EUROPEAN CHEMICALS AGENCY

Decision number: TPE-D-0000003185-77-03/F Helsinki, 25 September 2013

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

For O,O,O-tris(2(or 4)-C9-10-isoalkylphenyl) phosphorothioate, CAS No 126019-82-7 (EC No 406-940-1), 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 proposal submitted as part of the jointly submitted registration dossier in accordance with Articles 10(a)(ix) and 12(1)(d)thereof for O,O,O-tris(2(or 4)-C9-10-isoalkylphenyl) phosphorothioate, CAS No 126019-82-7 (EC No 406-940-1), by [redacted] (Registrant).

Testing proposal: Daphnia magna Reproduction Test, OECD Guideline 211

This decision is based on the registration dossier as submitted with submission number [redacted], for the tonnage band of 10 to 100 tonnes 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 registration at a later stage.

The examination of the testing proposal was initiated upon the date when receipt of the complete registration dossier was confirmed on 4 July 2012.

On 19 December 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 15 January 2013 ECHA received comments from the Registrant.

ECHA considered the Registrant's comments received. On the basis of the comments, Section II was amended. The Statement of Reasons (Section III) was changed 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 method and the registered substance subject to the present decision:

1. Long-term toxicity testing on aquatic invertebrates (Annex IX, 9.1.5.; test method: *Daphnia magna* reproduction test, EU C.20/OECD 211).

Pursuant to Articles 40(4) and 22 of the REACH Regulation, the Registrant shall submit to ECHA by **25 June 2014** an update of the registration dossier containing the information required by this decision.

Once results of the proposed test on long-term toxicity to aquatic invertebrates are available, the Registrant shall revise the chemical safety assessment as necessary according to Annex I of the REACH Regulation. If the revised chemical safety assessment indicates the need to investigate further the effects on aquatic organisms, the Registrant shall submit a testing proposal for a long-term toxicity test on fish in order to fulfil the standard information requirement of Annex IX, 9.1.6. If the Registrant comes to the conclusion that no further investigation of effects on aquatic organisms is required, he shall update his technical dossier by clearly stating the reasons for adapting the standard information requirement of Annex IX, 9.1.6.

At any time, the Registrant shall take into account that there may be an obligation to make every effort to agree on sharing of information and costs with other Registrants. In particular, ECHA has also requested the information required for the same substance from the following registrant:

[redacted]

III. Statement of reasons

The decision of ECHA is based on the examination of the testing proposal submitted by the Registrant for the registered substance.

1. Long-term toxicity testing on aquatic invertebrates

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 9.1.5 of Annex IX of the REACH Regulation, long-term toxicity testing on invertebrates is required to fulfil the standard information requirements. 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 provide information for this endpoint.

The Registrant provided the following justification for conducting the proposed test:

"Available studies on fish, algae and microorganisms did not reveal any toxic effect in the range of water solubility of the compound. The study on daphnia is not regarded as valid due to the limited exposure time of only 24 h instead of 48 h. Furthermore, undissolved parts of the test compound could be detected. Due to the low water solubility of the test compound a long-term toxicity study on daphnia is proposed to adequately assess the toxicity towards aquatic invertebrates."

"In Annex VII of Regulation (EC) No 1907/2006, it is laid down that in case of short-term toxicity on invertebrates (preferred species Daphnia) the registrant may consider long-term toxicity testing instead of short-term. An available short-term study on daphnia is disregarded due to the limited exposure time of only 24 h. Furthermore, in annex VII, column 2 of the above mentioned regulation the long-term toxicity study on Daphnia shall be considered if the substance is poorly water soluble. The water solubility of the substance is < 0.21 mg/L. Therefore, a long-term toxicity test according to OECD guideline 211 instead of the short-term study is proposed. ".

According to ECHA *Guidance on information requirements and chemical safety assessment* (version 1.1., August 2008), Chapter R7b, Figure R.7.8-4 page 53, if based on acute aquatic toxicity data neither fish nor invertebrates are shown to be substantially more sensitive, long-term studies may be required on both. According to the integrated testing strategy, the Daphnia study is to be conducted first. If based on the results of the long-term Daphnia study and an applied assessment factor of 50 no risks are indicated, no long-term fish testing may need to be conducted. However, if a risk is indicated when applying an assessment factor of 50, long-term fish testing may need to be conducted.

Therefore, pursuant to Article 40(3)(a) of the REACH Regulation, the Registrant is required to carry out the proposed study: Long-term toxicity testing on aquatic invertebrates (Annex IX, 9.1.5.; test method: *Daphnia magna* reproduction test, EU C.20/OECD 211) using the registered substance.

2. Existence of a final decision requiring the same study requested by this decision

ECHA has also requested the information required under point II for the same substance from the following Registrant:

[redacted]

The Registrant subject to this decision provided comments on the draft decision and noted that ECHA had informed them of the existence of a final decision addressed to an affiliate company, [redacted], which requires the same study to be conducted on the same substance by 19 December 2013. The Registrant commented that they intend to share the results of the test with [redacted]

Avoidance of duplication of tests is a general aim of the REACH Regulation (Article 25). The legal text foresees the sharing of information between registrants. Since the Registrant in question has not currently formed a joint submission with the Registrant of the substance who received a final decision requesting the same study, the present decision remains because there is an information gap in this dossier.

IV. Adequate identification of the composition of the tested material

The process of examination of testing proposals set out in Article 40 of the REACH Regulation aims at ensuring that the new study meets real information needs. Within this context, the Registrant's dossier was sufficient to confirm the identity of the substance to the extent necessary for examination of the testing proposal. The Registrant must note, however, that this information has not been checked for compliance with the substance identity requirements set out in Section 2 of Annex VI of the REACH Regulation.

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

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

Pursuant to Article 3(28) of the REACH Regulation, the robust study summary to be prepared for the study requested in Section II above shall contain sufficient information, including information on the test material identity, to make an assessment of the relevance of the study. This is also in line with the EU and OECD test guidelines. Amongst information on test material, the composition of the substance shall be given in such a detail that each individual constituent present in the substance at a concentration ≥ 10 % (w/w), any other known constituent and unknown constituents grouped as far as possible by a generic description of their chemical nature are specified and their respective concentrations in the test material are reported. The registrant shall ensure that the compositional information of the test material is sufficient to conclude also on the following:

- The overall carbon number distribution of the alkyl substituents on the phenyl rings;
- The overall abundance the of alkyl substituents present in ortho- position relative to para- of the phenyl rings;
- The chemical structure and relative concentration of the hydrocarbon classes (including linear and branched hydrocarbon classes) which the alkyl substituents on the phenyl rings belong to.

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]

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