EUROPEAN CHEMICALS AGENCY

Helsinki, 21 December 2017

Addressee: [redacted]

Decision number: CCH-D-2114381726-39-01/F
Substance name: 1-(4-methyl-2-nitrophenylazo)-2-naphthol
EC number: 219-372-2
CAS number: 2425-85-6
Registration number: [redacted]
Submission number: [redacted]
Submission date: 13.05.2013
Registered tonnage band: 10-100 tonnes per year (submission number: [redacted] latest tonnage band)

DECISION ON A COMPLIANCE CHECK

Based on Article 41 of Regulation (EC) No 1907/2006 (the 'REACH Regulation'), ECHA requests you to submit information on

1. **Long-term toxicity testing on fish (Annex VIII, Section 9.1.3., column 2; test method: Fish, early-life stage (FELS) toxicity test, OECD TG 210) with the registered substance.**

You may adapt the testing requested above according to the specific rules outlined in Annexes VI to X and/or according to the general rules contained in Annex XI of the REACH Regulation. In order to ensure compliance with the respective information requirement, any such adaptation will need to have a scientific justification, referring and conforming to the appropriate rules in the respective Annex, and an adequate and reliable documentation.

You are required to submit the requested information in an updated registration dossier by **3 January 2019**. You shall also update the chemical safety report, where relevant.

The reasons of this decision are set out in Appendix 1. The procedural history is described in Appendix 2. Advice and further observations are provided in Appendix 3.

Appeal

This decision can be appealed to the Board of Appeal of ECHA within three months of its notification. An appeal, together with the grounds thereof, shall be submitted to ECHA in writing. An appeal has suspensive effect and is subject to a fee. Further details are described under http://echa.europa.eu/regulations/appeals.

Authorised[1] by Claudio Carlon, Head of Unit, Evaluation E2

[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

The information requested in this decision is needed to meet the respective requirements of members of the joint submission registered at tonnages of 10 to 100 tonnes per annum (Annex VIII) as part of the jointly submitted registration dossier.

1. Long-term toxicity testing on fish (Annex VIII, Section 9.1.3., column 2)

In accordance with Articles 10(a) and 12(1) of the REACH Regulation, a technical dossier registered at 10 to 100 tonnes per year must contain, as a minimum, the information specified in Annexes VII to VIII of the REACH Regulation. The information to be generated for the dossier must fulfil the criteria in Article 13(4) of the same regulation.

"Short-term toxicity testing on fish" is a standard information requirement as laid down in Annex VIII, Section 9.1.3. of the REACH Regulation. Furthermore, pursuant to Annex VIII, Section 9.1.3, Column 2 the long-term aquatic toxicity study on fish (Annex IX, Section 9.1.6.) shall be considered if the substance is poorly water soluble. Adequate information on this endpoint needs to be present in the technical dossier for the registered substance to meet this information requirement. The choice of the appropriate test(s) will depend on the results of the chemical safety assessment.

ECHA considers that substances that are poorly soluble in water require longer time to be significantly taken up by the test organisms and so steady state conditions are likely not to be reached within the duration of a short-term toxicity test. For this reason, short-term tests may not give a true measure of toxicity for such substances and toxicity may actually not even occur at the water solubility limit of the substance if the test duration is too short. ECHA notes that the registered substance is poorly water soluble (WS < 1mg/l), but not highly insoluble in water (water solubility reported to be 3.3 µg/L).

Therefore, long-term toxicity needs to be investigated already at the tonnage band currently applicable for the substance subject to the present decision.

ECHA observes that no information on long-term fish toxicity is reported in the registration dossier. ECHA acknowledges that there is short-term toxicity study with fish reported in the dossier where no toxicity was observed at the water solubility limit of the substance. However, as noted above, the registered substance is poorly water soluble. Thus, short-term toxicity test with fish is not sufficient for the substance as the lack of toxicity at the short-term test cannot exclude long-term toxicity.

Moreover, ECHA notes that the information on fish toxicity is needed for the proper Chemical Safety Assessment of the substance. As noted in the Guidance on Information Requirements and Chemical Safety Assessment, Chapter R.7b (ECHA, version 4.0, June 2017) standard information on aquatic toxicity (on aquatic invertebrates, fish and aquatic plants) is necessary to enable the environmental hazard assessment, i.e. for use in classification and labelling and derivation of the PNECwater (Predicted No Effect Concentration for water), and for determination of the toxicity (T) criterion in the PBT assessment. As discussed above, the short-term data is not applicable in this case due to the substance being considered poorly soluble in water. Therefore long-term data on all three trophic levels is needed to derive the $PNEC_{water}$ and to perform the chemical safety assessment.

Furthermore, ECHA notes that due to the low water solubility the short-term data cannot serve as a compelling evidence to predict relative differences (or lack of) in species

sensitivity required to apply the aquatic ITS (*ECHA Guidance on information requirements and chemical safety assessment*, Chapter R.7b (version 4.0, June 2017), Section R.7.8.5.3.).

For the reasons stated above, the integrated testing strategy (*ECHA Guidance on information requirements and chemical safety assessment*, Chapter R.7b - version 4.0, June 2017 - Section R.7.8.5.3.) is not applicable and it is necessary to provide long-term data on both aquatic invertebrates and on fish.

As explained above, the information provided on this endpoint for the registered substance in the technical dossier does not meet the information requirement. Consequently there is an information gap and it is necessary to provide information for this endpoint.

You did not provide any comments on this endpoint on the draft decision.

Regarding the test method, ECHA considers that the FELS toxicity test according to OECD TG 210 is the most sensitive of the standard fish tests available as it covers several life stages of the fish from the newly fertilised egg, through hatch to early stages of growth and should therefore be used (see ECHA *Guidance on information requirements and chemical safety assessment* (version 4.0, June 2017), Chapter R7b, Figure R.7.8-4). The test method OECD TG 210 is also the only suitable test currently available for examining the potential toxic effects of bioaccumulation (ECHA Guidance Chapter R7b, version 4.0, June 2017). For these reasons, ECHA considers the FELS toxicity test using the test method OECD TG 210 as appropriate and suitable.

Therefore, pursuant to Article 41(1) and (3) of the REACH Regulation, you are requested to submit the following information derived with the registered substance subject to the present decision: Fish, early-life stage (FELS) toxicity test (test method: OECD TG 210).

Note for consideration for aquatic testing

Before conducting the above test you are advised to consult the ECHA Guidance on information requirements and chemical safety assessment, Chapters R.4 (version 1.1, December 2011), R.5 (version 2.1, December 2011), R.6 (May 2008), R.7b (version 4.0, June 2017) and R.7c (version 3.0, June 2017). If you decide to adapt the testing requested according to the specific rules outlined in Annexes VI to X and/or according to general rules contained in Annex XI of the REACH Regulation, you are referred to the advice provided in the Practical Guide on "*How to use alternatives to animal testing to fulfil your information requirements for REACH registration*".

Due to the low solubility and particulate nature of your substance, you should consult the OECD Guidance Document on Aquatic Toxicity Testing of Difficult Substances and Mixtures, ENV/JM/MONO (2000)6 and ECHA *Guidance on information requirements and chemical safety assessment* (version 4.0, June 2017), Chapter R7b, Table R.7.8-3 summarising aquatic toxicity testing of difficult substances for choosing the design of the requested ecotoxicity tests and for calculation and expression of the result of the tests. Alternatively you can also consult the OECD document ENV/JM/MONO (2014)40/1 as it could apply better to your substance with regard to its specific properties (particles, poorly water soluble and pigment).

ECHA notes that due to lack of effects in short-term studies it is not possible to determine the sensitivity of species. Therefore, the Integrated testing strategy (ITS) outlined in ECHA *Guidance on information requirements and chemical safety assessment* (version .0, June

2017), Chapter R7b (Section R.7.8.5 including Figure R.7.8-4), is not applicable in this case and it is necessary to have long-term data on both invertebrates and fish. ECHA notes that you already have a valid long-term aquatic invertebrate study in the technical dossier and therefore here only the long-term fish study is requested.

Appendix 2: Procedural history

For the purpose of the decision-making, this decision does not take into account any updates of your registration after the date when the draft decision was notified to you under Article 50(1) of the REACH Regulation. Exceptionally, following your comments on the draft decision indicating a tonnage band downgrade, ECHA has however taken into account the updated tonnage band (submission number: [redacted] on 31 March 2017).
Based on the average production or import volumes for the three preceding calendar years, the tonnage band has been changed from 100-1000 tonnes per year (submission number: [redacted]) to 10-100 tonnes per year (submission number: [redacted]).

ECHA notes that your own tonnage band is 1-10 tonnes per year but the tonnage band for several members of the joint submission is 10-100 tonnes per year.

The compliance check was initiated on 11 August 2016.

The decision making followed the procedure of Articles 50 and 51 of the REACH Regulation, as described below:

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

Given the exceptional circumstances, ECHA has taken into account the dossier update when processing this decision, as well as your comments. This has resulted in the removal of the following decision requests: pre-natal developmental toxicity study, bioaccumulation study in aquatic species and growth inhibition study aquatic plants, and the amendment of the following decision request in Appendix I: long-term toxicity testing in fish.
If a tonnage band increase occurs after ECHA has issued this decision, the requests which were removed may be requested in a future decision.

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

ECHA received proposal(s) for amendment and modified the draft decision.

ECHA invited you to comment on the proposed amendment(s).

ECHA referred the draft decision to the Member State Committee.

You did not provide any comments on the proposed amendment(s).

The Member State Committee reached a unanimous agreement on the draft decision in its MSC-55 written procedure and ECHA took the decision according to Article 51(6) of the REACH Regulation.

Appendix 3: Further information, observations and technical guidance

1. This compliance check decision does not prevent ECHA from initiating further compliance checks on the present registration at a later stage.

2. Failure to comply with the request(s) in this decision, or to fulfil otherwise the information requirement(s) with a valid and documented adaptation, will result in a notification to the enforcement authorities of your Member State.

3. In relation to the information required by the present decision, the sample of the substance used for the new test(s) must be suitable for use by all the joint registrants. Hence, the sample should have a composition that is suitable to fulfil the information requirement for the range of substance compositions manufactured or imported by the joint registrants. It is the responsibility of all joint registrants who manufacture or import the same substance to agree on the appropriate composition of the test material and to document the necessary information on their substance composition. In addition, it is important to ensure that the particular sample of the substance tested in the new test(s) is appropriate to assess the properties of the registered substance, taking into account any variation in the composition of the technical grade of the substance as actually manufactured or imported by each registrant. If the registration of the substance by any registrant covers different grades, the sample used for the new test(s) must be suitable to assess these grades. Finally there must be adequate information on substance identity for the sample tested and the grade(s) registered to enable the relevance of the test(s) to be assessed.