

Helsinki, 05/07/2012

Decision number: TPE-D-0000002128-78-05/F

**DECISION ON A TESTING PROPOSAL SET OUT IN A REGISTRATION PURSUANT TO ARTICLE 40(3) OF REGULATION (EC) NO 1907/2006****For Glycerides, C8-18 and C18-unsatd. mono- and di-, acetates, CAS No. 91052-13-0 (EC No. 293-170-2), 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)(e) thereof for Glycerides, C8-18 and C18-unsatd. mono- and di-, acetates, CAS No. 91052-13-0 (EC No. 293-170-2), by [REDACTED] (Registrant), latest submission number [REDACTED] for the tonnage band of 1000 tonnes or more per year:

- Viscosity (OECD Guideline 114)
- Long-term toxicity testing on invertebrates (OECD Guideline 222)
- Long-term toxicity testing on plants (ISO 22030). The test is proposed to be conducted in case of effects are observed in the proposed earthworm reproduction test.

On 30 November 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 30 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 22 December ECHA received comments from the Registrant agreeing to ECHA's draft decision, but asking for clarification on the tiered terrestrial testing.

ECHA considered the Registrant's comments received and modified the statement of reasons (section III.3) accordingly.

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.

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.

ECHA has reviewed the proposals for amendment received and decided to amend the draft decision accordingly.

On 16 April 2012 ECHA referred the draft decision to the Member State Committee.

On 27 April 2012 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 REACH requirements. The decision does not prevent ECHA to initiate a compliance check on the present dossier at a later stage.

## 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 method(s) and the registered substance subject to the present decision:

1. Viscosity (Annex IX, 7.17., test method: Viscosity of liquids, OECD 114);
2. Long-term toxicity to terrestrial invertebrates, (Annex X, 9.4.4., test method: Earthworm Reproduction Test [*Eisenia fetida*/*Eisenia andrei*], OECD 222); and
3. Toxicity to terrestrial plants (Annex X, 9.4.6. (test method: ISO standard 22030).

The Registrant shall conduct the earthworm reproduction test before conducting the test on chronic toxicity in higher plants. The Registrant shall consider whether the outcome of the chemical safety assessment based on the results of the earthworm reproduction test provides a possibility for waiving the long-term toxicity testing on plants according to Column 2 Annex X, 9.4.

Pursuant to Article 40(3)(c) of the REACH Regulation the Registrant is required to carry out the following additional test using the test method indicated on the registered substance:

4. Soil Microorganisms: Nitrogen Transformation test (Annex IX, 9.4.2. (test method: EU C.21 or OECD 216).

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.

## 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. Viscosity

Information on 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 generate the data for this endpoint. Therefore, pursuant to Article 40(3)(a) of the REACH Regulation, the Registrant is required to carry out the proposed test: Viscosity of liquids (test method: OECD 114) using the registered substance.

## 2. Toxicity to soil macro-organisms except arthropods

Long-term toxicity testing on 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 notes that there are no data available on the effects of Glycerides, C8-18 and C18-unsatd. mono and di-, acetates on terrestrial organisms. Therefore, the Registrant has used the equilibrium partitioning method to assess the hazard to soil organisms. The Registrant considers that in addition to this screening risk assessment, a confirmatory long-term soil toxicity test, the earthworm reproduction test according to OECD 222, is required. ECHA considers this justification appropriate for the testing of the registered substance. A long-term earthworm test allows uptake via all possible exposure routes, via surface contact, soil particle ingestion and the porewater. As such earthworms are highly exposed to toxicants in soil and may be sensitive to the potential adverse effects of a substance.

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

## 3. Toxicity to terrestrial plants

Long-term toxicity testing on terrestrial plants is a standard information requirement as laid down in Annex X, 9.4.6. 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 generate the data for this endpoint.

The Registrant is proposing to conduct the test only if effects are observed in the OECD 222 earthworm reproduction test. According to REACH "Guidance on information requirements and chemical safety assessment", Chapter R7c (version 1, August 2008) Table R.7.11-2, p. 131 a confirmatory long-term soil toxicity test, here the earthworm reproduction test referred to in point 2 of Section III above, is required when a substance falls in Hazard category 3. If based on the new results the  $PEC/PNEC_{screen} < 1$  and there is no indication of risk, no further studies are required. If the  $PEC/PNEC_{screen} > 1$  or there is indication of risk, further long-term studies according to the standard information requirements of Annex X are required, here the toxicity to terrestrial plants test proposed by the Registrant, and the lowest value should be used for  $PNEC_{soil}$  derivation.

Therefore, the registrant shall consider whether the outcome of the CSA based on the results of the earthworm reproduction test provides a possibility for waiving the long term toxicity testing on plants according to column 2 annex 9.4. If waiving of the plant toxicity

test is not possible, the Registrant is, pursuant to Article 40(3)(a) of the REACH Regulation, required to carry out the proposed toxicity test to plants: Chronic toxicity in higher plants test in *Brassica rapa* (dicots) and *Avena sativa* (monocots) (test method: ISO 22030) using the registered substance.

#### **4. Toxicity to terrestrial micro-organisms**

Pursuant to Article 40(3)(c) of the REACH Regulation, ECHA may accept a testing proposal in accordance with Article 40(3)(a) but require the Registrant to carry out additional tests in case of non-compliance of the testing proposal.

In order to fulfil the information requirements for terrestrial toxicity (section 9.4.) the Registrant proposed the tests referred to in points 2 and 3 above. These have been accepted in accordance with Article 40(3)(a).

A MSCA proposed that the Registrant also needs to determine the toxicity to terrestrial microorganisms in order to fulfil the information requirements of terrestrial toxicity. Indeed, pursuant to section 9.4.2. of Annex IX of REACH the hazard to soil microbial communities is part of the standard information requirements for measuring terrestrial toxicity.

Moreover, according to the Guidance the PNECscreen is calculated through EPM on the basis of aquatic toxicity data only. Intrinsic properties of soil microbial communities however are not addressed through the EPM extrapolation method and therefore such information needs to be generated.

Therefore, pursuant to Article 40(3)(c) of the REACH Regulation, the Registrant is required to carry out in addition to the tests referred to in points 2 and 3 above the following test using the indicated test method: Soil Microorganisms, Nitrogen transformation test (test method: EU C.21 or OECD 216) using the registered substance.

#### IV. 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 ecotoxicological and toxicological tests and analyses shall be carried out in compliance with the principles of good laboratory practice (GLP). National authorities monitoring GLP maintain lists of test facilities indicating the relevant areas of expertise of each facility.

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.

#### 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://echa.europa.eu/appeals/app\\_procedure\\_en.asp](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