

Final decision: TPE-D-0000001738-66-06/F

Helsinki, 04/07/2012

DECISION ON A TESTING PROPOSAL SET OUT IN A REGISTRATION PURSUANT TO ARTICLE 40(3) OF REGULATION (EC) NO 1907/2006**For 2,2-Bis[4-[bis(phenoxy)phosphoryloxy]phenyl]propane, CAS No [REDACTED] (EC No 425-220-8), 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 2,2-Bis[4-[bis(phenoxy)phosphoryloxy]phenyl]propane, CAS No [REDACTED] (EC No 425-220-8) submitted by [REDACTED] (Registrant), latest submission number [REDACTED], for 100 - 1000 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 registration dossier to fulfil the information requirements set out in Annex IX:

- a) Annex IX, 9.3.3 Further information on adsorption/desorption depending on the results of the study required in Annex VIII (Adsorption - Desorption Using a Batch Equilibrium Method) (EU test method C.18)
- b) Annex IX, 9.1.5 Long-term toxicity testing on aquatic invertebrates (Daphnia magna Reproduction Test) (EU test method C.20)
- c) Annex IX, 9.4.1 (column 2) Effects on terrestrial organisms - toxicity to invertebrates (Earthworm Reproduction Test) (test method: OECD 222)

The examination of the testing proposals was initiated upon the date when receipt of the complete registration dossier was confirmed on 29 December 2010.

On 27 June 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 27 July 2011 the Registrant did not provide to ECHA any comments on the draft decision.

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 submitted proposals for amendment to the draft decision.

On 23 February 2012 ECHA notified the Registrant of proposals for amendment to the draft decision and invited him pursuant to Article 51(5) of the REACH Regulation to provide comments on those proposals for amendment within 30 days of the receipt of the notification.

ECHA reviewed the proposals for amendment received and modified the draft decision accordingly without changing its content.

On 5 March 2012, the draft decision was referred to the Member State Committee.

The Registrant provided no comments on the proposals for amendment by 26 March 2012.

After discussion in the Member State Committee meeting on 24-27 April 2012 a unanimous agreement of the Member State Committee on the draft decision was reached on 25 April 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 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:

- a) Further information on adsorption/desorption depending on the results of the study required in Annex VIII (Annex IX, 9.3.3 EU Method C.18) (Adsorption - Desorption Using a Batch Equilibrium Method);
- b) Long-term toxicity testing on aquatic invertebrates (Annex IX, 9.1.5, EU Method C.20) (Daphnia magna Reproduction Test).
- c) Effects on terrestrial organisms - toxicity to invertebrates according to relevant test guideline (OECD 222 or OECD 220) (Annex IX, 9.4.1 (column 2)).

Pursuant to Article 3(28) of the REACH Regulation, robust study summaries to be prepared for the studies indicated above shall contain sufficient information, including information on the test material identity, to make an assessment of the relevance of the studies. This is also in line with the EU and OECD test guidelines indicated above. Among information on test material, the composition of the substance shall be given in such a detail that:

- all the impurities present at $\geq 1\%$ are specified, and
- all the impurities relevant for classification and labelling and/or PBT assessment are identified.

The Registrant shall ensure that the tested material is relevant for identifying the hazardous properties of the substance actually registered.

Pursuant to Articles 40(4) and 22 of the REACH Regulation, the Registrant shall submit to ECHA by **4 April 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.

The proposed tests (a) to (c) referred to in Section II above are part of the information requirements as laid down in Annex IX of the REACH Regulation (Annex IX 9.3.3, 9.1.5 and 9.4.1 respectively). As the information on these endpoints is not included in the technical dossier but need to be present in order to meet the information requirements, it is necessary to generate the data and to perform the tests.

Test (c) referred to in Section II

Regarding the Effects on terrestrial invertebrates, as the substance has a high potential to adsorb to soil, either Earthworm reproduction test (OECD 222) or Enchytraeid reproduction test (OECD 220) is considered to be appropriate in order to fulfil information requirements of Annex IX section 9.4.1 (column 2) under REACH Regulation. It is however the responsibility of the Registrant to select from those two options the one that uses the most appropriate and the most sensitive species for testing of the registered substance and to conduct the long term toxicity testing accordingly.

Please be informed that the performance of additional or higher tier tests on soil organisms may be requested depending on the outcome of the terrestrial invertebrates test as suggested in REACH Guidance R7c, Table R 7 11-2, p. 131.

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.



Geert Dancet
Executive Director