EUROPEAN CHEMICALS AGENCY

Decision number: TPE-D-0000002630-83-03/F Helsinki, 28 February 2014

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

For 1,2-Benzenedicarboxylic acid di C16-18-alkyl esters, CAS No 90193-76-3 (EC No 290-580-3), 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)(e) thereof for 1,2-Benzenedicarboxylic acid, di-C16-18-alkyl esters, CAS No 90193-76-3 (EC No 290-580-3), by [redacted] (Registrant).

- Earthworm Reproduction Test (Eisenia fetida/Eisenia andrei) (OECD Guideline 222)

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 31 October 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 2 November 2010, pursuant to Article 40(1) of the REACH Regulation, ECHA initiated the examination of the testing proposal set out by the Registrant in the registration dossier for the substance mentioned above.

On 29 June 2012 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 27 July 2012 ECHA received comments from the Registrant agreeing to ECHA's draft decision concerning long-term toxicity on terrestrial invertebrates and comments from the Registrant disagreeing to ECHA's draft decision concerning toxicity to micro-organisms.

ECHA considered the Registrant's comments received. On basis of the comments, Section II was amended. The Statement of Reasons (Section III) was changed accordingly.

On 31 October 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 did not propose amendments to the draft decision and ECHA took the decision pursuant to Article 51(3) of the REACH Regulation.

II. Testing required

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:

Long-term toxicity on terrestrial invertebrates (Annex X, 9.4.4.; test method: Earthworm reproduction test (*Eisenia fetida/Eisenia andrei*), OECD 222).

Pursuant to Articles 40(4) and 22 of the REACH Regulation, the Registrant shall submit to ECHA by **28 November 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 proposal submitted by the Registrant for the registered substance.

Long-term toxicity testing on terrestrial invertebrates is a standard information requirement as laid down in Annex X, section 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 proposed an earthworm reproduction test (OECD 222) and justified the testing proposal for this endpoint by the following statement: "In order to fulfil the standard information required according to EC1907/2006, Annex X, Column 1 (9.4), an earthworm long term toxicity test is proposed." In proposing the test it is apparent that the Registrant considered that there is a need to perform long-term toxicity testing on terrestrial invertebrates. With respect to the testing proposed ECHA has come to the conclusions set out below.

The earthworm reproduction test (OECD 222) is considered capable of generating information that is appropriate for the fulfilment of the standard information requirement of Annex X, section 9.4.4.

Therefore, pursuant to Article 40(3)(a) of the REACH Regulation, the Registrant is required to carry out the proposed study:

- Long-term toxicity on terrestrial invertebrates (Annex X, 9.4.4.; test method: Earthworm reproduction test (*Eisenia fetida/Eisenia andrei*), OECD 222)

using the registered substance.

The Registrant has proposed an earthworm reproduction test (OECD 222) in order to fulfil all three standard information requirements in section 9.4. of Annex X of the REACH Regulation.

However, the proposed test only addresses invertebrates (i.e. the information requirement in Annex X, section 9.4.4.) and does not address the other trophic level requested for this tonnage band (i.e. the information requirement in Annex IX, sections 9.4.2.).

However, ECHA notes that the request to perform a toxicity to micro-organisms (Annex IX, 9.4.2., EU Method C.21 or OECD 216) was removed from the draft decision as the Registrant in his comments provided justifications for waiving soil micro-organisms testing, based on a weight of evidence on the information available from a negative effect assessment on microbial sewage treatment communities (EC50 (3h) > 100 mg/L (nominal) and the key biodegradation study (where significant degradation (after 28 days, 51.5%)) was not toxic to the sewage treatment microorganisms at a concentration of 15.15 mg/L, therefore the concentration of the toxicity control is considered as NOEC for aquatic microorganisms.

According to ECHA Guidance on information requirements and chemical safety assessment (November 2012), Chapter R.7C, Table R.7.11-2, p. 134, the substance would fall into soil hazard category 3, where a confirmatory long-term soil toxicity test should be performed to ascertain any indication of risk / high hazard potential, prior to conducting additional soil testing in accordance with the standard information requirements.

Column 2 of Annex X, section 9.4. advises the Registrant to consider long term toxicity testing instead of short term in particular for substances that have a high potential to adsorb to soil or that are very persistent. Furthermore, long term toxicity testing is an Annex X 9.4.4. and Annex X 9.4.6. Column 1 requirement.

The Registrant in his comments agrees to undertake the long-term toxicity on terrestrial invertebrates test, as no adverse effects were observed up to the water solubility of the substance, the predicted no effect concentration for aquatic compartment (PNECwater) cannot be calculated and, respectively, equilibrium partitioning method is not appropriate to derive a valid PNECsoil value. The Registrant in his comments agrees he will revise the chemical safety assessment, as soon as the result of the Earthworm Reproduction test is available and demonstrate that the PEC/PNECsoil is < 1, i.e. no indication of risk from the confirmatory long-term soil toxicity testing to earthworms.

The Registrant also outlines in his comments the reasoning for selection of the test guideline, OECD 222 earthworm reproduction test as it uses one of the representatives soil fauna as its test species, toxicity on earthworm evaluates the exposure to the test substance via soil pore water, surface contact as well as by ingestion of soil particles and earthworms would be highly exposed to toxicants in soil and hence are sensitive to the potential adverse effects of the substance.

Based on the waiving statement for plant toxicity ("In order to fulfil the standard information required according to Regulation (EC) 1907/2006, Annex X, Column 2 (9.4), an earthworm long term toxicity test (OECD 222) is proposed for this substance. Based on those results, long term testing for terrestrial plants will be further considered if necessary.") ECHA acknowledge that the need to perform this test will depend on the outcome of the OECD 222 test and the considerations set out in Table R.7.11.-2 of Guidance R7.C.

Note for consideration of the Registrant:

Once the required long-term toxicity on terrestrial invertebrates test has been provided the Registrant shall revise the chemical safety assessment as necessary according to Annex I of the REACH Regulation. The Registrant shall then determine whether further testing on terrestrial plants is necessary to fulfil the information requirements of Annex X, 9.4.6., as outlined in ECHA guidance section R.7.11.6. The Registrant shall include the information on this information requirement or a justification for adapting this information requirement in the updated dossier.

IV. Adequate identification of the composition of the tested material

The process of evaluation of testing proposals set out in Article 40 of the REACH Regulation aims at ensuring that the new study meets real information needs. Within this context, the Registrant's dossier was sufficient to confirm the identity of the substance to the extent necessary for evaluation 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 study 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 study must be suitable to assess these.

Furthermore, there must be adequate information on substance identity for the sample tested and the grade registered to enable the relevance of the study 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). 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.

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.

[redacted]
Leena Ylä-Mononen
Director of Evaluation