

Helsinki, 17 April 2023

**Addressees**

Registrants of EC\_230-257-6 as listed in Appendix 3 of this decision

**Date of submission of the dossier subject to this decision**

06/03/2019

**Registered substance subject to this decision ("the Substance")**

Substance name: Zinc O,O',O',O'-tetrabutyl bis(phosphorodithioate)

EC number: 230-257-6

**Decision number:** Please refer to the REACH-IT message which delivered this communication (in format TPE-D-XXXXXXXXXX-XX-XX/F)**DECISION ON TESTING PROPOSAL(S)**

Under Article 40 of Regulation (EC) No 1907/2006 (REACH), you must submit the information listed below by **22 January 2027**.

Requested information must be generated using the Substance unless otherwise specified.

**Information required from all the Registrants subject to Annex IX of REACH**

1. Sub-chronic toxicity study (90-day) (Annex IX, Section 8.6.2.; test method: OECD TG 408) by oral route, in rats;
2. Pre-natal developmental toxicity study (Annex IX, Section 8.7.2.; test method: OECD TG 414) by oral route, in one species (rat or rabbit).

The reasons for the decision(s) are explained in Appendix 1.

**Information required depends on your tonnage band**

You must provide the information listed above for all REACH Annexes applicable to you in accordance with Articles 10(a) and 12(1) of REACH. The addressees of the decision and their corresponding information requirements based on registered tonnage band are listed in Appendix 3.

You are only required to share the costs of information that you must submit to fulfil your information requirements.

**How to comply with your information requirements**

To comply with your information requirements, you must submit the information requested by this decision in an updated registration dossier by the deadline indicated above. You must also **update the chemical safety report, where** relevant, including any changes to classification and labelling, based on the newly generated information.

You must follow the general requirements for testing and reporting new tests under REACH, see Appendix 4.

**Appeal**

This decision, when adopted under Article 51 of REACH, may be appealed to the Board of Appeal of ECHA within three months of its notification to you. Please refer to <http://echa.europa.eu/regulations/appeals> for further information.

**Failure to comply**

If you do not comply with the information required by this decision by the deadline indicated above, ECHA will notify the enforcement authorities of your Member State.

Authorised<sup>1</sup> under the authority of Mike Rasenberg, Director of Hazard Assessment

Appendix 1: Reasons for the decision

Appendix 2: Procedure

Appendix 3: Addressees of the decision and their individual information requirements

Appendix 4: Conducting and reporting new tests under REACH

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<sup>1</sup> 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 for the decision**

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## **0. Reasons common to several requests**

- 1 You have considered that the Substance subject to the present decision can be grouped with 12 other substances in a category ("ZDDP category") for the purpose of a read-across approach. You have provided the justification documents "[REDACTED]" and "[REDACTED]". These documents outline your testing strategy, including the proposal to test 4 category members, including the substance subject to the present decision as part of the read-across and grouping approach, in accordance with Annex XI, Section 1.5. of the REACH Regulation. ECHA has assessed the read-across approach and prediction possibility in the respective draft decisions on the substances that are members of the ZDDP category.

**Reasons for the decision(s) related to the information under Annex IX of REACH****1. Sub-chronic toxicity study (90-day)**

2 A sub-chronic toxicity study (90 day) is an information requirement under Annex IX to REACH (Section 8.6.2.).

1.1. Information provided to fulfil the information requirement

3 You have submitted a testing proposal for a Sub-chronic toxicity study (90 day) according to OECD TG 408 with the Substance.

4 ECHA requested your considerations for alternative methods to fulfil the information requirement for Repeated dose toxicity. You provided your considerations concluding that there were no alternative methods which could be used to adapt the information requirement(s) for which testing is proposed. ECHA has taken these considerations into account.

5 ECHA received third party information during the third-party consultation, but it was not relevant to the testing proposal on the Substance addressed in this decision.

6 ECHA agrees that a 90-day study is necessary.

1.2. Specification of the study design

7 You proposed testing in the rat. ECHA agrees with your proposal because the rat is the preferred species according to the OECD TG 408. Therefore, the study must be conducted in the rat.

8 You proposed testing by the oral route. ECHA agrees with your proposal because this route of administration is appropriate to investigate systemic toxicity; Guidance on IRs and CSA, Section R.7.5.4.3.2.

1.3. Outcome

9 Your testing proposal is accepted under Article 40(3)(a) and you are requested to conduct the test, as specified above.

10 In the comments to the draft decision, you agree to perform the requested study.

**2. Pre-natal developmental toxicity study in one species**

11 A pre-natal developmental toxicity (PNDT) study (OECD TG 414) in one species is an information requirement under Annex IX to REACH (Section 8.7.2.).

2.1. Information provided to fulfil the information requirement

12 You have submitted a testing proposal for a PNDT study according to the OECD TG 414 by the oral route with the Substance.

13 ECHA requested your considerations for alternative methods to fulfil the information requirement for Developmental toxicity. You provided your considerations concluding that there were no alternative methods which could be used to adapt the information requirement(s) for which testing is proposed. ECHA has taken these considerations into account.

14 ECHA received third party information during the third-party consultation, but it was not relevant to the testing proposal on the Substance addressed in this decision.

15 ECHA agrees that a PNDT study in a first species is necessary.

## 2.2. Specification of the study design

- 16 You proposed testing in the rat as a first species. You may select between the rat or the rabbit because both are preferred species under the OECD TG 414 (ECHA Guidance R.7a, Section R.7.6.2.3.2.).
- 17 You proposed testing by the oral route. ECHA agrees with your proposal because this route of administration is the most appropriate to investigate reproductive toxicity (ECHA Guidance R.7a, Section R.7.6.2.3.2.).

## 2.3. Outcome

- 18 Your testing proposal is accepted under Article 40(3)(a) and you are requested to conduct the test, as specified above.
- 19 In the comments to the draft decision, you agree to perform the requested study.

## References

The following documents may have been cited in the decision.

### **Guidance on information requirements and chemical safety assessment (Guidance on IRs & CSA)**

- Chapter R.4 Evaluation of available information; ECHA (2011).
- Chapter R.6 QSARs, read-across and grouping; ECHA (2008).  
Appendix to Chapter R.6 for nanoforms; ECHA (2019).
- Chapter R.7a Endpoint specific guidance, Sections R.7.1 – R.7.7; ECHA (2017).  
Appendix to Chapter R.7a for nanomaterials; ECHA (2017).
- Chapter R.7b Endpoint specific guidance, Sections R.7.8 – R.7.9; ECHA (2017).  
Appendix to Chapter R.7b for nanomaterials; ECHA (2017).
- Chapter R.7c Endpoint specific guidance, Sections R.7.10 – R.7.13; ECHA (2017).  
Appendix to Chapter R.7a for nanomaterials; ECHA (2017).  
Appendix R.7.13-2 Environmental risk assessment for metals and metal compounds; ECHA (2008).
- Chapter R.11 PBT/vPvB assessment; ECHA (2017).
- Chapter R.16 Environmental exposure assessment; ECHA (2016).

**Guidance on data-sharing**; ECHA (2017).

**Guidance for monomers and polymers**; ECHA (2012).

**Guidance on intermediates**; ECHA (2010).

All guidance documents are available online: <https://echa.europa.eu/guidance-documents/guidance-on-reach>

### **Read-across assessment framework (RAAF)**

- RAAF, 2017 Read-across assessment framework (RAAF); ECHA (2017)
- RAAF UVCB, 2017 Read-across assessment framework (RAAF) – considerations on multi- constituent substances and UVCBs); ECHA (2017).

The RAAF and related documents are available online:

<https://echa.europa.eu/support/registration/how-to-avoid-unnecessary-testing-on-animals/grouping-of-substances-and-read-across>

### **OECD Guidance documents (OECD GDs)**

- OECD GD 23 Guidance document on aquatic toxicity testing of difficult substances and mixtures; No. 23 in the OECD series on testing and assessment, OECD (2019).
- OECD GD 29 Guidance document on transformation/dissolution of metals and metal compounds in aqueous media; No. 29 in the OECD series on testing and assessment, OECD (2002).
- OECD GD 150 Revised guidance document 150 on standardised test guidelines for evaluating chemicals for endocrine disruption; No. 150 in the OECD series on testing and assessment, OECD (2018).
- OECD GD 151 Guidance document supporting OECD test guideline 443 on the extended one-generation reproductive toxicity test; No. 151 in the OECD series on testing and assessment, OECD (2013).

## Appendix 2: Procedure

ECHA started the testing proposal evaluation in accordance with Article 40(1) on 18 November 2021.

ECHA held a third-party consultation for the testing proposal(s) from 21 December 2021 until 4 February 2022. ECHA received information from third parties (see corresponding Appendix/Appendices)

ECHA followed the procedure detailed in Articles 50 and 51 of REACH.

The deadline of the decision is set based on standard practice for carrying out OECD TG tests. It has been exceptionally extended by 12 months from the standard deadline granted by ECHA to take into account currently longer lead times in contract research organisations.

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

ECHA took into account your comments and did not amend the requests.

### **Deadline to submit the requested information in this decision**

In the comments on the draft decision, you requested an extension of the deadline from 30 to 42 months from the date of adoption of the decision. To justify the additional time needed you stated that you like *“to conduct all testing for the substance (and other ZDDP substances for which Draft Decisions have recently been communicated) at the same test laboratory”* in order *“to ensure consistency in study set-up, conduct, evaluation, interpretation, and reporting and also ensures the most efficient use of animals”*. In addition, you provided information from a CRO, indicating that based on the current capacity of the laboratory, 42 months are needed to perform and submit the studies.

Based on the documentary evidence provided, ECHA has agreed with your request for a deadline extension and has extended the deadline to 42 months.

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

As no amendments were proposed, ECHA adopted the decision under Article 51(3) of REACH.

**Appendix 3: Addressees of this decision and their corresponding information requirements**

In accordance with Articles 10(a) and 12(1) of REACH, the information requirements for individual registrations are defined as follows:

- the information specified in Annex VII to REACH, for registration at 1-10 tonnes per year (tpa), or as a transported isolated intermediate in quantity above 1000 tpa;
- the information specified in Annexes VII and VIII to REACH, for registration at 10-100 tpa;
- the information specified in Annexes VII, VIII and IX to REACH, for registration at 100-1000 tpa;
- the information specified in Annexes VII to X to REACH, for registration at more than 1000 tpa.

<b>Registrant Name</b>	<b>Registration number</b>	<b>Highest REACH Annex applicable to you</b>
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████████████████████	████████████████████	████████

Where applicable, the name of a third-party representative (TPR) may be displayed in the list of recipients whereas ECHA will send the decision to the actual registrant.

## Appendix 4: Conducting and reporting new tests for REACH purposes

### 1. Requirements when conducting and reporting new tests for REACH purposes

#### 1.1. Test methods, GLP requirements and reporting

- (1) Under Article 13(3) of REACH, all new data generated as a result of this decision must be conducted according to the test methods laid down in a European Commission Regulation or to international test methods recognised by the Commission or ECHA as being appropriate.
- (2) Under Article 13(4) of REACH, ecotoxicological and toxicological tests and analyses must be carried out according to the GLP principles (Directive 2004/10/EC) or other international standards recognised by the Commission or ECHA.
- (3) Under Article 10(a)(vi) and (vii) of REACH, all new data generated as a result of this decision must be reported as study summaries, or as robust study summaries, if required under Annex I of REACH. See ECHA Practical Guide on How to report robust study summaries<sup>2</sup>.

#### 1.2. Test material

Before generating new data, you must agree within the joint submission on the chemical composition of the material to be tested (Test Material) which must be relevant for all the registrants of the Substance.

##### *Selection of the Test material(s)*

The Test Material used to generate the new data must be selected taking into account the following:

- a) the variation in compositions reported by all members of the joint submission,
- b) the boundary composition(s) of the Substance,
- c) the impact of each constituent/ impurity on the test results for the endpoint to be assessed. For example, if a constituent/ impurity of the Substance is known to have an impact on (eco)toxicity, the selected Test Material must contain that constituent/ impurity.

You reported within the joint submission the Substance as Zinc O,O,O',O'-tetrabutyl bis(phosphorodithioate) (EC number: 230-257-6). The Substance is registered as Unknown or Variable Composition, Complex reaction products and Biological materials (UVCB Substance). It is a zinc dithiodialkylphosphate (ZDDP) consisting of neutral and basic zinc salts as constituents. In addition, base oils are reported as constituents. The base oils are refined crude oils and UVCB substances.

ECHA considers it may be possible that the different possible constituent ratios result in different hazard properties, if tested in toxicity studies.

To avoid underestimation of the hazard caused by the inappropriate selection of the test

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<sup>2</sup> <https://echa.europa.eu/practical-guides>

material you should select a composition of the test material for the conduct of the requested studies, which represents a worst case in terms of expected absorption and expected toxicity for the possible constituent ratios. In this regard the specification of the ratio between the concentrations of the neutral tetrabutyl ZDDP and the concentration of the basic tetrabutyl ZDDP and the concentration of the base oils appears to be a relevant consideration.

*Information on the Test Material needed in the updated dossier*

- a) You must report the composition of the Test Material selected for each study, under the "Test material information" section, for each respective endpoint study record in IUCLID.
- b) The reported composition must include the careful identification and description of the characteristics of the Tests Materials in accordance with OECD GLP (ENV/MC/CHEM(98)16) and EU Test Methods Regulation (EU) 440/2008 (Note, Annex), namely all the constituents must be identified as far as possible as well as their concentration. Also, any constituents that have harmonised classification and labelling according to the CLP Regulation must be identified and quantified using the appropriate analytical methods,
- c) The reported composition must also include detailed information on the composition of the test material using appropriate analytical techniques. The reporting must include the concentration values of the monomeric neutral tetrabutyl ZDDP, the concentration values of the dimeric neutral tetrabutyl ZDDP, the concentration values of the basic tetrabutyl ZDDP, and the concentrations, identities and compositions of the base oils.

This information is needed to assess whether the Test Material is relevant for the Substance and whether it is suitable for use by all members of the joint submission.

Technical instructions on how to report the above is available in the manual on How to prepare registration and PPORD dossiers<sup>3</sup>.

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<sup>3</sup> <https://echa.europa.eu/manuals>