~~Confidential~~

Helsinki, 13 October 2023

Addressee(s)
Registrant(s) of [redacted] as listed in Appendix 3 of this decision

Date of submission of the dossier subject to this decision
15 November 2022

Registered substance subject to this decision ("the Substance")
Substance name: Alkali salt of sulfonated aryl azo amino sulfonyl aryl azo sulfonyl aryl azo aryl sulfonate
EC/List number: [redacted]

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 ***20 April 2026***.

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

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

1. Adsorption/desorption screening (Annex VIII, Section 9.3.1.; test method: EU C.18/OECD TG 106).

2. Simulation testing on ultimate degradation in surface water (triggered by Annex VIII, Section 9.2.; test method: EU C.25./OECD TG 309) at a temperature of 12°C.

3. Identification of degradation products (triggered by Annex VIII, Section 9.2; test method: EU C.25/OECD TG 309).

The reasons for the request(s) 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 addressee of the decision and its corresponding information requirements based on registered tonnage band are listed in Appendix 3.

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

Reasons related to the information under Annex VIII of REACH

1. Adsorption/desorption screening

1 Adsorption/desorption screening is an information requirement under Annex VIII to REACH (Section 9.3.1).

1.1. Information provided

2 In your registration dossier, you have adapted this information requirement by using Column 2 of Annex VIII, Section 9.2.2.1. To support the adaptation, you have provided the following justification:

3 "The study does not need to be conducted because the substance has a low octanol water partition coefficient and the adsorption potential of this substance is related to this parameter".

1.2. Assessment of the information provided

1.2.1. Low potential for adsorption based on physicochemical properties not demonstrated

4 Under Annex VIII, Section 9.3.1, Column 2, first indent, the study may be omitted if the substance can be expected to have a low potential for adsorption (e.g. the substance has a low octanol-water partition coefficient). In order to adapt this information requirement based on low octanol-water partition coefficient (log K_{ow}), lipophilicity must be the sole characteristic driving the adsorption potential of a substance. However, for some groups of substances (e.g. ionisable substances, surfactants) other mechanisms than lipophilicity may drive adsorption.

5 In your registration dossier, you claim that the Substance has a low octanol-water partition coefficient and has therefore a low potential for adsorption/desorption.

6 In your comments, you further explain that the main constituents of the Substance and their hydrolysis products are not lipophilic.

7 Neither in your registration dossier nor in your comments, you have provided any other evidence or argument to justify why you consider that the Substance has a low potential for adsorption.

8 The information in your dossier indicates that the Substance is ionisable. The two main constituents of the Substance are ionised under environmental pH (pH 4 – 9) due to the presence of dissociating groups in their structures (-OH from several sulphonic groups). Therefore, other mechanisms than lipophilicity may drive the adsorption/desorption of the Substance.

1.3. Column 2 adaptation provided in the comments to the draft decision

9 In the comments to the draft decision, you have provided a Column 2 adaptation stating that:

- the Substance will not be released in unhydrolyzed form into the environment and the hydrolysis products are not lipophilic.

1.4. Assessment of the information provided in the comments to the draft decision

1.4.1. Low potential for adsorption of the hydrolysis products not demonstrated

10 Under Annex VIII, Section 9.3.1, Column 2, second indent, the study may be omitted if the substance and its relevant degradation products decompose rapidly.

11 In your comments, you claim that the Substance will not be released in unhydrolyzed form into the environment but only as its hydrolysis products. You further claim that the hydrolysis products are not adsorptive because they are not lipophilic.

12 Based on the conditions of use of the Substance during the dyeing process (i.e. high temperature and high pH), hydrolysis products may constitute relevant degradation products of the Substance that can be released into the environment. However, you have not demonstrated that the hydrolysis products decompose rapidly. Therefore, hydrolysis of the Substance is as such not a valid basis to omit the information requirement.

13 As explained in section 1.2.1 above, information on lipophilicity of hydrolysis products is not relevant for this adaptation.

14 Information on adsorption/desorption is required for the Substance and/or its hydrolysis products.

1.5. Conclusion

15 You have not demonstrated that lipophilicity is the sole characteristic driving adsorption potential and that log K_{ow} is a valid descriptor for assessing the adsorption potential of the Substance or of its hydrolysis products.

16 You have also not demonstrated that the relevant degradation products of the Substance degrade rapidly.

17 Based on the above, your adaptations are rejected.

18 Therefore, the information requirement is not fulfilled.

2. Simulation testing on ultimate degradation in surface water

19 Under Annex VIII, Section 9.2., Column 2, further information on degradation or further testing as described in Annex IX must be generated if the chemical safety assessment (CSA) in accordance with Annex I indicates the need to investigate further the degradation of the substance.

2.1. Triggering of the information requirement

20 Therefore, this information requirement is triggered if for example additional information on degradation as set out in Annex XIII, point 3.2.1, is required to assess PBT or vPvB properties of the substance in accordance with subsection 2.1 of that Annex. This is the case if the Substance itself or any of its constituent or impurity present in concentration ≥ 0.1% (w/w) or relevant transformation/degradation product meets the following criteria:

- it is potentially persistent or very persistent (P/vP) as:
  - it is not readily biodegradable (i.e. <60% mineralisation after 28 days in OECD TG 301F), and
  - it shows <70% mineralisation within 14 days in an inherent biodegradability test OECD TG 302C;
- it is potentially bioaccumulative or very bioaccumulative (B/vB) as:
  - for some groups of substances (e.g. organometals, substances that are present in their ionised form(s) at environmentally relevant conditions (e.g. pH 4-9), surfactants) other partitioning mechanisms may drive

bioaccumulation (e.g. binding to protein/cell membranes) and high potential for bioaccumulation cannot be excluded solely based on its potential to partition to lipid, i.e. bioaccumulation cannot be waived on the basis of low log K_{ow} alone for such substances.

21 Your registration dossier provides the following:

- the Substance is not readily biodegradable (6% mineralisation after 28 days in OECD TG 301F);
- the Substance is not inherently biodegradable (46% mineralisation after 28 days in OECD TG 302C);
- the two main constituents of the Substance are ionised under environmental pH (pH 4 – 9) due to the presence of dissociating groups in their structures (-OH from several sulphonic groups). Therefore, a high potential for bioaccumulation cannot be excluded based on the available information.

22 Under section 2.3 of your IUCLID dossier and section 8 of your CSR ('PBT assessment'), you conclude that the Substance is potentially P/vP but that it is not B/vB.

23 You base your conclusion because of the low log K_{ow} value of the Substance and its low lipophilicity.

24 In your comments to the draft decision, you claim that the Substance is hydrophilic and not lipophilic.

25 However, your claim that Log K_{ow} is relevant to determine whether the Substance is a potential B/vB is incorrect. The two main constituents of the Substance are ionised under environmental pH. Therefore, the potential for bioaccumulation of the Substance may not be solely driven by lipophilicity and the octanol-water partition coefficient may not be a reliable predictor of the bioaccumulation potential for this type of substances. Your dossier does not include information on bioaccumulation that would allow you to conclude on the bioaccumulation potential of the Substance.

26 Therefore, the information provided in your dossier and in your comments on the draft decision for the PBT assessment is not adequate to rule out that the Substance is a potential PBT/vPvB substance.

27 Based on the above, the available information on the Substance indicates that it is a potential PBT/vPvB substance. Further, the information from your PBT assessment is not adequate to conclude on the PBT/vPvB properties of the Substance.

28 Therefore, the chemical safety assessment (CSA) indicates the need for further information on degradation.

2.1. Information provided in your dossier and its assessment

29 Your registration dossier does not include any information on simulation testing on ultimate degradation in surface water.

2.2. Information provided in your comments on the draft decision

30 ECHA understands that, in your comments, you have provided:

- An adaptation under Annex XI, Section 1.5, by referring to results available in the literature for other dyes, and
- An adaptation under Annex XI, Section 1.3, by referring to a QSAR prediction to claim that the main constituents of the Substance and their hydrolysis products are not bioavailable

2.2.1. Read-across from other dyes not justified

31 Annex XI, Section 1.5. specifies two conditions which must be fulfilled whenever a read-across approach is used. Firstly, there needs to be structural similarity between substances which results in a likelihood that the substances have similar physicochemical, toxicological and ecotoxicological properties so that the substances may be regarded as a group or category. Secondly, it is required that the relevant properties of a substance within the group may be predicted from data for reference substance(s) within the group. Additional information on what is necessary when justifying a read-across approach can be found in the Guidance on IRs and CSA, Chapter R.6. and related documents (RAAF, 2017; RAAF UVCB, 2017).

32 Annex XI, Section 1.5. requires that whenever read-across is used, adequate and reliable documentation of the applied method must be provided. Such documentation must include an explanation why the properties of the Substance may be predicted from information on the source substance(s).

33 In your comments, you refer to bioaccumulation studies performed with other dyes. Those studies are from the public literature or from unpublished reports. You have not provided documentation to explain why this information is relevant for the Substance and why the properties of the Substance may be predicted from information on those other dyes.

34 In the absence of such documentation, the bioaccumulation of the Substance cannot be reliably predicted from the literature results you refer to in your comments.

2.2.2. QSAR predictions for low bioavailability not supported by available experimental data

35 Under Annex XI, Section 1.3., the following conditions must be fulfilled whenever a (Q)SAR approach is used:

(1) the prediction needs to be derived from a scientifically valid model,
(2) the substance must fall within the applicability domain of the model,
(3) results need to be adequate for the purpose of risk assessment or classification and labelling, and
(4) adequate and reliable documentation of the method must be provided.

36 Guidance on IRs and CSA, Section R.6.1.5.3. specifies that, among others, a QSAR model must predict well substances that are similar to the substance of interest. By extension, the prediction of a QSAR model must be consistent with valid experimental results obtained for the Substance.

37 In your comments, you refer to the "Lipinski Rule of Five" which predicts that the main constituents of the Substance and their hydrolysis products are not bioavailable.

38 However, information provided in the registration dossier suggests that the Substance can be absorbed. For example, in the repeated dose toxicity study combined with the reproduction/developmental toxicity screening (OECD 422), discoloration of some inner organs was observed in rats.

39 Therefore, your predictions are not supported by available experimental data obtained for the Substance and you have not demonstrated that the Substance is not bioavailable.

2.3. Conclusion

40 Therefore, the information requirement is not fulfilled.

2.4. Study design

41 Simulation degradation studies must include two types of investigations (Guidance on IRs and CSA, Section R.7.9.4.1.):

(1) a degradation pathway study where transformation/degradation products are quantified and, if relevant, are identified, and

(2) a kinetic study where the degradation rate constants (and degradation half-lives) of the parent substance and of relevant transformation/degradation products are experimentally determined.

42 You must perform the test, by following the pelagic test option with natural surface water containing approximately 15 mg dw/L of suspended solids (acceptable concentration between 10 and 20 mg dw/L) (Guidance on IRs and CSA, Section R.11.4.1.1.3.).

43 The required test temperature is 12°C, which corresponds to the average environmental temperature for the EU (Guidance on IRs and CSA, Table R.16-8) and is in line with the applicable test conditions of the OECD TG 309.

44 As specified in Guidance on IRs and CSA, Section R.7.9.4.1., the organic carbon (OC) concentration in surface water simulation tests is typically 2 to 3 orders of magnitude higher than the test material concentration and the formation of non-extractable residues (NERs) may be significant in surface water tests. Paragraph 52 of the OECD TG 309 provides that the "total recovery (mass balance) at the end of the experiment should be between 90% and 110% for radiolabelled substances, whereas the initial recovery at the beginning of the experiment should be between 70% and 110% for non-labelled substances". NERs contribute towards the total recovery. Therefore, the quantity of the (total) NERs must be accounted for the total recovery (mass balance), when relevant, to achieve the objectives of the OECD TG 309 to derive degradation rate and half-life. The reporting of results must include a scientific justification of the used extraction procedures and solvents.

45 For the persistence assessment by default, total NERs is regarded as non-degraded Substance. However, if reasonably justified and analytically demonstrated a certain part of NERs may be differentiated and quantified as irreversibly bound or as degraded to biogenic NERs, such fractions could be regarded as removed when calculating the degradation half-life(s) (Guidance on IRs and CSA, Section R.11.4.1.1.3.). Further recommendations may be found in the background note on options to address non-extractable residues in regulatory persistence assessment available on the ECHA website (NER - summary 2019 (europa.eu)).

46 Relevant transformation/degradation products are at least those detected at ≥ 10% of the applied dose at any sampling time or those that are continuously increasing during the study even if their concentrations do not exceed 10% of the applied dose, as this may indicate persistence (OECD TG 309; Guidance on IRs and CSA, Section R.11.4.1.).

3. Identification of degradation products

47 Under Annex VIII, Section 9.2., Column 2, further information on degradation or further testing as described in Annex IX must be generated if the chemical safety assessment (CSA) in accordance with Annex I indicates the need to investigate further the degradation of the substance.

48 Therefore, this information requirement is triggered if for example additional information on degradation as set out in Annex XIII, point 3.2.1, is required to assess PBT or vPvB properties of the substance in accordance with subsection 2.1 of that Annex.

49 As already explained in request 2, which already addresses your comment on the draft decision, the Substance is a potential PBT/vPvB substance.

50 Therefore, the chemical safety assessment (CSA) indicates the need for further degradation investigation.

51 You have not submitted any information for this requirement.

3.1. Study design

52 Simulation degradation studies must include two types of investigations (Guidance on IRs and CSA, Section R.7.9.4.1.):

(1) a degradation pathway study where transformation/degradation products are quantified and, if relevant, are identified, and
(2) a kinetic study where the degradation rate constants (and degradation half-lives) of the parent substance and of relevant transformation/degradation products are experimentally determined.

53 Identity, stability, behaviour, and molar quantity of the degradation/transformation products relative to the Substance must be evaluated and reported. In addition, identified transformation/degradation products must be considered in the CSA including PBT assessment.

54 You must obtain this information from the degradation study requested in request 2.

55 To determine the degradation rate of the Substance, the requested study according to OECD TG 309 (request 2) must be conducted at 12°C and at a test concentration < 100 µg/L. However, to overcome potential analytical limitations with the identification and quantification of major transformation/degradation products, you may consider running a parallel test at higher temperature (but within the frame provided by the test guideline, e.g. 20°C) and at higher application rate (i.e. > 100 µg/L).

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 08 August 2022.

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

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

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 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(s) 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]

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

(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 (https://echa.europa.eu/practical-guides).

(4) 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

(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 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.

With that detailed information, ECHA can confirm whether the Test Material is relevant for the Substance.

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).

2. General recommendations for conducting and reporting new tests

2.1 Environmental testing for substances containing multiple constituents

Your Substance contains multiple constituents and, as indicated in Guidance on IRs & CSA, 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 synthesize its relevant constituents and/or fractions.

References to Guidance on REACH and other supporting documents can be found under Appendix 1.