ECHA
EUROPEAN CHEMICALS AGENCY

Helsinki, 19 July 2017

Addressee: [redacted]

Decision number: TPE-D-2114366656-37-01/F
Substance name: O,O,O-triphenyl phosphorothioate
EC number: 209-909-9
CAS number: 597-82-0
Registration number: [redacted]
Submission number: [redacted]
Submission date: 27.05.2016
Registered tonnage band: 100-1000T

DECISION ON A TESTING PROPOSAL

Based on Article 40 of Regulation (EC) No 1907/2006 (the 'REACH Regulation'), ECHA examined your testing proposal(s) and decided as follows.

You are requested to perform:

- **Sub-chronic toxicity study (90-day), oral route (Annex IX, Section 8.6.2.; test method: EU B.26./OECD TG 408) in rats with the registered substance.**

You may adapt the testing requested above according to the specific rules outlined in Annexes VI to X and/or according to the general rules contained in Annex XI of the REACH Regulation. In order to ensure compliance with the respective information requirement, any such adaptation will need to have a scientific justification, referring and conforming to the appropriate rules in the respective Annex, and an adequate and reliable documentation.

You are required to submit the requested information in an updated registration dossier by **28 January 2019**. You shall also update the chemical safety report, where relevant.

The reasons of this decision are set out in Appendix 1. The procedural history is described in Appendix 2. Advice and further observations are provided in Appendix 3.

Appeal

This decision can be appealed to the Board of Appeal of ECHA within three months of its notification. An appeal, together with the grounds thereof, shall be submitted to ECHA in writing. An appeal has suspensive effect and is subject to a fee. Further details are described under http://echa.europa.eu/regulations/appeals.

Authorised[1] by Claudio Carlon, Head of Unit, Evaluation E2

[1] As this is an electronic document, it is not physically signed. This communication has been approved according to ECHA's internal decision-approval process.

Appendix 1: Reasons

The decision of ECHA is based on the examination of the testing proposal(s) submitted by you.

Sub-chronic toxicity study (90-day) (Annex IX, Section 8.6.2.)

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

A sub-chronic toxicity study (90-day) is a standard information requirement as laid down in Annex IX, Section 8.6.2. 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. Consequently, there is an information gap for sub-chronic toxicity study (90-day) and it is necessary to provide information for this endpoint.

You have submitted a testing proposal for a sub-chronic toxicity study (90 days) in rats by the oral route according to EU B.26/ OECD TG 408.

ECHA requested your considerations for alternative methods to fulfil the information requirement for reproductive toxicity (extended one-generation reproductive toxicity study) and Sub-chronic toxicity (90-day): oral. ECHA notes that you provided your considerations concluding that there were no alternative methods which could be used to adapt the information requirement for which testing is proposed. ECHA has taken these considerations into account.

Adequate information on the endpoint sub-chronic toxicity (90-day) study needs to be present in the technical dossier for the registered substance to meet this information requirement. Thus, a sub-chronic toxicity study (90-day) according to EU B.26/OECD TG 408 is required.

You proposed testing in rats. According to the test method EU B.26./OECD TG 408, the rat is the preferred species. ECHA considers this species as being appropriate and testing should be performed with the rat.

You proposed testing by the oral route (gavage). Based on the information provided in the technical dossier and/or in the chemical safety report, ECHA agrees that the oral route - which is the preferred one as indicated in ECHA Guidance on information requirements and chemical safety assessment (version 4.1, October 2015) Chapter R.7a, section R.7.5.4.3 - is the most appropriate route of administration. More specifically,

- the registered substance is a solid with MMD= 809 µm with only 10% < 100µm, 0.2% < 10µm, and 0% < 4µm,
- spray applications are only reported for the registered substance in lubricant/ grease mixtures and not as solid as such; and
- the registered substance is not classified as irritating/ corrosive to skin/eyes.

Furthermore, ECHA considers that the oral route is the most appropriate route of administration for substances except gases to focus on the detection of hazardous properties on reproduction as indicated in ECHA *Guidance on information requirements and chemical safety assessment* (version 4.1, October 2015) R.7a, section R.7.6.2.3.2.

Hence, ECHA concludes that testing should be performed by the oral route.

In your comments to the draft decision, you proposed to "*include parameters addressing neurotoxic and immunotoxic endpoints*". ECHA notes, that it is at your discretion to perform

the intended additional examinations during the testing program as long as those additional examinations do not interfere with the examinations according to test method OECD TG 408, and use the results to ensure the safe use of the substance. However, you are reminded that the proposed extension of this study does not fulfil the standard information requirement in the registration dossier for reproductive toxicity set out in Annex X, Section 8.7.3.

Therefore, pursuant to Article 40(3)(a) of the REACH Regulation, you are requested to carry out proposed study with the registered substance subject to the present decision: Sub-chronic toxicity study (90-day) in rats, oral route (test method: EU B.26./OECD TG 408).

Appendix 2: Procedural history

ECHA received your registration containing the testing proposal(s) for examination pursuant to Article 40(1) on 27 May 2016, in response to your update of the registration dossier with submission number [redacted].

ECHA notes that the tonnage band for several members of the joint submission is 100 to 1000 tonnes per year.

ECHA held a third party consultation for the testing proposal on the EOGRT study, from 3 February 2016 until 21 March 2016 and for the sub-chronic toxicity study 16 December 2016 until 30 January 2017 ECHA did not receive information from third parties.

This decision does not take into account any updates after **12 April 2017**, 30 calendar days after the end of the commenting period.

The decision making followed the procedure of Articles 50 and 51 of the REACH Regulation, as described below:

ECHA notified you of the draft decision and invited you to provide comments.

ECHA did not receive any comments by the end of the commenting period.

ECHA notified the draft decision to the competent authorities of the Member States for proposals for amendment.

As no amendments were proposed, ECHA took the decision according to Article 51(3) of the REACH Regulation.

Appendix 3: Further information, observations and technical guidance

1. The substance subject to the present decision is listed in the Community rolling action plan (CoRAP) and the substance evaluation started in 2016.

2. This decision does not imply that the information provided in your 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.

3. Failure to comply with the request(s) in this decision, or to fulfil otherwise the information requirement(s) with a valid and documented adaptation, will result in a notification to the Enforcement Authorities of the Member States.

4. In relation to the information required by the present decision, the sample of the substance used for the new test(s) must be suitable for use by all the joint registrants. Hence, the sample should have a composition that is suitable to fulfil the information requirement for the range of substance compositions manufactured or imported by the joint registrants. It is the responsibility of all joint registrants who manufacture or import the same substance to agree on the appropriate composition of the test material and to document the necessary information on their substance composition. In addition, it is important to ensure that the particular sample of the substance tested in the new test(s) 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 or imported by each registrant. If the registration of the substance by any registrant covers different grades, the sample used for the new test(s) 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 test(s) to be assessed.