EUROPEAN CHEMICALS AGENCY

Decision number: TPE-D-0000003642-77-03/F Helsinki, 21 August 2013

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

For Phenol, isobutylenated, phosphate (3:1), EC No 273-065-8, 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 the following testing proposals submitted as part of the registration dossier in accordance with Articles 10(a)(ix) and 12(1)(e) thereof for Phenol, isobutylenated, phosphate (3:1), EC No 273-035-8, by [redacted] (Registrant).

- Short-term toxicity to invertebrates (OECD 207)
- Short-term toxicity to terrestrial plants (OECD 208)
- Toxicity to soil microorganisms (OECD 216)

This decision is based on the registration dossier as submitted with submission number [redacted], for the tonnage band of [redacted] per year. This decision does not take into account any updates after 20 June 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 present dossier at a later stage.

On 9 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 10 October 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 9 November 2012 the Registrant did not provide any comments on the draft decision to ECHA.

On 16 January 2013 the Registrant updated his registration dossier. ECHA modified Section III accordingly.

On 20 June 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 methods and the registered substance subject to the present decision:

1. Effects on soil micro-organisms (Annex IX, 9.4.2.; test method: Soil microorganisms: nitrogen transformation test, EU C.21/OECD 216)

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

2. Long-term toxicity on terrestrial invertebrates (Annex X, 9.4.; test method: Earthworm reproduction test (*Eisenia fetida/Eisenia andrei*), OECD 222; or Enchytraeid reproduction test, OECD 220; or Collembolan reproduction test in soil, OECD 232); and

3. Long-term toxicity testing on plants (Annex X, 9.4.6.; test method: Terrestrial Plant Test: Seedling emergence and seedling growth test, OECD 208, using at least six plant species or Soil Quality –Biological Methods – Chronic toxicity in higher plants – ISO 22030).

while the originally proposed tests for a short-term toxicity to terrestrial invertebrates (test method: EU C8/OECD 207) and for a short-term toxicity to terrestrial plants (test method: OECD 208 with three species) proposed to be carried out using the registered substance are rejected pursuant to Article 40(3)(d) of the REACH Regulation.

Pursuant to Articles 40(4) and 22 of the REACH Regulation, the Registrant shall submit to ECHA by **21 August 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 particular, the new information provided in the updated dossier on 10 January 2013 generated using the OECD TG 117 (HPLC method) for the IUCLID Section 4.7 partition coefficient was taken into account.

Toxicity testing on terrestrial organisms

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.

The Registrant must address the standard information requirements set out in Annexes IX and X, section 9.4., for different taxonomic groups: effects on soil micro-organisms (Annex IX, section 9.4.2.), short-term toxicity testing on invertebrates (Annex IX, section 9.4.1.), long-term toxicity testing on invertebrates (Annex X, section 9.4.4.), short-term toxicity testing on plants (Annex IX, section 9.4.3.) and long-term toxicity testing on plants (Annex X, section 9.4.6.).

The information on the endpoint 'effects on terrestrial organisms' is not available for the registered substance but needs to be present in the technical dossier to meet the information requirements.

1. Soil microorganisms (Annex IX, section 9.4.2.)

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. Column 2 of Section 9.4. of Annex IX of REACH specifies that in the absence of toxicity data for soil organisms, the equilibrium partitioning method may be applied to assess the hazard to soil organisms. However, ECHA considers that the intrinsic properties of soil microbial communities are not addressed through the equilibrium partitioning extrapolation method. Hence, the hazard to soil microbial communities needs to be evaluated as a standard information requirement under Annex IX, 9.4.2. Therefore, ECHA concludes that the effects on soil micro-organisms need to be ascertained by performing a relevant test.

The Registrant proposed a nitrogen transformation test (OECD 216) with the following justification "Study will be performed if deemed necessary and after aproval of the testing proposal by ECHA."According to ECHA *Guidance on information requirements and chemical safety assessment* (May 2008), Chapter R.7C, R.7.11.3.1. p112, the nitrogen transformation test (OECD 216) is considered sufficient for most non-agrochemicals.

Therefore, pursuant to Article 40(3)(a) of the REACH Regulation, the Registrant is required to carry out the proposed study: Effects on soil micro-organisms (Annex IX, 9.4.2.; test method: Soil microorganisms: nitrogen transformation test, EU C.21/OECD 216) using the registered substance.

2. Terrestrial invertebrates (Annex X, 9.4.4.)

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

The Registrant proposed a short-term toxicity test on terrestrial invertebrates (OECD 207), with the following justification: "Study will be performed if deemed necessary and after aproval of the testing proposal by ECHA."

However, ECHA considers that presently it is not possible to determine whether results obtained from the proposed short-term test (Annex IX, 9.4.1.) could be used to adequately justify an adaptation of the standard information requirement of Annex X, 9.4.4. for long-term testing. Additionally, ECHA notes that long-term tests are suitable to simultaneously address the information requirement of Annex X, section 9.4.4. and Annex IX, section 9.4.1.

Furthermore, according to section R.7.11.5.3., Chapter R.7c of the ECHA *Guidance on information requirements and chemical safety assessment* (May 2008), substances that are ionisable or have a log K_{ow}/K_{oc} >5 are considered highly adsorptive, whereas substances with a half-life >180 days are considered very persistent in soil. The data reported in the IUCLID Section 4.7 partition coefficient, conducted following the test guideline OECD 117 Partition coefficient (n-octanol/water) (HPLC method), and obtained with the substance Phosflex 71B, shows that the substance tested is composed of 4 main constituents: [redacted], with log P_{ow} of 3.78, 5.57, >6.5 and > 6.5, respectively. The Registrant has calculated that the weighted average log Pow for the mixture is 4.65. The weight average value excudes the two highest values obtained (> 6.5), as he justifies that given their low water solubility, of < 20.0 µg/L, they are not expected to bioaccumulate. ECHA notes that the justification is not acceptable, and that the weighted average log Pow of the substance should be considered as >5. As stated in section R.7.1.8.3, Chapter R.7a of the ECHA *Guidance on information requirements and chemical safety assessment* (May 2008) *"for complex mixtures, the HPLC method is ideal for determination of Kow, and a range of values should be presented, with an indication of the proportion of substance within a given range,(...) to allow the significance of these results to be reflected in the risk assessment".* ECHA would like to note that based upon the evidence presented within the registration dossier, one of the main constituents of the UVCB substance, present at a concentration of [redacted]%, shows a high potential to adsorb to soil, with a logK_{ow} of 5.57. The absorptive property of this main constituent should be adequately reflected in the selection of the test, for the purpose of conducting an adequate risk assessment for the soil compartment. Two of the additional components with log Pow value >6.5 also indicate the need for conducting long-term studies.

Therefore ECHA considers that long-term testing is warranted (Section 9.4.4 of Annex X).

The earthworm reproduction test (OECD 222), Enchytraeid reproduction test (OECD 220), and Collembolan reproduction test (OECD 232) are each considered capable of generating information appropriate for the fulfilment of the information requirements for long-term toxicity testing to terrestrial invertebrates. ECHA is not in a position to determine the most appropriate test protocol, since this decision is dependent upon species sensitivity and substance properties.

Therefore, pursuant to Article 40(3)(c), the Registrant is required to carry out one of the following studies: Long-term toxicity to terrestrial invertebrates (Annex X, 9.4.4.); test method: Earthworm reproduction test (*Eisenia fetida/Eisenia andrei*) OECD 222, or Enchytraeid reproduction test OECD 220, or Collembolan reproduction test in soil OECD 232), using the registered substance.

The originally proposed test for short-term toxicity on terrestrial invertebrates (Toxicity to earthworms: EU C.8/OECD 207) is rejected in accordance with Article 40(3)(d) of the REACH Regulation.

3. Terrestrial plants (Annex X, 9.4.6)

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

The Registrant proposed a short-term toxicity test on terrestrial plants (OECD 208), with the following justification: "Study will be performed if deemed necessary and after aproval of the testing proposal by ECHA."

The Registrant proposed to adapt this standard information requirement with the following justification: "Study will be performed if deemed necessary and after aproval of the testing proposal by ECHA".

However, ECHA considers that presently it is not possible to determine whether results obtained from the proposed short-term test (Annex IX, 9.4.3.) could be used to adequately justify an adaptation of the standard information requirement of Annex X, 9.4.6. for long-term testing. Additionally, ECHA notes that long-term tests are suitable to simultaneously address the information requirement of Annex X, section 9.4.6. and Annex IX, section 9.4.3.

Furthermore, according to section R.7.11.5.3., Chapter R.7c of the ECHA *Guidance on information requirements and chemical safety assessment* (May 2008), substances that are ionisable or have a log K_{ow}/K_{oc} >5 are considered highly adsorptive, whereas substances with a half-life >180 days are considered very persistent in soil. The data reported in the IUCLID Section 4.7 partition coefficient, conducted following the test guideline OECD 117 Partition coefficient (n-octanol/water) (HPLC method), and obtained with the substance Phosflex 71B, shows that the substance tested is composed of main 4 constituents: [redacted], with log P_{ow} of 3.78, 5.57, >6.5 and > 6.5, respectively. The Registrant has calculated that the weighted average log P_{ow} for mixture is 4.65. The weight average value excudes the two highest values obtaind (> 6.5), as he justifies that given their low water solubility, of < 20.0 µg/L, they are not expected to bioaccumulate. Furthermore, ECHA would like to note that the justification is not acceptable, and that the weighted average log Pow of the substance should be considered as >5. As stated in section R.7.1.8.3, Chapter R.7a of the ECHA *Guidance on information requirements and chemical safety assessment* (May 2008) *"for complex mixtures, the HPLC method is ideal for determination of Kow, and a range of values should be presented, with an indication of the proportion of substance within a given range,(...) to allow the significance of these results to be reflected in the risk assessment".* ECHA would like to note that based upon the evidence presented within the registration dossier, one of the main constituents of the UVCB substance, present at a concentration of [redacted] %, shows a high potential to adsorb to soil, with a logK_{ow} of 5.57. The absorptive property of this main constituent should be adequately reflected in the selection of the test, for the purpose of conducting an adequate risk assessment for the soil compartment. The two additional components with log Pow value >6.5 also indicate the need for conducting long-term studies.

Therefore ECHA considers that long-term testing is warranted.

OECD guideline 208 (Terrestrial plants, growth test) considers the need to select the number of test species according to relevant regulatory requirements, and the need for a reasonably broad selection of species to account for interspecies sensitivity distribution.

For long-term testing, ECHA considers six species as the minimum to achieve a reasonably broad selection. Testing shall be conducted with species from different families, as a minimum with two monocotyledonous species and four dicotyledonous species, selected according to the criteria indicated in the OECD 208 guideline. The Registrant should consider if testing on additional species is required to cover the information requirement.

Therefore, pursuant to Article 40(3)(c), the Registrant is required to carry out one of the following studies: Long-term toxicity testing on plants (Annex X, 9.4.6.); test method: Terrestrial plants, growth test (OECD 208), with at least six species tested (with as a minimum two monocotyledonous species and four dicotyledonous species), or the Soil Quality – Biological Methods – Chronic toxicity in higher plants (ISO 22030), using the registered substance.

The originally proposed test for short-term toxicity on terrestrial plants (Terrestrial plants, growth test (OECD 208)) is rejected in accordance with Article 40(3)(d) of the REACH Regulation.

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 studies meet 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, or the information submitted by other registrants of the same substance, may not be in compliance with the substance identity requirements set out in Section 2 of Annex VI of the REACH Regulation, and for this reason may be subject to a compliance check pursuant to Article 41 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 joint registrants of the same substance to agree to the tests proposed (as applicable to their tonnage level) and to document the necessary information on their substance composition.

In addition, it is important to ensure that the particular sample of substance tested in the new studies 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 by each registrant. If the registration of the substance by any registrant covers different grades, the sample used for the new studies must be suitable to assess these grades.

Finally there must be adequate information on substance identity for the sample tested and the grade(s) registered to enable the relevance of the studies 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).

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