~~Confidential~~

Helsinki, 18 October 2022

Addressees
Registrant of JS_DBl267_Na_NH4 as listed in Appendix 3 of this decision

Date of submission of the dossier subject to this decision
16/04/2021

Registered substance subject to this decision ("the Substance")
Substance name: [μ-[4-[[3,3'-dihydroxy-4'-[(2-hydroxy-6-sulpho-1-naphthyl)azo][1,1'-biphenyl]-4-yl]azo]-3-hydroxynaphthalene-2,7-disulphonato(7-)]]dicuprate(3-), ammonium and sodium salts
EC/List number: 945-577-8

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:

> Sub-chronic toxicity study (90-day), oral route (EU B.26./OECD TG 408) using the Substance.

The reasons for the decision(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.

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

Reasons for the decision(s) related to the information under Annex VIII of REACH

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

1.1. Information required under Annex VIII

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 You have not provided any indications of significant long-term exposure of consumers and professionals. Furthermore, you have not provided any data on the Substance which indicate that potential adverse effects cannot be detected in a short-term toxicity study. You have concluded that the Substance accumulated during the OECD TG 421 study, but there are no toxicokinetic studies on the Substance that would support the need for long-term study.

3 On this basis, ECHA finds that the conduct of a Sub-chronic toxicity study (90 days) is not required under Annex VIII to REACH.

1.2. Information provided

4 You have submitted a testing proposal for a sub-chronic toxicity (90-day) study according to OECD TG 408.

5 You have justified the proposed test by claiming that the results of the reproduction/developmental toxicity screening test (OECD TG 421, 2018) are "*not conclusive with regard to classification*" to determine whether the Substance is "*reproductive toxicant or not*". Therefore, you propose to perform a Sub-chronic toxicity study "*to determine possible adverse effects […] on reproduction parameters*".

6 You further provided your considerations concluding that there were no alternative methods which could be used to adapt the information for which testing is proposed.

7 However, as explained in section 1.1 above, performance of a Sub-chronic toxicity study (90 days) is not required for registrations subject to Annex VIII to REACH.

8 Moreover, ECHA notes that the proposed test is not an appropriate follow-up test to investigate potential reproductive toxicity effects mentioned in your justification for the proposed test. A study according to OECD TG 408 does not have higher statistical power or more key parameters to evaluate fertility than the available reproduction/developmental toxicity screening test (OECD TG 421, 2018).

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

1.3. Outcome

10 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 20 May 2021.

ECHA held a third party consultation for the testing proposal(s) from 1 September 2021 until 16 August 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.