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Helsinki, 20 February 2024

Addressees
Registrants of JS-Tetrakis14 as listed in Appendix 3 of this decision

Date of submission of the dossier subject to this decision
21/06/2021

Registered substance subject to this decision ("the Substance")
Substance name: tetrakis(phenylmethyl)thioperoxydi(carbothioamide)
EC number/List number: 404-310-0

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

DECISION ON A COMPLIANCE CHECK

Under Article 41 of Regulation (EC) No 1907/2006 (REACH), you must submit the information listed below by ***28 May 2026***.

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

Information required from all the Registrants subject to Annex VII of REACH

1. *In vitro* gene mutation study in bacteria (Annex VII, Section 8.4.1.; test method: Bacterial reverse mutation test, OECD TG 471 (2020) using one of the following strains: *E. coli* WP2 uvrA, or *E. coli* WP2 uvrA (pKM101), or *S. typhimurium* TA102.)

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

2. Long-term toxicity testing on terrestrial invertebrates (triggered by Annex IX, Section 9.4.1., column 2; test method: EU C.33/OECD TG 222 or EU C.32/OECD TG 220 or EU C.35/OECD TG 232)
3. Effects on soil micro-organisms (Annex IX, Section 9.4.2.; test method: EU C.21./OECD TG 216)
4. Long-term toxicity on terrestrial plants (triggered by Annex IX, Section 9.4.3., column 2; test method: EU C.31./OECD TG 208 with at least six species or ISO 22030)

The reasons for the requests 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[1] under the authority of Mike Rasenberg, Director of Hazard Assessment

Appendix 1: Reasons for the request(s)
Appendix 2: Procedure
Appendix 3: Addressees of the decision and their individual information requirements
Appendix 4: Conducting and reporting new tests under REACH

[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 request(s)

Contents

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Reasons related to the information under Annex VII of REACH

1. In vitro gene mutation study in bacteria

1 An in vitro gene mutation study in bacteria is an information requirement under Annex VII, Section 8.4.1.

1.1. Information provided

2 You have provided an *in vitro* gene mutation study in bacteria (1987) with the Substance.

1.2. Assessment of the information provided

1.2.1. The provided study does not meet the specifications of the test guideline

3 To fulfil the information requirement, a study must comply with OECD TG 471 (Article 13(3) of REACH). Therefore, the following specifications must be met:

a) the test is performed with 5 strains: four strains of *S. typhimurium* (TA98; TA100; TA1535; TA1537 or TA97a or TA97) and one strain which is either *S. typhimurium* TA102 or *E. coli* WP2 uvrA or *E. coli* WP2 uvrA (pKM101);

4 In the provided study:

a) the test was performed with the strains *S. typhimurium* TA 98, TA 100, TA 1535, TA 1537, TA 1538 (i.e., the strain *S. typhimurium* TA102 or *E. coli* WP2 uvrA or *E. coli* WP2 uvrA (pKM101) is missing);

5 The information provided does not cover the specification(s) required by the OECD TG 471.

6 In your comments to the draft decision, you have provided further information on the above study that addressed the reporting issues identified in the draft decision. You have updated your registration dossier to include this information. However, in your comments to the draft decision or in your dossier update, you still fail to provide information on either *S. typhimurium* TA102 or *E. coli* WP2 uvrA or *E. coli* WP2 uvrA (pKM101).

7 Therefore, the information requirement is not fulfilled.

1.3. Specification of the study design

8 To fulfil the information requirement for the Substance, the in vitro gene mutation study in bacteria (OECD TG 471) using one of the following strains: *E. coli* WP2 uvrA, or *E. coli* WP2 uvrA (pKM101), or *S. typhimurium* TA102, is considered suitable.

Reasons related to the information under Annex IX of REACH

2. Long-term toxicity on terrestrial invertebrates

9 Short-term toxicity to invertebrates is an information requirement under Annex IX to REACH (Section 9.4.1). Long-term toxicity testing must be considered (Section 9.4., column 2) if the substance has a high potential to adsorb to soil or is very persistent.

2.1. Triggering of the information requirement

10 Under Annex IX, Section 9.4., column 2, for substances that have a high potential to adsorb to soil or that are very persistent, long-term toxicity testing must be considered instead of short-term. Guidance on IRs and CSA, Section R.7.11.5.3. clarifies that a substance is considered to be very persistent in soil if it has a half-life >180 days. In the absence of specific soil data, high persistence is assumed unless the substance is readily biodegradable.

11 Based on the information from your registration dossier, the Substance is considered to be potentially highly persistent in soil as it is not readily biodegradable (2% degradation after 28 days based on EU Method C.5).

12 Therefore, the Substance is potentially very persistent. On this basis information on long-term toxicity on terrestrial invertebrates must be provided.

2.2. Information provided

13 You have provided a short-term toxicity study on invertebrates but no information on long-term toxicity on aquatic invertebrates for the Substance.

14 Therefore, the information requirement is not fulfilled.

2.3. Study design and test specifications

15 ECHA Guidance on IRs and CSA, Section R.7.11.3.1. specifies that the earthworm reproduction test (OECD TG 222), the Enchytraeid reproduction test (OECD TG 220), and the Collembolan reproduction test (OECD TG 232) are appropriate to cover the information requirement for long-term toxicity testing on terrestrial invertebrates.

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

3. Effects on soil micro-organisms

17 Effects on soil microorganisms is an information requirement under Annex IX to REACH (Section 9.4.2).

3.1. Information provided

18 You have adapted this information requirement under Annex IX, Section 9.4, column 2. To support your adaptation, you provided the following justification:

- "*the soil hazard category 3 applies to* [the Substance]. *Classification in this category involves performing a confirmatory long-term toxicity test*"

- "*Currently, the aquatic data-set does not allow the application of the equilibrium method partitioning due to the lack of observed toxic effects. The registrant proposes to perform as a first step an OECD 210 chronic fish toxicity testing (testing proposal) to conclude on the aquatic risk assessment. Depending on the result, the registrant will propose to perform a long-term terrestrial toxicity test on earthworm (preferred test in the absence of clear indication of selective toxicity) in a second step if needed (no toxic effect observed in the chronic fish testing or chronic effects leading to RCR > 1)".*

3.2. Assessment of the information provided

3.2.1. Your column 2 adaptation is rejected

19 Under Annex IX, Section 9.4., column 2, in the absence of toxicity data to soil organisms, the equilibrium partitioning method (EPM) may be applied to assess the hazard to soil organisms. In this context, the Guidance on IRs and CSA, Section R.7.11.5.3. and R.7.11.6. describe an integrated testing strategy (ITS) to adapt the information requirements on Effects on Terrestrial Organisms. The Guidance on IRs and CSA, Section R.7.11.5.3. states that "*where the data available are sufficient to derive a PNEC for aquatic organisms, this PNEC can be used in a screening assessment for soil risks through the use of the EPM approach*". Table R.7.11-2 from Section R.7.11.6. describes the confirmatory test that must be conducted depending on the Hazard category assigned to the Substance and the outcome of the screening assessment. Therefore, as a precondition for using the equilibrium partitioning method (EPM) to adapt the information requirement on Effects on Terrestrial Organisms, adequate information on aquatic toxicity must be available.

20 On 20 June 2022, ECHA has issued a final decision on a testing proposal for long-term toxicity on fish requesting to conduct a study according to OECD TG 210. The study has not yet been submitted. In addition, for the reasons explained under Request 3, the information requirement for Growth inhibition study on aquatic plants is not fulfilled. Therefore, your registration dossier currently does not include adequate information to derive a PNEC for aquatic organisms. As a result, the conditions to use the EPM to adapt the information requirement on Effects on Terrestrial Organisms are not met and you adaptation is rejected and the information requirement is not fulfilled.

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

3.3. Study design and test specifications

22 The Soil Microorganisms: Nitrogen Transformation Test (EU C.21/OECD TG 216) is appropriate to cover the information requirement on effects on soil microorganisms (Guidance on IRs and CSA, Section R.7.11.3.1.).

4. Long-term toxicity on terrestrial plants

Short-term toxicity to invertebrates is an information requirement under Annex IX to REACH (Section 9.4.1). Long-term toxicity testing must be considered (Section 9.4., column 2) if the substance has a high potential to adsorb to soil or is very persistent.

4.1. Triggering of the information requirement

23 For the reasons explained under Request 5, the Substance is potentially very persistent. On this basis information on long-term toxicity on terrestrial plants must be provided.

4.2. Information provided

24 You have adapted this information requirement under Annex IX, Section 9.4, column 2. To support your adaptation, you provided the same justification as already detailed under Request 6.

4.3. Assessment of the information provided

4.3.1. Your column2 adaptation is rejected

25 For the reasons already explained under Section 6.2., you adaptation under Annex IX, Section 9.4, column 2 is rejected.

26 Therefore, the information requirement is not fulfilled.

27 In your comments to the draft decision, you explain that once the information on the ongoing OECD TG 210 becomes available, you intend to assess whether this information requirement may be adapted under Annex IX, Section 9.4., column 2. If you conclude this is not possible, you agree to conduct the requested study.

28 As indicated in your comments, this strategy relies essentially on data which is yet to be generated, therefore no conclusion on the compliance can currently be made. You remain responsible for complying with this decision by the set deadline.

4.4. Test selection and study specifications

29 The Terrestrial Plant Test (EU C.31./OECD TG 208, with at least six species) is appropriate to cover the information requirement for long-term toxicity on terrestrial plants.

30 The OECD TG 208 (EU C.31.) considers the need to select the number of test species according to relevant regulatory requirements, and the need for a reasonably broad selection of species to account for interspecies sensitivity distribution. For long-term toxicity testing, ECHA considers six species as the minimum to achieve a reasonably broad selection. Testing must be conducted with species from different families, as a minimum with two monocotyledonous species and four dicotyledonous species, selected according to the criteria indicated in the OECD TG 208.

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

This decision does not prevent ECHA from initiating further compliance checks at a later stage on the registrations present.

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

The compliance check was initiated on 14 June 2022.

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 amended the requests. More specifically, you have provided comments during the decision-making phase which were found to address the incompliances identified in the draft decision for the following information requirements:

- Skin sensitisation (Annex VII, Section 8.3.),
- *in vitro* micronucleus study (Annex VIII, Section 8.4.2.),
- Growth inhibition study on aquatic plants (Annex VII, Section 9.1.2.)

You also provided comments which partially addressed the deficiencies identified in the draft decision for *In vitro* gene mutation study in bacteria (Annex VII, Section 8.4.1). Therefore, the draft decision now only requests to provide information on the missing fifth strain.

You have included the information from your comments in an update of your registration dossier (submission date: 15 May 2023). Therefore, the original requests were removed or modified accordingly.

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.

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

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

(2) 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.

(3) 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.

(4) 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[2].

(5) Under the introductory part of Annexes VII/VIII/IX/X to REACH, where a test method offers flexibility in the study design, for example in relation to the choice of dose levels or concentrations, the chosen study design must ensure that the data generated are adequate for hazard identification and risk assessment.

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.

(1) Selection of the Test material(s)

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

- the variation in compositions reported by all members of the joint submission,
- the boundary composition(s) of the Substance,
- 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.

(2) Information on the Test Material needed in the updated dossier

- 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.
- The reported composition must include all constituents of each Test Material and their concentration values.

[2] https://echa.europa.eu/practical-guides

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With that detailed information, ECHA can confirm 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 (https://echa.europa.eu/manuals).