~~Confidential~~

Helsinki, 24 June 2021

Addressees
Registrants of JS_Monoazored_PR4 as listed in the last Appendix of this decision

Date of submission of the dossier subject to this decision
03 May 2017

Registered substance subject to this decision ("the Substance")
Substance name: 1-[(2-chloro-4-nitrophenyl)azo]-2-naphthol
EC number: 220-562-2
CAS number: 2814-77-9

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 the deadline of ***31 March 2022***.

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

We note that the Substance has been notified as a nanoform under the French nano-particulate substances reporting system.[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.

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

1. Water solubility (Annex VII, Section 7.7.; test method: EU A.6./OECD TG 105)

2. Partition coefficient n-octanol/water (Annex VII, Section 7.8.; test method: EU A.8 or OECD TG 117 or OECD TG 123)

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

1. Adsorption/ desorption screening (Annex VIII, Section 9.3.1.; test method: OECD TG 121 or OECD TG 106)

Reasons for the request(s) are explained in the following appendices Appendix/Appendices

[1] "*Dispositif de déclaration des substances à l'état nanoparticulaire*", Decree 2012-232 of French *Conseil d'Etat* of 17 february 2012.

entitled "Reasons to request information required under Annexes VII to VIII of REACH", respectively.

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 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.

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, 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 Christel Schilliger-Musset, Director of Hazard Assessment

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

1. Water solubility

Water solubility is an information requirement under Annex VII to REACH (Section 7.7).

You have provided the following information:

i. Study similar to OECD TG 105, key study, [redacted] (2005).

We have assessed this information and identified the following issue:

To fulfil the information requirement, a study must comply with the OECD TG 105 or the EU Method A.6 (Article 13(3) of REACH). Therefore, the following specifications must be met:

- the shake-flask method is applicable to test material with a water solubility ≥ 10 mg/L;
- solids are pulverized before testing;
- the test is conducted with a loading of about five times the quantity required to saturate a given volume of water;
- three flasks are included which are shaken/stirred for 24, 48 and 72 hours, respectively;
- after shaking/stirring, each flask is equilibrated for 24 hours at 20°C;
- the results are considered acceptable, if the results of the flasks shaken for 48 and 72 hours differ by ≤ 15%. If the results shows a tendency of higher solubility with longer shaking/stirring period, the test is repeated with longer equilibration times;
- a reliable analytical method is available.

Your registration dossier provides a study showing the following:

- the water solubility was determined to be 3.3 µg/L, hence below 10 mg/L;
- the fact that the test material was pulverized or not before testing is not reported;
- about 5 mg of the test sample were suspended in 30 mL water in a sample flask;
- triplicate test samples were shaken for two hours at 30°C (+/- 2°C) and then at ambient temperature (c.a. 22-23°C) for 70 hours;
- the test material concentration was determined UV-VIS. The calibration curve was produced using chloroform as solvent. The lowest calibration point corresponded to a nominal concentration of 0.56 mg/L (absorbance at 489 nm of 0.0483 measured in chloroform with a 10 mm cuvette). The measured absorbance for the test material ranged from 0.00386 to 0.00424 (measured in water with a 100 mm cuvette).

Based on the above, the shake-flask method described in OECD TG 105 is not applicable to the Substance as its solubility is estimated to be well below 10 mg/L. Furthermore, the test design, the loading rate and the sample preparation method are not compliant with the guideline requirements. Finally, the analytical method used in this study did not allow providing a reliable estimate of dissolved concentration. The measured absorbance values in the test samples are more than an order of magnitude below the absorbance value of the lowest calibration point. Considering the inherent uncertainty related to the measurement of low absorbance values and the fact that the calibration curve and test samples use different solvents (i.e. chloroform versus water, which have different λmax), the reliability of the reported analytical method is not demonstrated.

On the basis of the above, the information requirement is not fulfilled.

Study design

Considering the properties of the Substance (solubility < 10 mg/L), the column elution described in EU A.6/OECD TG 105 is the most appropriate method to fulfil the information requirement for the Substance.

2. Partition coefficient n-octanol/water

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

You have provided the following information:

i. Study similar to OECD TG 107, [redacted] (2007).

We have assessed this information and identified the following issues:

A. To fulfil the information requirement, a study must comply with the OECD TG 107 or OECD TG 117 or OECD TG 123 or the EU Method A.8 (Article 13(3) of REACH). These test guidelines describe three methods (the shake flask method, the HPLC method and the slow-stirring method) for conducting the determining the partition coefficient between water and n-octanol (Log Kow). The EU test method A.8 specifies that the method selection must be based on the properties of the substance and on a preliminary determination of Log Kow using the individual solubilities of the test material in water and n-octanol. This preliminary estimate is considered sufficient only if none of the recommended method are technically feasible due to specific substance properties (*e.g.* surface active substances).

   However, your registration dossier provides a study claimed similar to OECD TG 107. The robust study summary reports that the study was conducted according to the ETAD method where log Kow is determined using the individual solubilities of the test material in water and n-octanol. You have not provided any justification as to why none of the methods listed above are technically feasible.

B. To provide an acceptable determination of the partition coefficient using individual solubilities in water and n-octanol, the calculation must be based on reliable individual solubilities estimates.

   You used the information discussed under Section A.1 as the water solubility estimated used in the calculation. You report that the n-octanol solubility estimate was determined using a similar method.

   As explained under Section A.1, the information provided in your registration does not fulfil the information requirement. Furthermore, as a similar approach was used to determine n-octanol solubility, similar issue identified under Section A.1 also apply to the determination of n-octanol solubility. Hence, the log Kow value reported in your registration dossier is not reliable.

On the basis of the above, the information requirement is not fulfilled.

Study design

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.

Appendix B: Reasons to request information required under Annex VIII of REACH

2. Adsorption/ desorption screening

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

You have adapted this information requirement under Annex XI, Section 1.5. (grouping of substances and read-across approach). In support of your adaptation you have provided the following information:

i. OECD TG 121 on the category member 1-(4-methyl-2-nitrophenylazo)-2-naphthol (EC No. 21119-372-2), key study, [redacted] (2013).

ECHA has considered the scientific and regulatory validity of your grouping and read-across approach in general before assessing the specific standard information requirements in the following appendices.

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 considered as a group or category (addressed under 'Scope of the grouping'). 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 (addressed under 'Assessment of prediction(s)').

Additional information on what is necessary when justifying a read-across approach can be found in the ECHA Guidance R.6 and related documents.

A. Scope of the grouping

In your registration dossier you have formed a group (category) of 'Monoazo Red Pigments'. You have provided a read-across justification document in Section 1 of your CSR.

For the purpose of this decision, the following abbreviations are used for the group members:

1) "PR3": C.I. PIGMENT RED 3, i.e. 1-(4-methyl-2-nitrophenylazo)-2-naphthol (EC No. 219-372-2);
2) "PO5": C.I. PIGMENT ORANGE 5, i.e. 1-[(2,4-dinitrophenyl)azo]-2-naphthol (EC No. 222-429-4);
3) The Substance.

You provide the following reasoning for the grouping the substances: *"The pigments grouped in this category* [...] *contain a substituted phenyl moiety, an azo moiety, and a 2-hydroxynaphthalene (β-naphthol)* [...]*".*

You define the structural basis for the grouping as all substances with the above structural groups but with *"different identity of the substituents of the phenyl ring"*. ECHA understands that this is the applicability domain of the grouping and will assess your predictions on this basis.

B. Predictions of environmental fate properties

You have provided the following reasoning for the prediction of environmental fate properties: *"All members of this category are solids, which decompose at high temperatures. The*

solubility of these red and orange pigments in water and n-octanol is limited, < 18 mg/L, resulting in a low partition coefficient in n-octanol/water (log Pow < 3.7) [...]".

ECHA understands that you predict the properties of the Substance using a read-across hypothesis which assumes that different compounds have the same type of effects. The properties of your Substance are predicted to be quantitatively equal to those of the source substance.

You intend to predict the adsorption/desorption property of the Substance from information obtained from the following source substance:

- PR3, i.e. 1-(4-methyl-2-nitrophenylazo)-2-naphthol (EC No. 219-372-2)

ECHA notes the following shortcoming with regards to prediction of environmental fate properties:

Supporting information

Annex XI, Section 1.5 of the REACH Regulation states that "[…] *environmental fate may be predicted from data for reference substance(s)*". For this purpose "*it is important to provide supporting information to strengthen the rationale for the read-across*"[3]. The set of supporting information should allow to verify the crucial aspects of the read-across hypothesis and establish that the properties of the Substance can be predicted from the data on other category members.

As indicated above, your read-across hypothesis is based on the assumption that the structurally similar category members cause the same type of effect(s). In this context, relevant, reliable and adequate information allowing to compare the properties of the category members is necessary to confirm that both substances cause the same type of effects.

The data set reported in the technical dossier does not include relevant, reliable and adequate information for the category members to support your read-across hypothesis. First as explained under request A.2 you have not provided reliable information on the partition coefficient in n-octanol/water for the Substance. Furthermore, you have not provided any supporting information on the category members to demonstrate that they may have similar adsorption/desorption properties.

In the absence of such information, you have not established that the category members are likely to have similar properties. Therefore you have not provided sufficient supporting information to strengthen the rationale for the read-across.

C. Conclusions on the grouping of substances and read-across approach

As explained above, you have not established that relevant properties of the Substance can be predicted from data on the selected analogue substance. Therefore, your adaptation does not comply with the general rules of adaptation as set out in Annex XI, Section 1.5. and your grouping and read-across approach is rejected.

On the basis of the above, the information requirement is not fulfilled.

Study design

[3] Guidance on information requirements and chemical safety assessment Chapter R.6: QSARs and grouping of Chemicals, Section R.6.2.2.1.f

Considering the properties of the Substance (sparingly soluble particles), the Estimation of the Adsorption Coefficient (Koc) on Soil and on Sewage Sludge using High Performance Liquid Chromatography (HPLC) (test method: OECD TG 121) or alternatively the Adsorption/Desorption Using a Batch Equilibrium Method (test method: OECD TG 106) are the most appropriate method to fulfil the information requirement for the Substance.

Appendix C: 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[4].

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[5].

[4] https://echa.europa.eu/practical-guides
[5] https://echa.europa.eu/manuals

Appendix D: Procedure

The Substance is listed in the Community rolling action plan (CoRAP) for the start of substance evaluation in 2019/2020.

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 March 2020.

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

ECHA did not receive any comments within the commenting period.

ECHA notified the draft decision to the competent authorities of the Member States for proposals for amendment.

As no amendments were proposed, ECHA adopted the decision under Article 51(3) of REACH.

Appendix E: List of references - ECHA Guidance[6] 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)[7]

RAAF - considerations on multiconstituent substances and UVCBs (RAAF UVCB, March 2017)[7]

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.

OECD Guidance documents[8]

[6] https://echa.europa.eu/guidance-documents/guidance-on-information-requirements-and-chemical-safety-assessment
[7] https://echa.europa.eu/support/registration/how-to-avoid-unnecessary-testing-on-animals/grouping-of-substances-and-read-across
[8] http://www.oecd.org/chemicalsafety/testing/series-testing-assessment-publications-number.htm

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.

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]
[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.