~~Confidential~~

Helsinki, 24 January 2024

Addressee(s)
Registrants of JS_SV_013 as listed in Appendix 3 of this decision

Date of submission of the dossier subject to this decision
26 July 2023

Registered substance subject to this decision ("the Substance")
Substance name: 1-hydroxy-4-(p-toluidino)anthraquinone
EC/List number: 201-353-5

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 ***4 May 2026***.

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

We note that the Substance has been notified as a nanoform under the EU cosmetics and Belgian nano-particulate substances reporting systems.[1] This indicates that the Substance is manufactured or imported in the European Union in nanoforms, possibly by any addressee of the present decision. However, the REACH Regulation (as amended by Regulation Commission Regulation (EU) 2018/1881) sets out explicit information requirements for nanoforms of substances. Manufacturers and importers of nanoforms must have fulfilled these specific information requirements by 1st January 2020. As far as the registration dossier currently submitted on the Substance does not cover any nanoform, the incompliances identified in the present decision relate only to information required on non-nanoforms.

Based on the above, the requested information must be generated using exclusively non-nanoforms of the Substance.

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

1. Partition coefficient n-octanol/water (Annex VII, Section 7.8.; test method: EU A.24/OECD TG 117).

2. Long-term toxicity testing on aquatic invertebrates (triggered by Annex VII, Section 9.1.1., Column 2; test method: EU C.20./OECD TG 211).

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

[1] Respectively, "*Catalogue of nanomaterials used in cosmetic products placed on the EU market*", according to to Article 16(10)(a) of Regulation (EC) No 1223/2009 of 22 December 2009 and "Royal Decree on the placing on the market of substances produced in nanoparticular state" of May 27 May 2014 (ref. KB20140527).

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

4. Long-term toxicity testing on fish (triggered by Annex VIII, Section 9.1.3., Column 2; test method: EU C.47./OECD TG 210).

The reasons for the requests 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 addressees of the decision and their 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[2] under the authority of Mike Rasenberg, Director of Hazard Assessment

Appendix 1: Reasons for the requests
Appendix 2: Procedure
Appendix 3: Addressees of the decision and their individual information requirements
Appendix 4: Conducting and reporting new tests under REACH

[2] 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 requests

Reasons related to the information under Annex VII of REACH

1. Partition coefficient n-octanol/water

1 Partition coefficient n-octanol/water is an information requirement under Annex VII to REACH (Section 7.8).

1.1. Information provided

2 You have provided a non Test guideline ETAD method of partition coefficient n-octanol/water study (2014) with the Substance.

1.2. Assessment of the information provided

1.2.1. The provided study does not meet the specifications of the test guideline(s)

3 To fulfil the information requirement, a study must comply with OECD TG 107/117/123 Article 13(3) of REACH).

4 These test guidelines describe three methods (the shake flask method, the HPLC method and the slow-stirring method) for conducting the determination of the partition coefficient between water and n-octanol (Log Kow). The OECD TG 107 specifies that, to select the appropriate test method, the properties of the substance and a preliminary determination of Log Kow using the individual solubilities of the test material in water and n-octanol must be considered. However, this preliminary estimate is considered sufficient only if none of the recommended method (i.e. OECD TG 107/117/123) are technically feasible due to specific substance properties.

5 You provide a Log Kow using the individual solubilities of the test material in water and n-octanol (described by you as the ETAD method). You have not provided any justification as to why none of the methods listed above are technically feasible.

6 In the absence of appropriate justification, this preliminary estimate, which bears a higher uncertainty compared to recommended test method, is not adequate to meet the information requirement.

7 Therefore, the information requirement is not fulfilled.

8 In your comments to the draft decision, you agree with the request.

1.3. Study design

9 To fulfil the information requirement, the test method(s) according to OECD TG 107, 117 or 123 are in general appropriate. Considering the properties of the Substance (sparingly soluble particles), the Partition Coefficient (n-octanol/water), HPLC Method (test method: OECD TG 117) or alternatively the Partition Coefficient (1-Octanol/Water): Slow-Stirring Method (test method: OECD TG 123) are the most appropriate method to fulfil the information requirement for the Substance. You can choose between these methods, but you must ensure that the Substance is within the applicability domain of the chosen test method.

2. Long-term toxicity testing on aquatic invertebrates

10 Short-term toxicity testing on aquatic invertebrates is an information requirement under Annex VII, Column 1, Section 9.1.1. However, under Column 2, long-term toxicity testing on aquatic invertebrates may be required by the Agency if the substance is poorly water soluble, i.e. solubility below 1 mg/L.

2.1. Triggering of the information requirement

11 You have provided information which indicates that the Substance is poorly water soluble (solubility in water of 0.0093 mg/L).

12 Therefore, the Substance is poorly water soluble and information on long-term toxicity on aquatic invertebrates must be provided.

2.2. Information requirement not fulfilled

13 You have provided a short-term toxicity study on aquatic invertebrates but no information on long-term toxicity on aquatic invertebrates for the Substance.

14 Therefore, the information requirement is not fulfilled.

15 In your comments to the draft decision, you indicate that you consider that the results of the analytical monitoring conducted in "*two available acute aquatic toxicity studies* […] *raise doubts that the Substance meets the requirement for poorly soluble substances, which is having a water solubility below 1 mg/L*". You intend to conduct an "*enhanced water solubility study according to OECD TG 105*" to confirm or infirm the results of the existing water solubility study. You then state that you will only conduct the requested study "[i]*f the results of the enhanced water solubility study according to OECD TG 105 verify the status as poorly soluble substance*".

16 As this strategy relies on data, which is yet to be generated for the substance, no conclusion on the compliance of the proposed approach can be made. You remain responsible for complying with this decision by the set deadline.

2.3. Study design

17 The Substance is difficult to test due to the low water solubility (0.0093 mg/L). OECD TG 211 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 211. 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.

3. Growth inhibition study aquatic plants

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

3.1. Information provided

19 You have provided a Growth inhibition study on algae (2018) with the Substance;

3.2. Assessment of the information provided

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

20 To fulfil the information requirement, a study must comply with OECD TG 201 and the specifications of OECD GD 23 if the substance is difficult to test (Article 13(3) of REACH). The Substance is difficult to test as it has low water solubility (WS = 0.0093 mg/L). Therefore, the following specifications must be met:

Technical specifications impacting the sensitivity/reliability of the test

a) the test concentrations are below the limit of solubility of the test material in the dilution water;

Additional requirements applicable to difficult to test substances

b) if the test material is tested at the saturation concentration, evidence must be provided that all reasonable efforts have been taken to achieve a saturation concentration, which include:

(1) an analytical method validation report demonstrating that the analytical method is appropriate;

(2) information on the saturation concentrations of the test material in water and in the test solution; and

(3) the results of a preliminary experiment demonstrating that the test solution preparation method is adequate to maximize the concentration of the test material in solution.

21 In study (i):

Technical specifications impacting the sensitivity/reliability of the test

a) the test concentrations were 25, 50, 100 mg/L nominal concentrations while your report in your dossier indicates a limit of solubility of the test material in water of 0.0093 mg/L;

Additional requirements applicable to difficult to test substances

b) you do not provide the information listed under (1) to (3)

22 Based on the above, the Substance is difficult to test and there are critical methodological deficiencies resulting in the rejection of the study results. More specifically, the loading rates used to prepare the test solutions were too high and therefore cannot be considered a reliable estimate of the exposure to the dissolved substance. Therefore, the reported effect concentrations based on loading rates does not reflect the intrinsic toxicity of the Substance. Furthermore, you have provided no experimental evidence to support that the methodology you used allowed to maximize the exposure to the test material.

23 In your comments to the draft decision, you acknowledge that "[w]*ith a mean measured concentration of 1.122 mg/L the saturation concentration of the Substance in OECD medium exceeds the water solubility limit determined in the OECD 105 study (0.0093 mg/L) by more than a factor of 100*". You consider that the similar value (*i.e.*, 1.2 mg/L DOC) was obtained in an acute Daphnia study "*confirms the correct procedure for the preparation of a maximum saturation concentration*".

24 You further argue that "*as specified in OECD GD 23 test solutions can be prepared by direct addition at higher nominal concentrations than the theoretical water solubility limit to achieve the maximum dissolved concentration provided any non-dissolved test chemical is separated before testing*". You specify that "*excess material was removed via filtration which is an appropriate separation technique for mono-constituent substances according to OECD GD 23*" and that you consider that "*the recommendations of OECD GD 23 have been implemented*".

25 However, ECHA notes that you still fail to provide the information listed under point b) above to demonstrate that the methodology you used was adequate to maximize the exposure to the test material. Furthermore, ECHA notes that you have provided no evidence to demonstrate the efficacy of the selected separation method (e.g. by checking for the Tyndall effect or by any other appropriate means). Therefore, you fail to demonstrate that reported values provide a reliable estimate of the dissolved fraction and is not biased by the presence of undissolved test material. As a results, your comments to the draft decision do not change the assessment outcome.

26 On this basis, the specifications of OECD TG 201 are not met and the information requirement is not fulfilled.

3.3. Study design

27 OECD TG 201 specifies 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" under request 2.3.

Reasons related to the information under Annex VIII of REACH

4. Long-term toxicity testing on fish

28 Short-term toxicity testing on fish is an information requirement under Annex VIII, Column 1, Section 9.1.3. However, long-term toxicity testing on fish may be required by the Agency (Section 9.1.3., Column 2) if the substance is poorly water soluble, i.e. solubility below 1 mg/L.

4.1. Triggering of the information requirement

29 As already explained in request 3, the Substance is poorly water soluble and information on long-term toxicity on fish must be provided.

4.2. Information requirement not fulfilled

30 You have provided a short-term toxicity study on fish but no information on long-term toxicity on fish for the Substance.

31 In your comments to the draft decision, you indicate that you consider that the results of the analytical monitoring conducted in "*two available acute aquatic toxicity studies* […] *raise doubts that the Substance meets the requirement for poorly soluble substances, which is having a water solubility below 1 mg/L*". You intend to conduct an "*enhanced water solubility study according to OECD TG 105*" to confirm or infirm the results of the existing water solubility study. You then state that you will only conduct the requested study "[i]*f the results of the enhanced water solubility study according to OECD TG 105 verify the status as poorly soluble substance*".

32 As this strategy relies on data, which is yet to be generated for the substance, no conclusion on the compliance of the proposed approach can be made. You remain responsible for complying with this decision by the set deadline.

33 Therefore, the information requirement is not fulfilled.

4.3. Study design

34 To fulfil the information requirement for the Substance, the Fish, Early-life Stage Toxicity Test (test method OECD TG 210) is the most appropriate (Guidance on IRs and CSA, Section R.7.8.2.).

35 OECD TG 210 specifies 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" under request 2.3.

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 (2023).
***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 31 October 2022.

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

You have provided comments during the decision-making phase which were found to address the incompliance identified in the draft decision and you included this information in an update of your registration dossier (submission date: 13 September 2023). Therefore, the original request to conduct an in vitro gene mutation study in bacteria (Annex VII, Section 8.4.1.) was removed.

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]
[redacted]	[redacted]	[redacted]
[redacted]	[redacted]	[redacted]
[redacted]	[redacted]	[redacted]
[redacted]	[redacted]	[redacted]
[redacted]	[redacted]	[redacted]
[redacted]	[redacted]	[redacted]
[redacted]	[redacted]	[redacted]
[redacted]	[redacted]	[redacted]
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[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.

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

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, in this case in this case purity and particle size distribution.

With that detailed information, ECHA can confirm 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 (https://echa.europa.eu/manuals).