

Decision number: TPE-D-0000002369-68-03/F

Helsinki, 21 December 2012

DECISION ON A TESTING PROPOSAL SET OUT IN A REGISTRATION PURSUANT TO ARTICLE 40(3) OF REGULATION (EC) NO 1907/2006**For Distillation residue, butyl alcohols production, rectification, List No 931-740-0, 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 Distillation residue, butyl alcohols production, rectification, List No 931-740-0, by [REDACTED] (Registrant).

- Earthworm, Acute Toxicity Test (OECD 207);
- Terrestrial Plants Tests: Seedling Emergence and Seedling Growth Test (OECD 208) **or** Measurement of Inhibition of Root Growth (ISO 11269-1).

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 14 June 2012, 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.

On 17 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 07 March 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.

By 10 April 2012 the Registrant did not provide any comments on the draft decision to ECHA.

On 14 June 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 did not propose amendments to the draft decision and ECHA took the decision pursuant to Article 51(3) 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 to initiate a compliance check on the present dossier at a later stage.

II. Testing required

The Registrant shall carry out one of the following additional tests pursuant to Article 40(3)(c) of the REACH Regulation using the indicated test method and the registered substance subject to the present decision:

1. Long-term toxicity testing on invertebrates (Annex X, 9.4.4.):

- Earthworm reproduction test (test method: OECD 222);
or
- Enchytraeid reproduction test (test method: OECD 220);
or
- Collembolan reproduction test (test method: OECD 232);
or
- Predatory mite reproduction test (test method: OECD 226).

The Registrant shall carry out one of the following tests pursuant to Article 40(3)(a) of the REACH Regulation using the indicated test method and the registered substance subject to the present decision:

2. Long-term toxicity testing on plants (Annex X, 9.4.6.):

- Seedling emergence and seedling growth test (test method: OECD 208);
or
- Chronic toxicity in higher plant (test method: ISO 22030);

while the following originally proposed tests are rejected pursuant to Article 40(3)(d) of the REACH Regulation:

- Measurement of Inhibition of Root Growth (ISO 11269-1); and
- Earthworm acute toxicity according to OECD 207.

Pursuant to Articles 40(4) and 22 of the REACH Regulation, the Registrant shall submit to ECHA by **23 September 2013** 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. Effects on terrestrial organisms – Long-term toxicity to soil invertebrates

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

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 proposed to conduct an earthworm, acute toxicity test (OECD 207). This proposed test is an acute study that is not capable to fulfil the information requirement for substances registered for 1000 tones or more per year. It is not in line with the REACH Guidance on information requirements and chemical safety assessment, Chapter R7c, Table R.7.11-2, p. 131 (May 2008). According to the cited table in the Guidance, a confirmatory long-term soil toxicity test is needed. This is to verify the possible toxicity to soil invertebrates that the proposed acute study cannot generate. Dependent on the properties of the registered substance the Registrant can choose between any of the four long-term studies listed above in section II which as such are all capable to generate appropriate information on long-term toxicity on terrestrial organisms.

Therefore, pursuant to Article 40(3)(d) of the REACH Regulation, the proposed study: earthworm, acute toxicity test (OECD 207) is rejected. Pursuant to Article 40(3)(c) of the REACH Regulation, the Registrant is required to carry out one of the following studies: earthworm reproduction test (test method: OECD 222) or enchytraeid reproduction test (test method: OECD 220) or Collembolan reproduction test (test method: OECD 232) or predatory mite reproduction test (test method: OECD 226).

2. Effects on terrestrial organisms – Long-term toxicity to terrestrial plants

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

Long-term toxicity testing to 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 objective of the testing proposal is to generate the necessary information for the environmental hazard assessment. Performing a chronic toxicity test is needed in order to generate the data for this endpoint. In order to do so, either the proposed seedling emergence and seedling growth (OECD 208) or chronic toxicity in higher plants (ISO 22030) should be applied, whereas the alternative test proposed, namely measurement of inhibition of root growth, according to the test method ISO 11269-1 is intended for a rapid estimation of soil quality by comparing the growth of roots of a specific plant under standard conditions with that in the test soil. Moreover, this method is applicable to substances deliberately added to the soil which does not apply for the registered substance.

Therefore, pursuant to Article 40(3)(d) of the REACH Regulation, the proposed study: higher plant test according to ISO 11269-1 soil quality – determination of the effects of pollutants on soil flora – part 1: method for the measurement of inhibition of root growth is rejected. Pursuant to Article 40(3)(a) of the REACH Regulation, the proposed study: terrestrial plants test: seedling emergence and seedling growth test (test method: OECD 208) or Chronic toxicity in higher plants (test method: ISO 22030) using the registered

substance is required to be carried out.

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. The notice of appeal will be deemed to be filed only when the appeal fee has been paid.



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