EUROPEAN CHEMICALS AGENCY

Decision number: TPE-D-0000002627-70-05/F Helsinki, 3 July 2013

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

For tris (2-butoxyethyl) phosphate, CAS No 78-51-3 (EC No 201-122-9), 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 jointly submitted registration dossier in accordance with Articles 10(a)(ix) and 12(1)(e) thereof for tris (2-butoxyethyl) phosphate, CAS No 78-51-3 (EC No 201-122-9), by [redacted] (Registrant):

- Earthworm, acute toxicity test, (OECD 207)
- Terrestrial Plant Test: Seedling Emergence and Seedling Growth Test (OECD 208)
- Two-generation reproductive toxicity study (OECD 416)

The present decision relates solely to the examination of testing proposals for Terrestrial Plant and Earthworm tests. The other testing proposal for a Two-generation reproductive toxicity study is addressed in a separate decision although all testing proposals were initially addressed together in the same draft decision.

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 18 January 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 8 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 13 July 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 13 August 2012 the Registrant did not provide any comments on the draft decision to ECHA.

On 18 January 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 submitted proposals for amendment including a proposal for amendment regarding elements covered by this decision.

On 21 February 2013 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 decided to amend the draft decision according to the proposal for amendment regarding elements covered by this decision.

On 4 March 2013 ECHA referred the draft decision to the Member State Committee.

On 11 March 2013 the Registrant provided comments on the proposed amendments. The Member State Committee took the comments of the Registrant into account.

The draft decision was split into two draft decision documents: one relating to the testing proposal for a two-generation reproductive toxicity study and one relating to the testing proposals for short-term toxicity to terrestrial invertebrates and short-term toxicity to plants.

A unanimous agreement of the Member State Committee on the draft decision relating to the testing proposal for short-term toxicity to terrestrial invertebrates and short-term toxicity to plants was reached on 8 April 2013 in a written procedure launched on 27 March 2013. ECHA took the decision pursuant to Article 51(6) of the REACH Regulation.

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 and the registered substance subject to the present decision:

1. Short-term toxicity to terrestrial invertebrates (Annex IX, 9.4.1; test method: Toxicity for earthworms, EU C.8/OECD 207).

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

2. Short-term toxicity testing on plants (Annex IX, 9.4.3; test method: Terrestrial plants, growth test, OECD 208, with at least three species tested, minimum one monocotyledonous and two dicotyledonous species from different groups)

Pursuant to Articles 40(4) and 22 of the REACH Regulation, the Registrant shall submit to ECHA by **3 April 2014** an update of the registration dossier containing the information required by this decision.

Once results of the requested tests are available, in accordance with Annex I of the Reach Regulation, the Registrant is required to revise the chemical safety assessment. He should furthermore consider whether there is a need to investigate further the effects on terrestrial organisms in order to fulfil the information requirements of section 9.4 of Annexes IX and X, and if necessary, submit testing proposals for additional terrestrial toxicity tests. If the Registrant concludes that no further investigation of effects on terrestrial organisms is required, he should update his technical dossier by clearly stating the reasons for adapting the information requirements of Annexes IX and X, section 9.4 of the REACH Regulation.

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. Short-term toxicity to terrestrial invertebrates

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 for above 1000 tonnes per year in the joint submission. It is thus necessary to generate data performing the studies as indicated in Section II above using the registered substance subject to the present decision as the test material.

The Registrant has justified the reason for performing the tests as to "aquire some knowledge about the toxicity potential of the registered substance to terrestrial organisms and plants. The registered substance is not expected to be strongly adsorbed to soil, neither persistent in the environment. However belonging to a group of substances that may have flame retardant properties, it has been monitored and detected in soils and therefore it is proposed to get more information on its toxicity to terrestrial organisms".

According to the information provided in the dossier, the substance is ready biodegradable and there is no indication of bioaccumulation. However, the Registrant indicates a potential for exposure to soil. Therefore, ECHA considers the justification provided as sufficient in terms of regarding the short-term test as suitable and necessary.

Therefore, pursuant to Article 40(3)(a) of the REACH Regulation, the Registrant is required to carry out the proposed test.

2. Short-term toxicity to plants

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

A short-term toxicity study on plants is a standard information requirement as laid down in Annex IX, section 9.4.3., 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 for above 100 tonnes per year. It is thus necessary to generate data performing the studies as indicated in Section II above using the registered substance subject to the present decision as the test material.

The Registrant has justified the reason for performing the tests as to "aquire some knowledge about the toxicity potential of the registered substance to terrestrial organisms and plants. The registered substance is not expected to be strongly adsorbed to soil, neither persistent in the environment. However belonging to a group of substances that may have flame retardant properties, it has been monitored and detected in soils and therefore it is proposed to get more information on its toxicity to plants".

According to the information provided in the dossier, the substance is ready biodegradable and there is no indication of bioaccumulation. However, the Registrant indicates for the registered substance a potential for exposure to soil. Therefore, ECHA considers the justification provided as sufficient in terms of regarding the short-term test as suitable and necessary.

The OECD test guideline 208 reflects on the need to choose the number of species to be tested depending on relevant regulatory requirements and on the need for a reasonably broad selection of species to account for interspecies sensitivity distribution. For short-term toxicity testing (Annex IX, 9.4.3) ECHA considers three species as the minimum to achieve a reasonably broad selection. The short term toxicity testing shall be conducted as a minimum with one monocotyledonous species and two dicotyledonous species from different groups, selected according to the criteria indicated in the OECD 208 guideline. The Registrant should consider if testing on additional species is needed to cover the information requirement.

Therefore, pursuant to Article 40(3)(b) of the REACH Regulation, the Registrant is required to carry out the proposed test.

3. Further notes on testing for effects on terrestrial organisms

The information on the endpoint 'effects on terrestrial organisms' needs to be present in the technical dossier to meet the information requirements. For covering this endpoint, 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 testing proposals accepted by the present decision cover two of these five endpoints.

No information on soil micro-organisms is available for the registered substance. Once results of the requested toxicity test(s) on soil invertebrates and plants are available, in accordance with Annex I of the Reach Regulation, the Registrant is required to derive a PNECsoil and to revise the chemical safety assessment. He should furthermore consider whether there is a need to investigate further the effects on terrestrial organisms in order to fulfil the information requirements of section 9.4 of Annexes IX and X, and if necessary, submit testing proposals for additional terrestrial toxicity tests.

If the Registrant concludes that no further investigation of effects on terrestrial organisms is required, he should update his technical dossier by clearly stating the reasons for adapting the information requirement(s) of Annexes IX and X, section 9.4. of the REACH Regulation, in particular, regarding effects on soil micro-organisms (Annex IX, section 9.4.2.), long-term toxicity testing on invertebrates (Annex X, section 9.4.4.), and long-term toxicity testing on plants (Annex X, section 9.4.6.).

4. Deadline for submitting the information

In the draft decision communicated to the Registrant the time indicated to provide the requested information was 24 months from the date of adoption of the decision. This period of time took into account the fact that the draft decision also requested a reproductive toxicity study according to the standard information requirement of Annex X, 8.7.3. of the REACH Regulation. As the testing proposal for this study is not addressed in the present decision, ECHA considers that a reasonable time period for providing the required information in the form of an updated registration is 9 months from the date of the adoption of the decision. The decision was therefore modified accordingly.

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, 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 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 study/studies must be suitable to assess these grades.

Finally there must be adequate information on substance identity for the sample tested and the grades 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.

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