~~Confidential~~

Helsinki, 13 October 2023

Addressee
Registrant as listed in Appendix 3 of this decision

Date of submission of the dossier subject to this decision
30/05/2012

Registered substance subject to this decision ("the Substance")
Substance name: Disodium 6-(4,6-dichloro-1,3,5-triazin-2-ylamino)-1-hydroxy-2-(4-(2-(sulfonatooxy)ethylsulfonyl)phenylazo)naphthalene-3-sulfonate
EC number: 404-600-7

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 ***21 October 2024***.

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

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

1. In vitro gene mutation study in bacteria (Annex VII, Section 8.4.1.; test method: OECD TG 471, 2020) using one of the following strains: E. coli WP2 uvrA, or E. coli WP2 uvrA (pKM101), or S. typhimurium TA102 with Prival modification

2. Short-term toxicity testing on aquatic invertebrates (Annex VII, Section 9.1.1.; test method: EU C.2./OECD TG 202)

3. Growth inhibition study aquatic plants (Annex VII, Section 9.1.2.; test method: EU C.3./OECD TG 201 or EU C.26./OECD TG 221)

4. Ready biodegradability (Annex VII, Section 9.2.1.1.; test method: EU C.4. A/B/C/D/E/F/OECD TG 301A/B/C/D/E/F or EU C.29./OECD TG 310)

The reasons for the decision(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.

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 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 VII of REACH

1. In vitro gene mutation study in bacteria

1 An in vitro gene mutation study in bacteria is an information requirement under Annex VII, Section 8.4.1.

2 You have provided:

(i) An in vitro bacterial reverse mutation study (study year not reported) with the Substance.

1.1. Assessment of the information provided

1.1.1. The provided study does not meet the specifications of the test guideline

3 To fulfil the information requirement, a study must comply with the OECD TG 471 (Article 13(3) of REACH). Therefore, the following specifications must be met:

a) the test is performed with 5 strains: four strains of *S. typhimurium* (TA98; TA100; TA1535; TA1537 or TA97a or TA97) and one strain which is either *S. typhimurium* TA102 or *E. coli* WP2 uvrA or *E. coli* WP2 uvrA (pKM101);

4 In study (i) described as an in vitro bacterial mutation test:

a) the test was performed with the strains TA 1535, TA1537, TA98, TA100 (i.e., the strain(s) S. typhimurium TA102 or E. coli WP2 uvrA or E. coli WP2 uvrA (pKM101) is missing);

5 The information provided does not cover the specification(s) required by the OECD TG 471.

6 Therefore, the information requirement is not fulfilled.

1.2. Specification of the study design

7 To fulfil the information requirement for the Substance, the in vitro gene mutation study in bacteria (OECD TG 471, 2020) should be performed using one of the following strains: E. coli WP2 uvrA, or E. coli WP2 uvrA (pKM101), or S. typhimurium TA102.

8 Your Substance is an azo dye for which the standard procedure may not detect all mutations. Therefore, you are required to use the Prival modification (see Paragraph 10 of OECD TG 471).

1.3. Information regarding data sharing

9 Regarding the 4 missing strains tested without the Prival modification, the Joint Submission registration dossier for the same Substance contains a TG 471 study (1997) which is adequate for this information requirement. In accordance with Title III of the REACH Regulation, you may request it from the other registrants and then make every effort to reach an agreement on the sharing of data and costs (Guidance on data-sharing).

10 In your comments on the draft decision, you indicated your intention to obtain access to the information available in the jointly submitted registration dossier of the Substance. This would address the issues identified above but, this decision must be based on the information currently available and therefore the request remains.

2. Short-term toxicity testing on aquatic invertebrates

11 Short-term toxicity testing on aquatic invertebrates is an information requirement under Annex VII to REACH (Section 9.1.1.).

2.1. Information provided

12 You have provided:

(i) A short-term toxicity study (study year, test material, test guideline and test species are not reported);

13 To fulfil the information requirement, a study that complies with the requirements of OECD TG 202 must be provided (Article 13(3) of REACH).

2.2. Assessment of the information provided

2.2.1. The provided study does not meet the specifications of the test guideline

14 To fulfil the information requirement, a study must comply with OECD TG 202 (Article 13(3) of REACH). Therefore, the following specifications must be met:

15 Reporting of the methodology and results

a) the test design is reported (e.g. static or semi-static test, number of replicates);

b) the test procedure is reported (e.g. composition of the test medium, loading in number of Daphnia per test vessel);

c) the methods used to prepare stock and test solutions is reported.

16 In study (i) described as short-term toxicity study on aquatic invertebrates:

17 Reporting of the methodology and results

a) on the test design, you have not specified

- the test type (i.e., whether study (i) was done with a semi-static or a static test design);
- the number of replicates (i.e., the number of test vessels that were used per concentration);
- whether the test was a limit test;

b) on the test procedure, you have not specified

- the type and volume of test vessels used;
- the volume of solution per test vessel;
- the number of daphnids per test vessel;

c) the methods used to prepare stock and test solutions is not reported.

18 Based on the above,

- the reporting of the study is not sufficient to conduct an independent assessment of its reliability. More specifically, your IUCLID dossier does not include key pieces of information that would allow ECHA to assess whether the test design and test conditions described in OECD TG 202 were followed and to interpret the results.

19 Therefore, the requirements of OECD TG 202 are not met.

20 Therefore, the information requirement is not fulfilled.

2.3. Study design and test specifications

21 The Substance is difficult to test due to its colouring property (technical function reported in section 3 of the IUCLID dossier: dye). OECD TG 202 specifies that, for difficult to test substances, you must consider the approach described in OECD GD 23 or other approaches, if more appropriate for your substance. In all cases, the approach selected must be justified and documented. Due to the properties of Substance, it may be difficult to achieve and maintain the desired exposure concentrations. Therefore, you must monitor the test concentration(s) of the Substance throughout the exposure duration and report the results. If it is not possible to demonstrate the stability of exposure concentrations (i.e. measured concentration(s) not within 80-120% of the nominal concentration(s)), you must express the effect concentration based on measured values as described in OECD TG 202. In case a dose-response relationship cannot be established (no observed effects), you must demonstrate that the approach used to prepare test solutions was adequate to maximise the concentration of the Substance in the test solution.

2.1. Information regarding data sharing

22 Another registration for the same Substance contains a study on short-term toxicity to daphnia (1997) which is adequate for this information requirement. In accordance with Title III of the REACH Regulation, you may request it from the other registrants and then make every effort to reach an agreement on the sharing of data and costs (Guidance on data-sharing).

23 In your comments on the draft decision, you indicated your intention to obtain access to the information available in the jointly submitted registration dossier of the Substance. This would address the issues identified above but, this decision must be based on the information currently available and therefore the request remains.

3. Growth inhibition study aquatic plants

24 Growth inhibition study on aquatic plants is an information requirement under Annex VII to REACH (Section 9.1.2.).

3.1. Information provided

25 You have provided:

(i) a growth inhibition study on algae (study year and test material not reported);

3.2. Assessment of the information provided

3.2.1. The provided study does not meet the specifications of the test guideline

26 To fulfil the information requirement, a study must comply with OECD TG 201 (Article 13(3) of REACH). Therefore, the following specifications must be met:

27 Reporting of the methodology and results

a) the test design is reported (*e.g.*, number of replicates, number of test concentrations and geometric progression used);

b) the test conditions are reported (*e.g.*, composition of the test medium, test temperature, test species, biomass density at the beginning of the test);

c) the methods used to prepare stock and test solutions are reported.

28 In study (i) described as growth inhibition study on aquatic plants/algae:

29 Reporting of the methodology and results

a) on the test design, you have not specified

- the number and spacing of test concentrations used;
- the number of replicates;

b) on the test conditions, you have not specified

- the composition of the test medium;
- the test temperature;
- the biomass density at the beginning of the test;

c) on the test procedure, you have not specified

- the methods used to prepare stock and test solutions.

30 Based on the above,

- the reporting of the study is not sufficient to conduct an independent assessment of its reliability. More specifically, your IUCLID dossier does not include key pieces of information that would allow ECHA to assess whether the test design and test conditions described in OECD TG 201 were followed and to interpret the results. Therefore, the requirements of OECD TG 201 are not met.

31 Therefore, the information requirement is not fulfilled.

3.3. Study design and test specifications

32 OECD TG 201 and OECD TG 221 specify that, for difficult to test substances, OECD GD 23 must be followed. As already explained above, the Substance is difficult to test. Therefore, you must fulfil the requirements described in 'Study design and test specifications' under Request 2.

3.4. Information regarding data sharing

33 Under Article 25(1), it is necessary to take measures limiting duplication of non-vertebrate test(s).

34 The jointly submitted registration dossier for the Substance contains an algal growth inhibition study (2008) which is adequate for this information requirement. You may request it from the other registrants and then make every effort to reach an agreement on the sharing of data and costs.

35 In your comments on the draft decision, you indicated your intention to obtain access to the information available in the jointly submitted registration dossier of the Substance. This would address the issues identified above but, this decision must be based on the information currently available and therefore the request remains.

4. Ready biodegradability

36 Ready biodegradability is an information requirement in Annex VII to REACH (Section 9.2.1.1.).

4.1. Information provided

37 You have provided:

(i) a ready biodegradability study (study year and test material not reported);

4.2. Assessment of the information provided

38 To fulfil the information requirement, a study that complies with the requirements of OECD TG 301 or OECD TG 310 must be provided (Article 13(3) of REACH).

4.2.1. The provided study does not meet the specifications of the test guideline

39 To fulfil the information requirement, a study must comply with the OECD TG 301 or 310 (Article 13(3) of REACH). Therefore, for a study according to OECD TG 301, the following requirements must be met:

40 Reporting of the methodology and results

a) the source of the inoculum, its concentration in the test and any pre-conditioning treatment are reported;

b) the test temperature is reported;

c) the results of measurements at each sampling point in each replicate is reported in a tabular form;

d) any observed inhibition phenomena and/or abiotic degradation are reported.

41 In study (i) described as a ready biodegradability study:

42 Reporting of the methodology and results

a) the source of the inoculum, its concentration in the test and any pre-conditioning treatment are not reported;

b) the test temperature is not reported;

c) the results of measurements at each sampling point in each replicate is not reported;

d) no information is provided on inhibition phenomena and/or abiotic degradation (if any).

43 Based on the above,

- the reporting of the study is not sufficient to conduct an independent assessment of its reliability. More specifically, your IUCLID dossier does not include key pieces of information that would allow ECHA to assess whether the test conditions described in OECD TG 301 were followed and to interpret the results.

44 Therefore, the requirements of OECD TG 301 are not met.

4.3. Therefore, the information requirement is not fulfilled.Information regarding data sharing

45 The other registrants of the joint submission relied on an adaptation to meet this information requirement. You may consider sharing this information.In your comments on the draft decision, you indicated your intention to obtain access to the information available in the jointly submitted registration dossier of the Substance. This would address the issues

identified above but, this decision must be based on the information currently available and therefore the request remains.

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 06 April 2022.

The deadline of the decision is set based on standard practice for carrying out OECD TG tests. It has been exceptionally extended by 6 months from the standard deadline granted by ECHA to take into account currently longer lead times in contract research organisations.

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

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

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 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;

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[2].

(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

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.

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

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. General recommendations for conducting and reporting new tests

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

[3] https://echa.europa.eu/manuals