~~Confidential~~

Helsinki, 15 June 2022

Addressees
Registrant(s) of JS_EC_809-986-4 as listed in Appendix 3 of this decision

Date of submission of the dossier subject to this decision
04/05/2021

Registered substance subject to this decision ("the Substance")
Substance name: Bis(O,O-diisopropyl dithiophosphate)bis(cyclohexylamine) zinc
EC number: 809-986-4

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)

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

Testing proposal under Annex VIII to REACH

1. In vivo mammalian erythrocyte micronucleus test (OECD TG 474) using the Substance.

Reasons for the rejection 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.

Authorised[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 rejection

Contents

~~Confidential~~

Testing proposal under Annex VIII of REACH

1. In vivo mammalian erythrocyte micronucleus test

1 Appropriate in vivo mutagenicity studies must be considered under Annex VIII to REACH (Section 8.4., Column 2) in case of a positive result in any of the in vitro genotoxicity studies under Annex VII or VIII to REACH.

2 Your dossier contains positive results for the in vitro micronucleus test (OECD TG 487, 2016), which raise a concern for chromosomal aberration. However, additionally your dossier contains an appropriate in vivo mammalian alkaline comet assay ("comet assay", OECD TG 489, 2020) that addresses this concern for chromosomal aberration.

3 Therefore, in your dossier you already provided an appropriate in vivo study according to Annex VIII.

1.1. Information provided

4 Nevertheless, you have submitted a testing proposal for an *In vivo* mammalian erythrocyte micronucleus test to be performed with the Substance to follow-up the positive result of the comet assay.

5 ECHA notes that you are proposing a second *in vivo* test under Annex VIII.

6 According to the Guidance on IRs & CSA R.7a, section R.7.7.6.3 (p. 573) the "*second in vivo test should only then be proposed if it is required to make a conclusion on the genotoxic potential of the substance under investigation; i.e. if the in vitro data show the substance to have potential to induce both gene and chromosome mutations and the first in vivo test has not addressed this comprehensively*."

7 As indicated above, you have already provided an appropriate *in vivo* study to follow-up the positive result in the OECD TG 487 study.

8 Therefore, ECHA considers that a second *in vivo* study in somatic cells is not necessary at this tonnage band.

1.2. Outcome

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

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).

All Guidance on REACH is 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 26 March 2021.

ECHA held a third party consultation for the testing proposal(s) from 22 April 2021 until 7 June 2021. ECHA did not receive information from third parties.

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: Addressees 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.