~~Confidential~~

Helsinki,17 April 2023

Addressee
Registrant of JS_272-723-1 as listed in Appendix 3 of this decision

Date of submission of the dossier subject to this decision
27/07/2021

Registered substance subject to this decision ("the Substance")
Substance name: Phosphorodithioic acid, mixed O,O-bis(2-ethylhexyl and iso-Pr) esters, zinc salts
EC number: 272-723-1

Decision number: Please refer to the REACH-IT message which delivered this communication (in format TPE-XXXXXXXXXX-XX-XX/F)

DECISION ON TESTING PROPOSAL(S)

Under on Article 40(3)(d) of Regulation (EC) No 1907/2006 (REACH), the testing proposal(s) listed below are rejected:

Testing proposal(s) under Annex VIII to REACH

1. Sub-chronic toxicity study (90-days; OECD TG 408) using the Substance and the analogue substances: Zinc O,O,O',O'-tetrabutyl bis(phosphorodithioate (CAS:6990-43-8; EC: 230-257-6); Phosphorodithioic acid, mixed O,O-bis(1,3-dimethylbutyl and iso-Pr) esters, zinc salts (CAS:84605-29-8; EC: 283-392-8); Zinc bis[O,O-bis(2-ethylhexyl)] bis(dithiophosphate) (CAS: CAS: 4259-15-8; EC: 224-235-5) .

2. Pre-natal developmental toxicity study (OECD TG 414) using the Substance and the analogue substances: Zinc O,O,O',O'-tetrabutyl bis(phosphorodithioate (CAS:6990-43-8; EC: 230-257-6); Phosphorodithioic acid, mixed O,O-bis(1,3-dimethylbutyl and iso-Pr) esters, zinc salts (CAS:84605-29-8; EC: 283-392-8); Zinc bis[O,O-bis(2-ethylhexyl)] bis(dithiophosphate) (CAS: CAS: 4259-15-8; EC: 224-235-5).

Reasons for the rejection(s) are explained in Appendix 1.

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.

Approved[1] 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

[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 for the decision

Contents

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Testing proposal(s) under Annex VIII to REACH

1. Sub-chronic toxicity study (90-days)

1 A sub-chronic toxicity study (90 days) is an information requirement under Annex VIII to REACH (Section 8.6.1., Column 2) if: the duration of human exposure indicates a longer term study appropriate, such as in case of uses leading to significant long-term exposure of consumers and professionals; and one of the following conditions are met:

(1) other available data indicate that the substance may have a dangerous property that cannot be detected in a short-term toxicity study; or
(2) appropriately designed toxicokinetic studies reveal that the substance (or its metabolites) accumulates in certain tissues or organs which would possibly remain undetected in a short-term toxicity study but which are liable to result in adverse effects after prolonged exposure

2 The use of the Substance reported in the joint submission is leading to significant long-term exposure of consumers and professionals because the Substance is used as lubricating agent in vehicles or machinery by professionals (PROCs 8a, 8b.) and consumers. However, you have not provided any data on the Substance which indicate that potential adverse effects cannot be detected in a short-term toxicity study. Furthermore, there are no toxicokinetic studies on the Substance. On this basis, the criteria for conducting a Sub-chronic toxicity study are not met.

1.1. Information provided

3 You have submitted a testing proposal for a sub-chronic toxicity (90-day) study according to OECD TG 408 with the Substance as well as with the analogue substances: Zinc O,O,O',O'-tetrabutyl bis(phosphorodithioate (CAS:6990-43-8; EC: 230-257-6); Phosphorodithioic acid, mixed O,O-bis(1,3-dimethylbutyl and iso-Pr) esters, zinc salts (CAS:84605-29-8; EC: 283-392-8); Zinc bis[O,O-bis(2-ethylhexyl)] bis(dithiophosphate) (CAS: CAS: 4259-15-8; EC: 224-235-5)

4 ECHA received third party information concerning the testing proposal during the third-party consultation, but it did not concern the testing proposal on the Substance addressed in this decision

5 ECHA considers that a sub-chronic toxicity (90 days) is not necessary at this tonnage band.

1.2. Outcome

6 Under Article 40(3)(d) of REACH, the proposed test is rejected.

7 In the testing proposal examination, ECHA has only assessed the need for the test. This assessment resulted in the rejection of the testing proposal. Therefore, no assessment of the adequacy the proposed test material nor the adequacy of the proposed test in relation to the information requirement at this tonnage band were performed.

2. Pre-natal developmental toxicity study

8 According to column 2 of Annex VIII, Section 8.7.1. to REACH, a pre-natal developmental toxicity (PNDT) study may be proposed instead of a screening study in cases where there are serious concerns about the potential for adverse effects on development.

9 The data in your dossier does not indicate adverse effects on development. Therefore, there is no need for a PNDT study

2.1. Information provided

10 You have submitted a testing proposal for a PNDT study according to the OECD TG 414 with the Substance, as well as with the analogue substances: Zinc O,O,O',O'-tetrabutyl bis(phosphorodithioate (CAS:6990-43-8; EC: 230-257-6); Phosphorodithioic acid, mixed O,O-bis(1,3-dimethylbutyl and iso-Pr) esters, zinc salts (CAS:84605-29-8; EC: 283-392-8); Zinc bis[O,O-bis(2-ethylhexyl)] bis(dithiophosphate) (CAS: CAS: 4259-15-8; EC: 224-235-5).

11 ECHA received third party information concerning the testing proposal during the third-party consultation, but it did not concern the testing proposal on the Substance addressed in this decision.

12 ECHA considers that a PNDT study is not necessary at this tonnage band.

2.2. Outcome

13 Under Article 40(3)(d) of REACH, the proposed test is rejected.

14 In the testing proposal examination, ECHA has only assessed the need for the test. This assessment resulted in the rejection of the testing proposal. Therefore, no assessment of the adequacy the proposed test material nor the adequacy of the proposed test in relation to the information requirement at this tonnage band were performed.

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.

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

ECHA did not receive any comments within 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 adopted the decision under Article 51(3) of REACH.

Appendix 3: Addressee of this decision

Registrant Name	Registration number	Highest REACH Annex applicable to you
[redacted]	[redacted]	[redacted]

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.