ECHA
EUROPEAN CHEMICALS AGENCY

Helsinki, 4 November 2019

Addressee: [redacted]

Decision number: TPE-D-2114489549-26-01/F
Substance name: Reaction mass of 2,7-Naphthalenedisulfonic acid, 5-amino-3-[[4-[2-[4-[(7-amino-1-hydroxy-3-sulfo-2-naphthalenyl)azo]-2-sulfophenyl]ethenyl]-3-sulfophenyl]azo]-4-hydroxy-, compd. with 2,2',2''-nitrilotris[ethanol] (1:5) and 3,3'-[ethylenebis[(3-sulpho-p-phenylene)azo]]bis[5-amino-4-hydroxynaphthalene-2,7-disulphonic] acid, compound with 2,2',2''-nitrilotriethanol (1:6) and 3,3'-[vinylenebis[(3-sulpho-p-phenylene)azo]]bis[6-amino-4-hydroxynaphthalene-2-sulphonic] acid, compound with 2,2',2''-nitrilotriethanol (1:4)
EC number: 916-899-6
CAS number: NS
Registration number: [redacted]
Submission number: [redacted]
Submission date: 06/03/2018
Registered tonnage band: 100-1000

DECISION ON A TESTING PROPOSAL

Based on Article 40 of Regulation ((EC) No 1907/2006) (the REACH Regulation), ECHA examined your testing proposal(s) and decided as follows.

Your testing proposal is accepted and you are requested to carry out:

1. **Sub-chronic toxicity study (90-day), oral route (Annex IX, Section 8.6.2.; test method: OECD TG 408) in rats using the registered substance.**

You have to submit the requested information in an updated registration dossier by ***11 August 2021***. You shall also update the chemical safety report, where relevant.

The reasons for this decision are set out in Appendix 1. The procedural history is described in Appendix 2 and 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, has to 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 Ofelia Bercaru, Head of Unit, Hazard Assessment

[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 decision of ECHA is based on the examination of the testing proposal you submitted.

1. Sub-chronic toxicity study (90-day) (Annex IX, Section 8.6.2.)

Pursuant to Article 40(3)(a) of the REACH Regulation, ECHA may require the Registrant to carry out the proposed test.

A sub-chronic toxicity study (90 day) is a standard information requirement as laid down in Annex IX, Section 8.6.2. of the REACH Regulation. The information on this endpoint is not available for the registered substance but needs to be present in the technical dossier to meet the information requirements. Consequently there is an information gap and it is necessary to provide information for this endpoint.

You have submitted a testing proposal for a sub-chronic toxicity study (90 day) in rats by the oral route according to OECD TG 408.

ECHA requested your considerations for alternative methods to fulfil the information requirement for Sub-chronic toxicity (90-day): oral. ECHA notes that you provided your considerations concluding that there were no alternative methods which could be used to adapt the information requirement(s) for which testing is proposed. ECHA has taken these considerations into account.

You proposed testing in rats by the oral route. Based on the information provided in the technical dossier and/or in the chemical safety report, ECHA agrees that the oral route - which is the preferred one as indicated in ECHA *Guidance on information requirements and chemical safety assessment* (version 6.0, July 2017) Chapter R.7a, Section R.7.5.4.3 - is the most appropriate route of administration. More specifically, the substance is a liquid of very low vapour pressure. Hence, the test shall be performed by the oral route using the test method EU B.26./OECD TG 408.

Therefore, ECHA considers that the proposed study performed by the oral route with the registered substance is appropriate to fulfil the information requirement of Annex IX, Section 8.6.2. of the REACH Regulation. In addition, according to the test method OECD TG 408 the rat is the preferred species. ECHA considers this species as being appropriate and testing should be performed with the rat.

Therefore, pursuant to Article 40(3)(a) of the REACH Regulation, you are requested to carry out the proposed study with the registered substance subject to the present decision: Sub-chronic toxicity study (90-day) in rats, oral route (test method: OECD TG 408).

Deadline to submit the requested information in this decision

The timeline indicated in the draft decision to provide the information requested is 18 months from the date of adoption of the decision. In your comments on the draft decision, you requested an extension of the timeline to 3 months, stating that "*the registered substance EC 916-899-6 is only synthesized as aqueous solution. OECD 408 oral rat requires approx. 2 kg dried substance. It is time consuming and requires special equipment to dry the aqueous solution in a way that does not destroy the registered substance.*"

As the administration has not been specified, ECHA reminds you that you may perform the test by gavage or drinking water. Therefore you may not even need to get a dry substance,

but concentrate or dilute the manufactured aqueous solution. As this was not discussed in the decision, ECHA considers that extra time can be granted.

Therefore, ECHA has modified the deadline of the decision and set the deadline to 21 months.

Appendix 2: Procedural history

ECHA started the testing proposal evaluation in accordance with Article 40(1) on 16 March 2018.

ECHA held a third party consultation for the testing proposals from 10 August 2018 until 24 September 2018. ECHA did not receive information from third parties.

This decision does not take into account any updates after **27 February 2019**, 30 calendar days after the end of the commenting period.

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 within 30 days of the notification.

ECHA took into account your comments and amended the deadline.

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 imply that the information provided in your registration dossier is in compliance with the REACH requirements. The decision does not prevent ECHA from initiating a compliance check on the registration at a later stage.

2. Failure to comply with the requests in this decision will result in a notification to the enforcement authorities of the Member States.

3. In carrying out the tests required by the present decision, it is important to ensure that the particular sample of substance tested 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. If the registration of the substance covers different grades, the sample used for the new tests must be suitable to assess these.

   Furthermore, there must be adequate information on substance identity for the sample tested and the grades registered to enable the relevance of the tests to be assessed.