ECHA
EUROPEAN CHEMICALS AGENCY

Helsinki, 10 April 2012

Decision number: TPE-D-0000001917-66-03/F

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

For Cloquintocet-mexyl, CAS No 99607-70-2 (EC No 619-447-3), 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 testing proposals set out in the registration dossier for Cloquintocet-mexyl, CAS No 99607-70-2 (EC No 619-447-3) submitted by [redacted] (the Registrant), latest submission number [redacted] for 10 to 100 tonnes per year.

In accordance with Articles 10(a)(ix) and 12(1)(d) of the REACH Regulation, the Registrant submitted the following testing proposals as part of the jointly submitted registration dossier to fulfil the information requirements set out in Annex IX:

- Effects on soil micro-organisms according, Annex IX, 9.4.2., test method: OECD 216 (Soil Microorganisms: Nitrogen Transformation Test); and
- Short-term toxicity to plants, Annex IX, 9.4.3., test method: OECD 208 (Terrestrial Plants Test: Seedling Emergence and Seedling Growth Test).

The examination of the testing proposals was initiated upon the date when receipt of the complete registration dossier was confirmed on 29 April 2011.

On 24 October 2011 ECHA notified the Registrant of its draft decision and invited him pursuant to Article 50(1) of the REACH Regulation to provide comments within 30 days of the receipt of the draft decision.

By 23 November 2011 the Registrant did not provide any comments on the draft decision to ECHA.

On 20 January 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 requirements of the REACH Regulation. The decision does not prevent ECHA to initiate a compliance check on the present dossier at a later stage.

II. Testing required

Pursuant to Article 40(3)(a) of the REACH Regulation, the Registrant shall carry out the following tests using the indicated test method:

- Effects on soil micro-organisms, Annex IX, 9.4.2, test method: EU C.21/ OECD 216 (Soil Microorganisms: Nitrogen Transformation Test);
- Short-term toxicity to plants, Annex IX, 9.4.3., test method: OECD 208 (Terrestrial Plants Test: Seedling Emergence and Seedling Growth Test)

Pursuant to Articles 40(4) and 22 of the REACH Regulation, the Registrant shall submit to ECHA by **10 October 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 proposal of the Registrant for the registered substance. Pursuant to Article 40(3)(a) of the REACH Regulation, ECHA may require a registrant to carry out a proposed test.

The proposed tests on soil micro-organisms and on terrestrial plants referred to in Section II above are part of the information requirements as laid down in Annex IX of the REACH Regulation. As no valid information on these endpoints is available for the registered substance but needs to be present in the technical dossier to meet the information requirements when reaching the tonnage level of 100 to 1000 tonnes per annum, it is in principle necessary to generate the data and to perform the tests.

Moreover, the Registrant stated in the registration dossier that a member of the joint submission for which the Registrant acts as lead registrant increased the manufacture of the registered substance to a tonnage band of 100-1000 tonnes per annum, i.e. a tonnage level where the data requirements of the proposed tests have to be met. As indicated by the testing proposed of the Registrant, there is a necessity to generate the proposed data in order to be compliant with the information requirements of the REACH Regulation at a tonnage band of 100-1000 tonnes per annum, at least for members to the joint submission. Therefore, the Registrant shall carry out the proposed tests on effects on soil micro-organisms, Annex IX, 9.4.2, test method: EU C.21/ OECD 216 (Soil Microorganisms: Nitrogen Transformation Test) and short-term toxicity to plants, Annex IX, 9.4.3., test method: OECD 208 (Terrestrial Plants Test: Seedling Emergence and Seedling Growth Test).

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 generation of information is tailored to real information needs in order to prevent unnecessary testing. The information submitted in the dossier was sufficient to confirm the identity of the substance for the purpose of assessing the testing proposal. It is noted, however, that this information, or the information submitted by other registrants of the same substance, has not been checked for compliance with the substance identity requirements set out in Section 2 of Annex VI of the REACH Regulation.

In relation to the proposed tests, the sample of substance used for the new studies must be suitable for use by all the joint registrants. Hence, the sample should have a composition that is within the specifications of the substance composition that are given by the joint registrants. It is the responsibility of all the joint registrants of the same substance to agree with the tests proposed in the testing proposal (as applicable to their tonnage level) and to document the necessary information on its composition. The substance identity information of the registered substance and of the sample tested must enable ECHA to confirm the relevance of the testing for the substance actually registered by each joint registrant. Finally, the studies must be shared by the joint registrants concerned.

V. 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.

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]

Jukka Malm
Director of Regulatory Affairs