On basis of this information, only the deadline in Section II was amended from 12 to 15 months.

On 11 June 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) and 13(4) of the REACH Regulation using the indicated test methods and the registered substance subject to the present decision:

1. Fish, early-life stage (FELS) toxicity test (Annex IX, Section 9.1.6.1.; test method: Fish, early-life stage toxicity test, OECD 210);
2. Long-term toxicity on terrestrial invertebrates (Annex X, Section 9.4.4.; test method: Earthworm reproduction test (*Eisenia fetida*/*Eisenia andrei*), OECD 222);

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:

3. Effects on soil micro-organisms (Annex IX, Section 9.4.2.; test method: Soil microorganisms: nitrogen transformation test, EU C.21/OECD 216);

Pursuant to Articles 41(1), 41(3), 10(b) and 14 as well as Annex I of the REACH Regulation, once the results of the above terrestrial studies are available to the Registrant, he shall revise the chemical safety assessment as necessary according to Annex I of the REACH Regulation, including an updated derivation of the terrestrial PNEC.

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 **07 November 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. Long-term toxicity testing on fish (Annex IX, Section 9.1.6.)

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 fish" is a standard information requirement as laid down in Annex IX, Section 9.1.6. 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 the registered substance for long-term toxicity testing on fish, Fish early-life stage toxicity test, OECD 210 with the following justification: *'The results of the risk evaluation (see section 9 and 10 of CSR) indicate the need for restrictive risk management measures to control the risk for the aquatic compartment. Therefore, in accordance with annex IX of the EC 1907/2006 regulation, it is proposed to perform an OECD 210 test: "Fish early-life stage toxicity test" to refine the aquatic PNECs'*. ECHA considers that the proposed study is appropriate to fulfil the information requirement of Annex IX, Section 9.1.6 of the REACH Regulation.

ECHA notes that in the registration dossier a long-term study on aquatic invertebrates has already been submitted. The Registrant has considered the long-term study on fish necessary to refine the aquatic PNECs.

Outcome

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: Fish, early-life stage (FELS) toxicity test (Annex IX, 9.1.6.1.; test method: Fish, early-life stage toxicity test, OECD 210).

2. – 3. Effects on terrestrial organisms

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

The Registrant must address the standard information requirements set out in Annexes IX and X, section 9.4., for different taxonomic groups: effects on soil micro-organisms (Annex IX, section 9.4.2.), short-term toxicity testing on invertebrates (Annex IX, section 9.4.1.), long-term toxicity testing on invertebrates (Annex X, section 9.4.4.), short-term toxicity testing on plants (Annex IX, section 9.4.3.) and long-term toxicity testing on plants (Annex X, section 9.4.6.).

The information on the endpoint 'effects on terrestrial organisms' is not available for the registered substance but needs to be present in the technical dossier to meet the information requirements.

2) Terrestrial Invertebrates (Annex IX, Section 9.4.1. and Annex X, Section 9.4.4.)

The Registrant proposed a long-term toxicity test on terrestrial invertebrates (OECD 222), with the following justification: *'In Annex IX of Regulation (EC) No 1907/2006, it is laid down that long-term toxicity testing shall be proposed by the registrant if the chemical*

safety assessment indicates the need to investigate further the effects on terrestrial organisms. Undecylenic acid is readily biodegradable but very toxic to aquatic life (72h-EC50 < 1 mg/L for algae). Therefore, it falls within the Soil Hazard Category 2 of Table R.7.11 -2 of ECHA's Guidance on information requirements and chemical safety assessment R7c: Endpoint specific guidance (November 2012, v1.1, p. 134). The results of the risk evaluation (see section 9 and 10 of CSR) indicate the need for restrictive risk management measures to control the risk for the soil compartment, as a consequence it is necessary to conduct one long-term toxicity test on soil organisms. Since the Guidance R7c (p. 125) indicates that in a first step, an earthworm reproduction test is preferred to long-term studies on microorganisms or plants, it is proposed to perform an OECD 222 Earthworm Reproduction Test in a test plan.'

ECHA considers that the proposed test is suitable to address the information requirement of Annex X, section 9.4.4. and at the same time that of Annex IX, section 9.4.1.

Furthermore, based upon the available aquatic toxicity information and the physico-chemical properties of the substance, and in relation to section R.7.11.6., Chapter R.7c of the ECHA *Guidance on information requirements and chemical safety assessment* (version 2.0, November 2014), ECHA confirms that the substance would fall into soil hazard category 2. In the context of an integrated testing strategy for soil toxicity, the Guidance advocates performing an initial screening assessment based upon the Equilibrium Partitioning Method (EPM), together with a confirmatory soil toxicity test.

Outcome

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 Earthworm reproduction test (*Eisenia fetida/Eisenia andrei*) (OECD 222)

3) Soil microorganisms (Annex IX, section 9.4.2.)

The hazard to soil microbial communities is a standard information requirement under Annex IX, section 9.4.2. of the REACH Regulation. ECHA notes that the registration dossier does not contain data for this endpoint and that the proposed test that ECHA accepted under subsection 2 above is not sufficient to address this standard information requirement. ECHA concludes that the effects on soil microorganisms need to be ascertained by performing a relevant test (test method: EU C.21 or OECD 216).

Outcome

Therefore, pursuant to Article 40(3)(c) of the REACH Regulation, the Registrant is required to carry out the following additional study using the registered substance subject to the present decision: Soil microorganisms: nitrogen transformation test, EU C.21/OECD 216).

Notes for consideration by the Registrant

The Guidance advocates performing an initial screening assessment based upon the EPM, together with a confirmatory soil toxicity test (the long-term toxicity to terrestrial invertebrates test as proposed by the Registrant, specified above), which the Registrant is requested to carry out by the present decision. Therefore ECHA considers that at this stage it is not possible to determine whether another test will be required to fulfil the standard information requirements of Annex IX, Section 9.4.3. and Annex X, Section 9.4.6. of the REACH Regulation.

Therefore, once results of the requested toxicity test on terrestrial invertebrates are available, the Registrant shall consider whether there is a need to investigate further the effects on terrestrial organisms in order to fulfil the information requirements of section 9.4 of Annex IX, and if necessary, submit testing proposals for additional terrestrial toxicity tests. If the Registrant concludes that no further investigation of effects on terrestrial organisms is required, he shall update his technical dossier by clearly stating the reasons for adapting the information requirements of Annex IX, Section 9.4.3. and Annex X, Section 9.4.6. of the REACH Regulation.

ECHA emphasises that the intrinsic properties of soil microbial communities are not addressed through the EPM extrapolation method and therefore the potential adaptation possibility outlined for the information requirement of Annex IX, Section 9.4.3. does not apply for the present endpoint.

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.

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. 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 Guilhem De Seze, Head of Unit, Evaluation E1

^[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.