EUROPEAN CHEMICALS AGENCY

Decision number: TPE-D-2114308501-64-01/F Helsinki, 4 September 2015

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

For Propanol, oxybis-, oligomeric reaction products with 1,1'-methylenebis[isocyanatobenzene], propylene glycol monomethacrylate-blocked, CAS No NS (EC No 923-201-3), 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)(d) thereof for Propanol, oxybis-, oligomeric reaction products with 1,1'-methylenebis[isocyanatobenzene], propylene glycol monomethacrylate-blocked, CAS No NS (EC No 923-201-3, submitted by [redacted] (Registrant).

- Earthworm Reproduction Test (*Eisenia fetida/Eisenia andrei*) (OECD Guideline 222) with registered substance

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 submitted after the deadline for updating (14 March 2015) communicated to the Registrant by ECHA on 5 February 2015.

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 28 May 2013.

On 14 November 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.

By 22 December 2014 the Registrant did not provide any comments on the draft decision to ECHA.

On 23 July 2015, ECHA notified the competent authorities of the Member States of its draft decision and invited them to propose amendment to the draft decision under Article 51 of the REACH Regulation.

As no amendment was proposed, 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) of the REACH Regulation using the indicated test method and the registered substance subject to the present decision:

1. Long-term toxicity to terrestrial invertebrates (Annex IX, 9.4.1., column 2; 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:

2. Long-term toxicity testing on plants (Annex IX, 9.4.3., column 2); test method: Terrestrial plants, growth test (OECD 208), with at least six species tested (with as a minimum two monocotyledonous species and four dicotyledonous species) or test method: Soil Quality – Biological Methods – Chronic toxicity in higher plants (ISO 22030);
3. Effects on soil micro-organisms (Annex IX, 9.4.2.; test method: Soil microorganisms: nitrogen transformation test, EU C.21/OECD 216);

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 **12 September 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)

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 Annex IX, 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.), and short-term toxicity testing on plants (Annex IX, section 9.4.3.). Column 2 of section 9.4 of Annex IX specifies that long-term toxicity testing shall be considered by the Registrant instead of short-term, in particular for substances that have a high potential to adsorb to soil or that are very persistent.

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.

1. Long-term toxicity to terrestrial invertebrates (Annex IX, 9.4.1. and column 2)

a) Examination of the testing proposal

The Registrant proposed a long-term toxicity test on terrestrial invertebrates (OECD Guideline 222), with the following justification:

"No experimental data are available on the toxicity of UMA 121 to terrestrial organisms. Therefore, a testing proposal is entered for a chronic earthworm study according to OECD Guideline 222. The dossier will be updated as soon as possible and the Chemical Safety Assessment according to Annex I of Regulation (EC) No 1907/2006 will be re-evaluated based on the outcome of this new study".

According to section R.7.11.5.3., Chapter R.7c of the ECHA *Guidance on information requirements and chemical safety assessment* (version 1.1, November 2012), substances that are ionisable or have a log K_{ow}/K_{oc} >5 are considered highly adsorptive, whereas substances with a half-life >180 days are considered very persistent in soil. According to the evidence presented within the Registration dossier, the substance has a high potential to adsorb to soil (logK_{ow} 3.9-7/ Log K_{oc} >4) and is likely to persist in the environment (14.8-16.6% degradation in 28 days from the screening study). Therefore, ECHA agrees that long-term testing is indicated (Column 2 of Section 9.4. of Annex IX). The proposed test is suitable to address the information requirement of Annex IX, section 9.4.1.

b) 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.

2. Long-term toxicity testing on plants (Annex IX, 9.4.3., column 2)

The proposed long-term test on invertebrates only address the information requirement of Annex IX, section 9.4.1. It is not sufficient by itself to address the standard information requirement of Annex IX, section 9.4.3. ECHA notes that the registration dossier does not contain data for this endpoint.

As described above, the Registrant included a testing proposal for terrestrial invertebrates. The Registrant waived the plant study as follows: *"No terrestrial studies are available for UMA 121. Therefore, a testing proposal is entered for a chronic earthworm study according to OECD Guideline 222. The dossier will be updated as soon as possible and the Chemical Safety Assessment according to Annex I of Regulation (EC) No 1907/2006 will be re-evaluated based on the outcome of this new study".*

Furthermore, the Registrant has considered that it is unfeasible, with the currently available information, to derive a PNEC value for aquatic organisms. Thus, it is not possible to waive the standard information requirements for the terrestrial compartment through an initial screening assessment based upon the Equilibrium Partitioning Method (EPM), mentioned in Column 2 of Annex IX, section 9.4. Consequently there is an information gap and it is necessary to provide information for the standard information requirement of Annex IX, Section 9.4.3.

By proposing a long-term toxicity test (accepted by ECHA under the subsection above), ECHA considers that the Registrant has concluded on the need for long-term toxicity testing to be performed instead of short-term, on the basis that the substance meets the column 2 adaptation criteria of Annex IX, section 9.4. Further, ECHA considers based on the substance properties as discussed under subsection (III.1.a) above, that there is indication for a high adsorption potential/high persistence of the substance in soil. High adsorption potential/high persistence of the substance indicates the need for long-term testing to be performed (Column 2 of Section 9.4. of Annex IX). On this basis, ECHA considers that long-term testing is indicated (Column 2 of Section 9.4. of Annex IX). Moreover, section R.10.6.2., Chapter R10 of the abovementioned Guidance allows the potential application of a lower assessment factor if information on additional long-term terrestrial toxicity test of two trophic levels were available. In contrast, the Guidance does not allow for a lower assessment factor to be applied if information on a short-term study were to become available in addition to the long-term invertebrate study, which ECHA accepted under subsection A 1 above.

OECD guideline 208 (Terrestrial plants, growth test) considers the need to select the number of test species according to relevant regulatory requirements, and the need for a reasonably broad selection of species to account for interspecies sensitivity distribution. For long-term toxicity testing, ECHA considers six species as the minimum to achieve a reasonably broad selection. Testing shall be conducted with species from different families, as a minimum with two monocotyledonous species and four dicotyledonous species, selected according to the criteria indicated in the OECD 208 guideline. The Registrant should consider if testing on additional species is required to cover the information requirement.

Therefore, pursuant to Article 40(3)(c) of the REACH Regulation, the Registrant is required to carry out one of the following additional studies using the registered substance subject to the present decision: Terrestrial plants, growth test (OECD 208), with at least six species tested (with as a minimum two monocotyledonous species and four dicotyledonous species), or Soil Quality – Biological Methods – Chronic toxicity in higher plants (ISO 22030).

3. Effects on soil micro-organisms (Annex IX, 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 III A 1 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).

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).

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 Ofelia Bercaru, Head of Unit, Evaluation

[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.