

Decision number: TPE-D-0000002417-75-05/F

Helsinki, 12 November 2012

DECISION ON A TESTING PROPOSAL SET OUT IN A REGISTRATION PURSUANT TO ARTICLE 40(3) OF REGULATION (EC) NO 1907/2006**For List No 920-762-6, 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(e) thereof for List No 920-762-6, by [REDACTED] (Registrant), latest submission number [REDACTED] for the tonnage band of 1000 tonnes or more per year:

- Soil simulation testing (OECD Guideline 307);
- Short-term toxicity to terrestrial invertebrates (OECD Guideline 207);
- Effects on soil microorganisms: Nitrogen transformation test (OECD Guideline 216).

On 28 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 11 April 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 10 May 2012 ECHA received comments from the Registrant agreeing to ECHA's draft decision.

ECHA considered the Registrant's comments received and did amend the draft decision.

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, one Competent Authority of a Member State submitted a proposal for amendment to the draft decision.

On 18 July 2012 ECHA notified the Registrant of the proposal for amendment to the draft decision and invited him pursuant to Article 51(5) of the REACH Regulation to provide comments on that proposal for amendment within 30 days of the receipt of the notification.

ECHA reviewed the proposal for amendment received and decided to amend the draft

decision.

On 30 July 2012 ECHA referred the draft decision to the Member State Committee.

On 17 August 2012, the Registrant provided comments on the proposed amendment. 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 3 September 2012 in a written procedure launched on 22 August 2012 and ECHA took the decision pursuant to Article 51(6) 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 the following proposed tests pursuant to Article 40(3)(a) of the REACH Regulation using the indicated test methods:

1. Aerobic and anaerobic transformation in soil (Annex IX, 9.2.1.3., test method: EU C.23./OECD 307);
2. Earthworm, acute toxicity tests (Annex IX, 9.4.1., test method: EU C.8./OECD 207);
and
3. Soil microorganisms: Nitrogen transformation test (Annex IX, 9.4.2., test method: EU C.21./OECD 216).

The Registrant shall carry out the following additional test pursuant to Article 40(3)(c) of the REACH Regulation using the indicated test method:

4. Soil microorganisms: Carbon transformation test (Annex IX, 9.4.2., test method: EU C.22./OECD 217).

Pursuant to Articles 40(4) and 22 of the REACH Regulation, the Registrant shall submit to ECHA by **12 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 proposals submitted by the Registrant for the registered substance.

In the original draft decision ECHA requested that the Registrant shall submit an update of the registration dossier containing the required information within 12 months from the date of the decision. During the commenting period on the draft decision, the Registrant indicated that given the difficulty of development of the most suitable analytical technique for the soil simulation test, given the short-term toxicity test on terrestrial invertebrates and the effects on soil microorganisms tests incubation periods, given the need to conduct the tests in a specific order, and given the time needed to evaluate the results and update the dossier, an additional period of 12 months was requested. ECHA considers that the request for extension of the deadline was adequately justified. Therefore ECHA is requesting the Registrant to provide the required information within 24 months of the date of the final decision.

1. Aerobic and anaerobic transformation in soil

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

According to column 1 of Section 9.2.1.3 of Annex IX of the REACH Regulation, soil simulation testing is a standard information requirement for substances with a high potential for adsorption to soil.

The Registrant has submitted a testing proposal to cover this endpoint and has provided no adaptation to the standard information requirement according to column 2. The Registrant has based their proposal on the results for the screening test for biodegradability reported in the registration dossier, which indicated that the criteria for ready biodegradability are not met. The Registrant specifically noted that *"As screening ready biodegradability tests have not shown a rapid mineralisation of this organic content, it is worthwhile to propose testing for biodegradation in soil. An OECD 307 is proposed, but its feasibility has to be further investigated depending on recovery and quantitative analytical determination of the various molecules"*. ECHA further notes that the substance is used as fertilizer and therefore the soil is directly exposed.

The method described in OECD 307 test guideline (Aerobic and Anaerobic Transformation in Soil) is designed to determine the rate of transformation of the test substance, and the nature and rates of formation and decline of transformation products to which plants and soil organisms may be exposed. The Registrant should apply the most suitable analytical technique to quantify to the extent possible those constituents and relevant transformation/degradation products that are present or being generated in individual amounts ≥ 0.1 % (w/w). The Registrant should also consider the potential volatility of the constituents when deciding on the test design and analytics.

Therefore, pursuant to Article 40(3)(a) of the REACH Regulation, the Registrant is required to carry out the proposed study: Aerobic and anaerobic transformation in soil (Annex IX, 9.2.1.3., method C.23 of Regulation (EC) No 440/2008, OECD Guideline 307).

2. Earthworm acute toxicity test

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

A short-term toxicity study on terrestrial invertebrates is a standard information requirement as laid down in Annex IX, section 9.4.1., column 1 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 has proposed an earthworm acute test (OECD 207) to cover the endpoint in question. The Registrant has justified the testing proposal by the following statement: *"According to REACH Regulation and guidance R.7.11.5.3. three terrestrial trophic level results are needed to derive a PNEC_{soil}: micro-organisms, plants and invertebrates. Concerning invertebrates, we choose to plan a test on worms rather than arthropods."*

ECHA notes that the substance has a low potential to adsorb to soil and the substance is not likely to be very persistent. ECHA further notes that the substance is not acutely very toxic

to aquatic organisms. According to the ECHA Guidance on information requirements and chemical safety assessment, R.7C, R.7.11.6.3., p. 131, the substance would accordingly fall into soil hazard category 1.

According to soil hazard category 1, short-term toxicity tests according to the standard information requirements of Annex IX (invertebrates, micro-organisms and plants) are needed in case the screening assessment indicates risk. The Registrant has not been able to conduct the soil hazard category 1 screening assessment and the Registrant has justified this with the following statement: "*the substance being a complex UVCB, it is not possible to calculate a PNEC_{soil} using equilibrium partitioning method*". However, the Registrant has indicated that the terrestrial compartment is relevant for risk assessment of the registered substance and submitted testing proposals on soil macro- and micro-organisms. The Registrant therefore follows the soil hazard category 1 testing strategy.

Therefore, pursuant to Article 40(3)(a) of the REACH Regulation, the Registrant is required to carry out the proposed study: Earthworm acute toxicity tests (Annex IX, 9.4.1., test method C.8 of Regulation (EC) No 440/2008, OECD Guideline 207).

3. Soil microorganisms: Nitrogen transformation test

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

Effects on soil micro-organisms is a standard information requirement as laid down in Annex IX, section 9.4.2. 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 has justified the testing proposal by the following statement: "*According to REACH Regulation and guidance R.7.11.5.3. three terrestrial trophic level results are needed to derive a PNEC_{soil}: micro-organisms, plants and invertebrates*". The Registrant has also indicated that the terrestrial compartment is relevant for risk assessment of the registered substance.

Therefore, pursuant to Article 40(3)(a) of the REACH Regulation, the Registrant is required to carry out the proposed study: Soil micro-organisms: Nitrogen transformation test (Annex IX, 9.4.2., test method C.21 of Regulation (EC) No 440/2008, OECD Guideline 216).

4. Soil microorganisms: Carbon transformation test

Pursuant to Article 40(3)(c) of the REACH Regulation, ECHA may require the Registrant to carry out the additional test in case of non-compliance of the testing proposal with Annexes IX and X of the REACH Regulation.

According to the ECHA Guidance on information requirements and chemical safety assessment, R.7C, R.7.11.3.1., p. 112, the nitrogen transformation test (OECD guideline 216) is considered sufficient for most non-agrochemicals, whereas the carbon transformation test (OECD guideline 217) is needed for substances in agrochemical use. As the substance is applied directly to soil as a fertilizer, ECHA considers this as an agrochemical use and the carbon transformation test is required in addition to the nitrogen transformation test.

Therefore, pursuant to Article 40(3)(c) of the REACH Regulation, the Registrant is required to carry out the additional study: Soil micro-organisms: Carbon transformation test (Annex IX, 9.4.2., test method C.22 of Regulation (EC) No 440/2008, OECD Guideline 217).

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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