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Helsinki, 17 November 2022

Addressees
Registrant(s) of JS_Direct_Black_19 as listed in Appendix 3 of this decision

Date of submission of the dossier subject to this decision
08/09/2021

Registered substance subject to this decision ("the Substance")
Substance name: Disodium 4-amino-3,6-bis[[4-[(2,4-diaminophenyl)azo]phenyl]azo]-5-hydroxynaphthalene-2,7-disulphonate
EC number: 229-208-1

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(s) listed below are rejected:

A. Testing proposal(s) under Annex VIII to REACH

1. In vivo mammalian alkaline comet assay (OECD TG 489) using the Substance.

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

For references used in this decision, please consult the Appendix entitled "Guidance on REACH and other supporting documents".

Appeal

This decision can be appealed to the Board of Appeal of ECHA within three months of its notification. An appeal, together with the grounds thereof, has to be submitted to ECHA in writing. An appeal has suspensive effect and is subject to a fee. Further details are described under: http://echa.europa.eu/regulations/appeals.

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.

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Appendix 1: Reasons for the decision

Contents

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Testing proposal(s) under Annex VIII of REACH

1. *In vivo mammalian alkaline comet assay*

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 You have submitted a testing proposal for an *in vivo* mammalian alkaline comet assay ("comet assay") to be performed with the Substance with the following justification: you consider the available information on *in vitro* gene mutation in bacteria (OECD TG 471) to be "*a possible evidence of Direct Black 19 mutagenic activity*".

3 ECHA received third party information concerning the testing proposal during the third-party consultation. A third party has indicated that the dossier contains negative *in vitro* mutagenicity studies, and therefore an *in vivo* genotoxicity study is not justified.

4 As notified to you in a separate decision on a compliance check (CCH) on the Substance on 3 October 2022, the information requirements for *in vitro* gene mutation study in bacteria (Annex VII, Section 8.4.1.), *in vitro* cytogenicity in mammalian cells or micronucleus study (Annex VIII, Section 8.4.2.) and *in vitro* gene mutation study in mammalian cells (Annex VIII, Section 8.4.2.) are not met.

5 Consequently, as your registration dossier currently does not include reliable information for the information requirements listed above, no conclusion can yet be reached whether the Substance induces chromosomal aberrations and/or gene mutations. Therefore, the *in vivo* somatic cell genotoxicity study (Annex VIII, Section 8.4., column 2) is not triggered and your testing proposal for a comet assay with the Substance is not required.

6 Therefore, under Article 40(3)(d) of REACH, your 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 July 2021 until 16 August 2021. ECHA received information from third parties (see corresponding Appendix)

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 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 Annexes VII and VIII to REACH, for registration at 10-100 tpa.

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