~~Confidential~~

Helsinki, 01 February 2022

Addressees
Registrants of JS_Direct_Brown_44 listed in the last Appendix of this decision

Date of submission of the dossier subject of a decision
29/09/2020

Registered substance subject to this decision, hereafter 'the Substance'
Substance name: Reaction products of diazotised m-phenylendiamine, subsequently coupled with diazotised 4-aminobenzene-1-sulfonic acid, sodium salts
List number: 939-292-8
CAS number: NS

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 of Regulation (EC) No 1907/2006 (REACH), you must submit the information listed below by ***6 November 2023***.

The requested information must be generated using the Substance unless otherwise specified.

A. Information required from the Registrants subject to Annex IX of REACH

1. Long-term toxicity testing on aquatic invertebrates (Annex IX, Section 9.1.5.; test method: EU C.20./OECD TG 211)

2. Long-term toxicity testing on fish (Annex IX, Section 9.1.6.; test method: EU C.47./OECD TG 210)

Reasons for the request(s) are explained in the following Appendix entitled "Reasons to request information required under Annex IX of REACH".

Information required depends on your tonnage band

You must provide the information listed above for all REACH Annexes applicable to you, and in accordance with Articles 10(a) and 12(1) of REACH, the information specified in Annexes VII, VIII and IX to REACH, for registration at 100-1000 tpa.

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 testing and reporting requirements provided under the Appendix

entitled "Requirements to fulfil when conducting and reporting new tests for REACH purposes". In addition, you should follow the general recommendations provided under the Appendix entitled "General recommendations when conducting and reporting new tests for REACH purposes". For references used in this decision, please consult the Appendix entitled "List of references".

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

[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 A: Reasons to request information required under Annex IX of REACH

This decision is based on the examination of the testing proposals you submitted.

1. Long-term toxicity testing on aquatic invertebrates

Long-term toxicity testing on aquatic invertebrates is an information requirement under Annex IX to REACH (Section 9.1.5.).

1.1. Information provided to fulfil the information requirement

You have submitted a testing proposal for a *Daphnia magna* reproduction test (test method: EU C.20/OECD TG 211) "[…] *because the results of the acute test indicate Daphnia as the most sensitive species with a 48 hour–EC50 = 8.9 mg/L (nominal concentration)*."

Your registration dossier does not include any information on long-term toxicity on aquatic invertebrates.

ECHA agrees that an appropriate study on long-term toxicity on aquatic invertebrates is needed.

1.2. Test selection and study specifications

The proposed *Daphnia magna* reproduction test (test method: EU C.20/OECD TG 211) is appropriate to cover the information requirement for long-term toxicity on aquatic invertebrates (ECHA Guidance R.7.8.4.1.).

1.3. Outcome

Your testing proposal is accepted under Article 40(3)(a) and you are requested to conduct the test with the Substance, as specified above.

In your comments to the draft decision, you agree to conduct the study.

2. Long-term toxicity testing on fish

Long-term toxicity testing on fish is an information requirement under Annex IX to REACH (Section 9.1.6.).

Under Article 40(3)(c) of REACH, ECHA may require a registrant to carry out one or more additional tests in case of non-compliance of the testing proposal with Annexes IX, X or XI of the REACH Regulation. The information requirement on Aquatic toxicity at Annex IX covers both long-term toxicity on invertebrates (Section 9.1.5.) and on fish (Section 9.1.6.). However, you have provided a testing proposal for long-term testing on aquatic invertebrates only. In case of data gap for long-term toxicity testing on fish, it is necessary to request this information as an additional test to ensure compliance with the endpoint.

2.1. Information provided to fulfil the information requirement

Your registration dossier does not include any information on long-term toxicity on fish.

You have provided the following information to omit the study which you consider to be based on Annex IX, Section 9.1., Column 2. In support of your adaptation, you provided the following justification: *"long-term toxicity testing is not proposed by the registrant because the chemical safety assessment, according to Annex I, does not indicate the need to investigate*

further the effects on aquatic organisms."

We have assessed this information and identified the following issue:

Annex IX, Section 9.1., Column 2 does not allow omitting the need to submit information on long-term toxicity to fish under Column 1. It must be understood as a trigger for providing further information on long-term toxicity to fish if the chemical safety assessment according to Annex I indicates the need (Decision of the Board of Appeal in case A-011-2018).

Your adaptation is therefore rejected.

In your comments to the draft decision, you agree that this information requirement cannot be adapted based on the provisions set out under Annex IX, Section 9.1., Column 2. You explain that you now intend to adapt this information requirement under Annex XI, Section 3 ('Substance-tailored exposure-driven testing'). In support of your adaptation, you provide the following justification:

- On the conditions set out under Annex XI, Section 3.2(a):
  - You state that "*In the CSR report the exposure of the environment to the substance, after the application of the conditions of uses and RMM, is considered safe, since it is well below the derived PNEC*";
  - You provide revised estimates of the total release to the environment per year as well as revised local and regional estimates of predicted environmental concentrations (PEC);
  - You state that a "*relevant and appropriate PNEC, in fact, could be calculated based on the results on short-term toxicity studies, in particular Daphnia Magna (OECD 202) that was shown to be the most sensitive species (LC50, 48h = 8.6 mg/l) by applying the related assessment factor as reported Guidance on IR&CSA, Chapter R.10 Table R.10-4 Assessment factors to derive a PNECaquatic*".
- On the conditions set out under Annex XI, Section 3.2(b), you state that this provision is not relevant "*since the substance is incorporated in a matrix*".
- On the conditions set out under Annex XI, Section 3.2(c), you state that this provision is not relevant since "*the substance is not an intermediate*".

Based on the above ECHA understands that you intend to adapt this information requirement under Annex XI, Section 3.

We have assessed the information from your comments on the draft decision and identified the following issue:

Under Annex XI, Section 3, this information may be omitted based on the exposure scenario(s) developed in the Chemical Safety Report. The justification must be based on a rigorous exposure assessment in accordance with Annex I, Section 5 and must meet any one of the following criteria:

(a) It can be demonstrated that all the following conditions are met:
   i. the absence or no significant exposure in all scenarios of the manufacture and all identified uses referred to in Annex VI, Section 3.5., and
   ii. a predicted no effect concentration (PNEC) can be derived from available data, which:
      - must be relevant and appropriate both to the information requirement to be omitted and for risk assessment purposes and therefore must be based on reliable information on the hazardous properties of the substance on at least three trophic levels;

- must take into account the increased uncertainty resulting from the omission of the information requirement, in this case by selecting an appropriate assessment factor (AF) as described in ECHA Guidance R.10.3.

iii. the ratio between the results of the exposure assessment (PECs) and the PNEC are always well below 1

(b) For substances that are not included in articles, it must be demonstrated for all relevant scenarios that strictly controlled conditions as set out in Article 18(4)(a) to (f) apply throughout the life cycle

(c) For substances incorporated in articles with no intended releases, the following conditions are met:

i. the substance is not released during its life cycle and,
ii. the likelihood that workers and the general public are exposed to the substance under normal or reasonably foreseeable conditions is negligible, and
iii. the substance is handled according to the conditions as set out in Article 18(4)(a) to (f) during all manufacturing and production stages including the waste management of the substance during these stages.

In your comments on the draft decision, as already explained above, you consider that the conditions set out under Annex XI, Section 3.2(a) are met. You also consider that the conditions set out under Annex XI, Section 3.2(b) and 3.2(c) do not apply to the Substance because it is included in articles and it is not an intermediate.

ECHA assesses if the Substance meets any of the conditions set out under Annex XI, Section 3.2., as follows:

A. *The Substance screens as PBT/vPvB and therefore the conditions of Annex XI, Section 3.2(a) cannot be demonstrated with sufficient reliability*

For substances satisfying the PBT and vPvB criteria of Annex XIII, long-term effects and the estimation of the long-term exposure cannot be carried out with sufficient reliability (Annex I, Section 4.0.1). As a result, for such substances, PNEC and PECs cannot be derived with sufficient reliability to demonstrate that, the ratio between PECs and the PNEC are always well below 1 (conditions (a)(ii) and (iii) above). Consequently, such information cannot be used to demonstrate that no significant exposure occurs in all scenarios of the manufacture and all identified uses referred to in Annex VI, Section 3.5 (condition (a)(i) above).

In your comments on the draft decision, you report that the total releases to the environment per year for all life cycle stages are [redacted] kg/year, [redacted] kg/year and [redacted] kg/year for the water, air and soil compartment, respectively.

Your registration dossier also provides the following:

- The Substance is not readily biodegradable;
- The Substance is not inherently biodegradable (49.7% degradation after 15 days in OECD TG 302B with lag phase of 6 days);
- The Substance is ionisable and therefore high potential for bioaccumulation cannot be excluded based on available information.

Furthermore, the information in your dossier is currently incomplete and therefore:

- it is not possible to conclude on the aquatic toxicity of the Substance (see Appendices A.1-2 of this decision).

ECHA notes that the above information indicates that exposure of the environment does occur. In addition, for the reasons explained above, the information from your dossier, currently does not allow excluding that the Substance may be PBT/vPvB. Therefore, you have not demonstrated that the ratio between the reported PECs and the currently available PNEC provide a reliable mean to demonstrate the absence of significant exposure of the environment. Therefore, the conditions set out under Annex XI, Section 3.2(a) (i) to (iii) are not met.

B. *The Substance is used in articles and therefore the provisions of Annex XI, Section 3.2(b) do not apply to the Substance*

In your comments on the draft decision, you state that the provisions of Annex XI, Section 3.2(b) are not relevant "*since the substance is incorporated in a matrix*". Under Section 3 of your IUCLID dossier, you report industrial and professional uses in textile dyeing and industrial uses in paper finishing and coating, leather dyeing and paper production. You report that the articles containing the Substance are used by consumers.

Based on the above information, ECHA agrees that the provisions of Annex XI, Section 3.2(b) cannot be used to omit this information requirement as the Substance is used in articles.

C. *The Substance is used in articles and you have not demonstrated that the conditions of Annex XI, Section 3.2(c) are met*

In your comments on the draft decision, you state that the provisions of Annex XI, Section 3.2(c) are not relevant as "*the substance is incorporated in the final article with no intended release or negligible release and it is not an intermediate*" without any further justification.

ECHA notes that Annex XI, Section 3.2(c) applies to substances that are not used as intermediate, as well. For the sake of completeness, ECHA has assessed the information available in your dossier against the requirements of Annex XI, Section 3.2(c).

ECHA Guidance R.5.1.5.2. specifies that such adaptation "*may be appropriate if the justification documents that a substance is handled under strictly controlled conditions (including rigorous containment) during its manufacture and industrial use, that there is no dispersive use and no consumers' exposure*".

As explained under point A. above, the results of the exposure assessment show significant exposure of the environment which indicates the Substance is not handled under strictly controlled conditions. Furthermore, the Substance is used in consumer products and you have not provided any justification as to why there is no consumer exposure. Such justification should demonstrate why significant exposure of consumers can be excluded due, for instance, to chemical and physical design of the article (for instance, when it can be demonstrated that the Substance is covalently bound to a matrix, that there is no significant unbound residual amount, and that the covalent binding is stable (i.e., the substance does not leach out from the article) under typical use or environmental conditions). Therefore, the information currently

available in your dossier indicates that the conditions set out under Annex XI, Section 3.2(c) are not met.

Conclusion

On the above basis, the information from your comments on the draft decision or your registration dossier does not support that any of the provisions of Annex XI, Section 3.2 are met.

On this basis, the information requirement is not fulfilled.

2.2. Test selection and study specifications

The Fish, Early-Life Stage Toxicity Test (test method: OECD TG 210) is appropriate to cover the information requirement for long-term toxicity on fish (ECHA Guidance R.7.8.4.1.).

2.3. Outcome

Under Article 40(3)(c) of REACH, you are requested to carry out the additional test with the Substance, as specified above.

Appendix B: Requirements to fulfil when conducting and reporting new tests for REACH purposes

A. Test methods, GLP requirements and reporting

1. 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.

2. 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.

3. 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].

B. 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 and other parameters relevant for the property to be tested.

This information is needed to assess 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[3].

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

Appendix C: General recommendations when conducting and reporting new tests for REACH purposes

A. Environmental testing for substances containing multiple constituents

Your Substance contains multiple constituents and, as indicated in ECHA Guidance R.11 (Section R.11.4.2.2), you are advised to consider the following approaches for persistency, bioaccumulation and aquatic toxicity testing:

- the "known constituents approach" (by assessing specific constituents), or
- the "fraction/block approach, (performed on the basis of fractions/blocks of constituents), or
- the "whole substance approach", or
- various combinations of the approaches described above

Selection of the appropriate approach must take into account the possibility to characterise the Substance (i.e. knowledge of its constituents and/or fractions and any differences in their properties) and the possibility to isolate or synthetize its relevant constituents and/or fractions.

Appendix D: Procedure

ECHA started the testing proposal evaluation in accordance with Article 40(1) on 18 February 2021.

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

ECHA notified you of the draft decision and invited to provide comments.

ECHA took into account your comments and did not amend the request.

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 E: List of references - ECHA Guidance[4] and other supporting documents

Evaluation of available information
Guidance on information requirements and chemical safety assessment, Chapter R.4 (version 1.1., December 2011), referred to as ECHA Guidance R.4 where relevant.

QSARs, read-across and grouping
Guidance on information requirements and chemical safety assessment, Chapter R.6 (version 1.0, May 2008), referred to as ECHA Guidance R.6 where relevant.

Read-across assessment framework (RAAF, March 2017)[5]

RAAF - considerations on multi-constituent substances and UVCBs (RAAF UVCB, March 2017)[6]

Physical-chemical properties
Guidance on information requirements and chemical safety assessment, Chapter R.7a (version 6.0, July 2017), referred to as ECHA Guidance R.7a in this decision.

Toxicology
Guidance on information requirements and chemical safety assessment, Chapter R.7a (version 6.0, July 2017), referred to as ECHA Guidance R.7a in this decision.

Guidance on information requirements and chemical safety assessment, Chapter R.7c (version 3.0, June 2017), referred to as ECHA Guidance R.7c in this decision.

Environmental toxicology and fate
Guidance on information requirements and chemical safety assessment, Chapter R.7a (version 6.0, July 2017), referred to as ECHA Guidance R.7a in this decision.

Guidance on information requirements and chemical safety assessment, Chapter R.7b (version 4.0, June 2017), referred to as ECHA Guidance R.7b in this decision.

Guidance on information requirements and chemical safety assessment, Chapter R.7c (version 3.0, June 2017), referred to as ECHA Guidance R.7c in this decision.

PBT assessment
Guidance on information requirements and chemical safety assessment, Chapter R.11 (version 3.0, June 2017), referred to as ECHA Guidance R.11 in this decision.

Guidance on information requirements and chemical safety assessment, Chapter R.16 (version 3.0, February 2016), referred to as ECHA Guidance R.16 in this decision.

Data sharing
Guidance on data-sharing (version 3.1, January 2017), referred to as ECHA Guidance on data sharing in this decision.

[4] https://echa.europa.eu/guidance-documents/guidance-on-information-requirements-and-chemical-safety-assessment
[5] https://echa.europa.eu/support/registration/how-to-avoid-unnecessary-testing-on-animals/grouping-of-substances-and-read-across
[6] https://echa.europa.eu/documents/10162/13630/raaf_uvcb_report_en.pdf/3f79684d-07a5-e439-16c3-d2c8da96a316

OECD Guidance documents[7]
Guidance Document on aqueous–phase aquatic toxicity testing of difficult test chemicals – No 23, referred to as OECD GD 23.

Guidance document on transformation/dissolution of metals and metal compounds in aqueous media – No 29, referred to as OECD GD 29.

Guidance Document on Standardised Test Guidelines for Evaluating Chemicals for Endocrine Disruption – No 150, referred to as OECD GD 150.

Guidance Document supporting OECD test guideline 443 on the extended one-generation reproductive toxicity test – No 151, referred to as OECD GD 151.

[7] http://www.oecd.org/chemicalsafety/testing/series-testing-assessment-publications-number.htm

Appendix F: Addressees of this decision and the corresponding information requirements applicable to them

You must provide the information requested in this decision for all REACH Annexes applicable to you.

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