~~Confidential~~

Helsinki, 20 October 2020

Addressee: [redacted]

Decision number: CCH-D-2114526514-53-01/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 subject to follow-up evaluation: [redacted]
Submission date subject to follow-up evaluation: 23 May 2019

DECISION TAKEN UNDER ARTICLE 42(1) OF THE REACH REGULATION

By decision CCH-D-2114381726-39-01/F of 21 December 2017 ("the original decision") ECHA requested you to submit information by 3 January 2019 in an update of your registration dossier.

Based on Article 42(1) of Regulation (EC) No 1907/2006 (the 'REACH Regulation'), ECHA examined the information you submitted with the registration update specified in the header above, and concludes that

Your registration still does not comply with the following information requirement(s) requested in the original decision:

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 are therefore still expected to provide this information.

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.

The respective Member State competent authority (MSCA) and National enforcement authority (NEA) will be informed of this decision. They may consider enforcement actions to secure the implementation of the original decision and exercise the powers reserved to them under Article 126 of Regulation No 1907/2006 (penalties for non-compliance)[1].

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.

Approved[2] under the authority of Christel Schilliger-Musset, Director of Hazard Assessment

[1] See paragraphs 61 and 114 of the judgment of 8 May of the General Court of the European Court of Justice in Case T-283/15 Esso Raffinage v. ECHA
[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

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

In the original decision you were requested to submit information derived with the registered substance 1-(4-methyl-2-nitrophenylazo)-2-naphthol in a 'Fish, Early-Life Stage' (FELS) toxicity test (test method: OECD TG 210), by 3 January 2019. A note for consideration was included in the statement of reasons of the original decision advising you to consult a number of guidance documents in order to determine the best test design for your substance.

In the updated registration dossier subject to follow-up evaluation, you did not provide the requested study. Instead, you provided the following data waiving justification:

"In various decisions on a compliance check for pigments, ECHA requests long term toxicity testing on fish using the Fish Early Life Stage (FELS) toxicity test (OECD 210). One of these decisions is for Pigment Red 3 (decision CCH-D-2114381726-39-01/F). ECHA defined/described the substances as composed of particles that are poorly water soluble and small or very small and gave some recommendations to apply a test design which is optimized for the specific profile of the substances:

> *"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 (= Guidance 23) and ECHA Guidance on information requirements and chemical safety assessment (version 4.0, June 2017), Chapter R7b, Table R.7.8-3 summarizing 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)."*

After intensive review of the mentioned guidance (including also the OECD Guidance on sample preparation No 36 (2012) and OECD draft guidance document on aquatic and sediment toxicological testing of nanomaterials (2018) as well a scientific literature the registrants came to the conclusion that the existing guidance gives not sufficient information to carry out a FELS test with this specific type of substances on a scientifically sound basis.

The registrants also contacted different GLP certified contract research labs to get an offer for the tests requested. No lab was able to offer a reliable test design since no experience is existing on testing of small particles with low water solubility and the related substance analysis.

Summarizing, there is no guidance/guideline existing for conducting chronic aquatic tests using vertebrates with small particles with low water solubility.

Additionally, in the same decision for Pigment Red 3, ECHA has accepted a long-term aquatic invertebrate study (OECD 211) with a "traditional" test design using DMF as solvent to prepare a stock solution for the preparation of a saturated aqueous solution for testing according to: ENV/JM/MONO(2000)6: OECD SERIES ON TESTING AND ASSESSMENT Number 23: GUIDANCE DOCUMENT ON AQUATIC TOXICITY TESTING OF DIFFICULT SUBSTANCES AND MIXTURES section 3.1.2.

It therefore could be suggested that the same method for preparation may be used to prepare the media for the long-term toxicity testing on fish (FELS) OECD210 since the use of solvents is allowed in both long-term invertebrates and fish testing.

But this would be contradictory to the request to perform the study according to the guidance for small particles with low water solubility.

In conclusion, according to animal welfare aspects and the necessity to produce reliable results which help to assess the potential aquatic long-term toxicity of the mentioned substance and to achieve acceptance of the results by the authorities, a clarification of some issues is an imperative prerequisite before conducting the FELS tests.

To develop a reliable test design on basis of the above-mentioned issues the companies concerned kindly ask ECHA for a meeting to discuss the following issues:

Characterization of the test substance

Which information on substance characteristics (e.g. dissolution rate, agglomeration behavior, particle number, particle size distribution) is a prerequisite for conducting a long term aquatic toxicity study?

What are the consequences of this characterization for the test design (e.g. necessity of stable dispersion, feasibility of flow through testing, test concentration levels)?

Analytical verification/behavior of test concentration

Which measures are sufficient/feasible to describe the substance behavior during the test (dissolution rate, agglomeration behavior, particle number, particle size distribution, mass analysis, frequency of the measurements of concentration of the test material)?

Test design

Rational for establishing test concentrations

Preparation of exposure suspensions

Stability of suspension and consequences for study design (e.g. sedimentation accepted in FELS, maintaining stable dispersion or testing soluble part of the substance to prevent physical effects)

Presence of threshold (e.g. particle size, solubility) to discriminate between "traditional" test design and "adopted to small particles" test design

Feasibility of using flow through design for testing particles in FELS

Ecological meaningfulness of water column testing instead of sediment/soil testing?

Should the environmental test compartment be adapted according to dispersion stability of the substances?"

First, you consider that ECHA's 'Note for consideration for aquatic testing' is effectively a request to develop an alternative test design to the standard design of the OECD 210.

In response, ECHA notes that you already raised this issue in a query to the ECHA Helpdesk on 20 December 2018 (which was in fact only two weeks before the deadline set in the decision). The text you used in the query is identical to what you submitted in the dossier update.

On 2 February 2019 ECHA responded to you as follows with respect to the "note for consideration":

"the 'Note for consideration for aquatic testing' is merely advising you to consult a number of guidance documents in order to determine the best test design for your substance. The note for consideration is however not imposing any specific test design on your substance. Hence, you are still free to determine the most appropriate test design for your substance.

For the reasons outlined above, ECHA cannot additionally provide concrete and specific advice on the most appropriate testing strategy. As a registrant of the substance, it is your responsibility to characterise the substance you place on the market and to determine the most appropriate testing design. The guidance documents referred to in the Note for consideration was aimed to help you make that determination."

Indeed, due to the poor water solubility of the substance and the fact that the registered substance belongs to a category of substances (i.e. pigments), which have a very broad range of particle size and water solubility, ECHA considered it appropriate to provide you some advice to determine the best test design for your substance. For this reason the note for consideration was included in the original decision. Therefore, ECHA stands by its response in the letter of 2 February 2020 that it is clear from the wording of the decision that (i) the note for consideration is merely advisory in nature and is not imposing any test design for your substance, and (ii) that it is ultimately your responsibility to characterise the substance you place on the market and to determine the most appropriate testing design.

Second, you consider that the 'Note for consideration' contradicts the fact that the registration dossier contains information from a long-term toxicity study on aquatic invertebrates, performed following the standard test design according to OECD 211, which ECHA did not consider as incompliant.

In response, ECHA repeats that as a registrant of the substance, it is your responsibility to characterise the substance you place on the market and to determine the most appropriate testing design. The guidance documents referred to in the 'Note for consideration' aimed to help you make that determination.

As outlined on page 1 of the original decision, based on Article 41 of the REACH Regulation, you were requested to submit information on a FELS study with the registered substance.

Therefore, you could have carried out a FELS study adapted as per the OECD Guideline 23, following similar choices as you took for the long-term toxicity study to aquatic invertebrates. For this purpose you could have followed the OECD Guideline 23 revised version (ENV/JM/MONO(2000)6/REV1), which expanded the advice on the conditions and test material data required to decide on the method for preparation and testing the "difficult to test substances". In particular, it is specified under Section 5 that a preliminary assessment of the stability of test chemical should be obtained before commencing testing. This needs to be done with the review of existing data on the test chemical. This is sufficient to set up the type of experimental test set up as reiterated under Section 7.1 of the same guidance document.

Therefore, ECHA rejects your statement that there is a contradiction between the request for long-term toxicity to fish and the already existing study on long-term toxicity to aquatic invertebrates. Consequently, your justification for not providing the information requested in the decision cannot be accepted and there is still a data gap for long-term toxicity on fish.

Third, in response to the decision, you submitted what could be considered as an adaptation based on Annex XI, Section 2, 'Study technically not possible'. You claim that after review of the guidance documents referred to in the 'Note for consideration' and scientific literature, "*...the registrants came to the conclusion that the existing guidance gives not sufficient information to carry out a FELS test with this specific type of substances on a scientifically sound basis.*"

However, ECHA notes that you have not provided sufficient evidence to support that carrying out a FELS with this specific type of substance is not scientifically sound.

Fourth, you indicate that you have contacted different test laboratories, but that none of them was able to offer a reliable test design because of the lack of experience with this type of substance. The registration dossier contains two documents from two different test laboratories. In relation to these documents, ECHA notes the following:

- [redacted] from now on), which is dated 9 April 2019. In this document, the test laboratory points out that they cannot perform the test due to limited information available from ECHA on how to specifically determine the required properties, provided that the substance is considered as a nanomaterial.

However, as explained above, the Agency did not require you to test the substance as a nanomaterial. In the note for consideration the Agency merely advised you to consult a number of guidance documents to determine the most appropriate test design. Nothing would have prevented the test laboratory to conclude that the substance should be tested in the same way as the long-term toxicity to aquatic invertebrates test.

- [redacted] from now on), which is dated 18 March 2019. The [redacted] provides information on a preliminary study to test dispersion stability to further consider a semi-static long-term aquatic toxicity study, which suggests non-reproducible test conditions with invalid test results.

In this regard, ECHA notes that the preliminary study does not follow the recommendations outlined in the OECD 318 test guideline for nanomaterials. In ECHA's opinion, this test does not indicate that long-term toxicity testing is not feasible, but it shows that that the long-term toxicity testing should be better performed using a flow through regime.

As detailed above, the request in the original decision was not met, and you are still required to provide the long-term toxicity study on fish: Fish, early-life stage (FELS) toxicity test (test method: OECD TG 210).

Appendix 2: Procedural history

In accordance with Article 42(1) of the REACH Regulation, the Agency examined the information submitted by you in consequence of decision CCH-D-2114381726-39-01/F. The Agency considered that this information did not meet one or more of the requests contained in that decision. Therefore, a new decision-making process was initiated under Article 41 of the REACH Regulation.

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 of this decision was notified to the Member States Competent Authorities according to Article 51(1) of the REACH Regulation.

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

ECHA did not receive any comments within the 30-day notification 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 3: Further information, observations and technical guidance

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

2. The Article 42(2) notification for the original decision is on hold until all information requested in the original decision has been received.