~~Confidential~~

Helsinki, 31 October 2022

Addressees
Registrant of JS 701-399-0 as listed in Appendix 3 of this decision

Date of submission of the dossier subject to this decision
21/09/2021

Registered substance subject to this decision ("the Substance")
Substance name: copper sulfate;N'-[2-(2-aminoethylamino)ethyl]ethane-1,2-diamine
EC/List number: 701-399-0

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 VII to REACH

Transgenic rodent somatic and germ cell gene mutation assays (OECD TG 488) using the Substance.

The 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 decision

Contents

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Testing proposal under Annex VII to REACH

1. Transgenic rodent somatic and germ cell gene mutation assays

1 Further mutagenicity studies must be considered under Annex VII to REACH in case of a positive result in an *in vitro* gene mutation study in bacteria (Section 8.4., Column 2).

1.1. Information provided in your dossier

2 You have submitted a testing proposal for a transgenic rodent somatic and germ cell gene mutation assay to be performed with the analogue substance reaction product of copper sulfate and TEPA (EC No. 701-400-4).

3 Your dossier contains positive results for the *in vitro* gene mutation study in bacteria (OECD TG 471, 2017) performed with the analogue substance substance reaction product of copper sulfate and TEPA (EC No. 701-400-4).

1.2. Read-across adaptation rejected

4 As explained in a parallel separate compliance check decision (CCH-D-2114615734-49-01/F) concerning this registration, your adaptation based on grouping of substances and read-across approach under Annex XI, Section 1.5 is rejected.

1.3. Outcome

5 On the basis of the rejection of your read-across adaptation and the other information available in your dossier, in particular the absence of positive *in vitro* mutagenicity results with your Substance, ECHA considers that, at this point in time, no further *in vivo* study needs to be performed, to further investigate the mutagenic properties of the Substance.

6 Therefore, your testing proposal is rejected under Article 40(3)(d) of REACH.

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 1 July 2020.

ECHA held a third party consultation for the testing proposal from 25 November 2021 until 10 January 2022. 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: 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.