EUROPEAN CHEMICALS AGENCY

Decision number: TPE-D-0000003258-72-04/F Helsinki, 25 July 2013

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

For Fatty acids, C18-unsaturated, dimers, distillation product, CAS No. 61788-89-4 (EC No. 500-148-0), 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 Fatty acids, C18-unsaturated, dimers, distillation product, CAS No. 61788-89-4 (EC No. 500-148-0), by [redacted] (Registrant).

- Toxicity to soil macroorganisms (OECD 222)
- Toxicity to terrestrial plants (ISO 22030). The test is proposed to be conducted only if effects are observed in the OECD 222 earthworm reproduction test.

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 18 January 2013, 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 19 October 2010, 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.

On 21 November 2011 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 21 December 2011 and subsequently on 16 January 2012 ECHA received comments from the Registrant indicating a changed testing plan and read-across approach and the commitment to update the dossier within the set deadline. ECHA considered the Registrant's comments received. On the basis of the comments ECHA decided to wait for the Registrant to update the dossier.

Subsequently on 28 March 2012 the Registrant updated his registration dossier with a changed testing plan and an amended read-across approach for the category while maintaining the original testing proposals for the substance subject to this decision. On the basis of the comments and the updated registration dossier, Section II and Section III of the present decision were amended.

On 18 January 2013 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.

On 21 February 2013 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.

ECHA reviewed the proposals for amendment received and decided not to amend the draft decision.

On 4 March 2013 ECHA referred the draft decision to the Member State Committee.

On 25 March 2013, the Registrant provided comments on the proposed amendment. The Member State Committee took the comments of the Registrant into account.

After discussion in the Member State Committee meeting on 24-25 April 2013, a unanimous agreement of the Member State Committee on the draft decision as provided for the meeting was reached on 24 April 2013. ECHA took the decision pursuant to Article 51(6) of the REACH Regulation.

II. Testing required

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:

1. Long-term toxicity to terrestrial invertebrates, Annex X, 9.4.4. (test method: Earthworm Reproduction Test (*Eisenia fetida/Eisenia andrei*), OECD 222); and

2. Long-term toxicity to terrestrial plants, Annex X, 9.4.6. (test method: Soil quality – Biological methods – Chronic toxicity in higher plants, ISO 22030).

Once results of the requested toxicity test on terrestrial invertebrates are available, the Registrant shall revise the chemical safety assessment as necessary according to Annex I of the REACH Regulation. He shall furthermore 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 Annexes IX and X. If the Registrant concludes that further investigation of effects on terrestrial organisms is required, he shall conduct the requested long-term toxicity test on plants. 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 any information requirement of Annex IX, section 9.4. and Annex X, section 9.4. of the REACH Regulation for which no information has been provided.

Pursuant to Articles 40(4) and 22 of the REACH Regulation, the Registrant shall submit to ECHA by **25 January 2015** an update of the registration dossier containing the information required by this decision.

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.

1. Long-term toxicity to terrestrial invertebrates

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

Long-term toxicity to terrestrial invertebrates is a standard information requirement as laid down in Annex X, 9.4.4. 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 provided the following justification for conducting the proposed test: "*Due to the fact that the sub-category 2 members of the Dimerised Fatty Acids and its derivatives have the general estimated logkow >4 and logKoc > 5 (i.e. adsorption to organic carbon in soils is expected) and considering that a direct and indirect exposure of the soil compartment cannot be ruled out, data on terrestrial toxicity is required for the chemical safety assessment. No data available on the effects of the category members Dimerised Fatty Acids and its Derivatives (sub-category "predominantly oligomers") on terrestrial organisms are available, thus in order to fulfil the standard information required according to Regulation (EC) No. 1907/2006, Annex X, Column I (9.4) a long-term toxicity test with soil macroorganisms (earthworms, OECD 222) is proposed for the category member Fatty acids, C18-unsatd., dimers (CAS No. 61788-89-4). A long-term test is considered in order to take the potential persistence of the category members into account, as well as the low water solubility. Testing of the toxicity on earthworm evaluates the exposure to the test substance via soil pore water, surface contact as well as by ingestion of soil particles. In the case of observed effects in the proposed test, additionally a long-term toxicity test with higher plants will be conducted according to ISO 22030 with the same substance. Otherwise it is assumed, that due to the lack of effects in long-term toxicity tests with soil invertebrates, as well as in a long-term toxicity test with fish within the solubility limit of the tested substance (CAS 68783-41-5) and their low bioaccumulation potential, toxicity to plants cannot be expected. Therefore an additional long-term toxicity test with higher plants would not be reasonable.*" ECHA notes that the test on long-term toxicity to terrestrial invertebrates 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.

Pursuant to Article 40(3)(a) of the REACH Regulation, the Registrant shall carry out the proposed test: Earthworm reproduction test in Eisenia fetida or Eisenia andrei (test method: OECD 222) using the registered substance.

2. Long-term toxicity to terrestrial plants

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.

The proposed test that ECHA accepted under subsection 1. above is not sufficient by itself to address the standard information requirements of Annex IX, section 9.4.3. and Annex X, section 9.4.6. ECHA notes that the registration dossier does not contain data for this endpoint.

The Registrant provided the following justification for conducting the proposed test: "In the case of observed effects in the proposed test, additionally a long-term toxicity test with higher plants will be conducted according to ISO 22030 with the same substance. Otherwise it is assumed, that due to the lack of effects in long-term toxicity tests with soil invertebrates, as well as in a long-term toxicity test with fish within the solubility limit of the tested substance (CAS 68783-41-5) and their low bioaccumulation potential, toxicity to plants cannot be expected. Therefore an additional long-term toxicity test with higher plants would not be reasonable."
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* (May 2008), ECHA considers that the substance would fall into soil hazard category 3. 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 long-term soil toxicity test.

As the Guidance advocates performing an initial screening assessment based upon the EPM, together with a confirmatory long-term soil toxicity test (the long-term toxicity to terrestrial invertebrates test, specified in 1. above), which the Registrant is requested to carry out by the present decision, ECHA considers that at this stage it is not possible to determine whether a test will be required to fulfil the standard information requirements of Annex IX, 9.4.3. and Annex X, 9.4.6. of the REACH Regulation.

The Registrant shall determine the need to perform further terrestrial toxicity tests on plants based on the outcome of the requested toxicity test on terrestrial invertebrates and the considerations set out in Table R.7.11.-2, section R7.C. of the ECHA *Guidance on information requirements and chemical safety assessment* (May 2008).

Pursuant to Article 40(3)(a) of the REACH Regulation, the Registrant shall carry out the proposed test: Soil Quality –Biological Methods – Chronic toxicity in higher plants – ISO 22030 using the registered substance, if the outcome of the test specified in Section II point 1. above indicates the need for further testing. In any case the registrant needs to state the reasons for his decision to perform or waive the experimental testing.

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. 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://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.

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Geert Dancet
Executive Director