

Decision number: TPE-D-2114310441-68-01/F

Helsinki, 25 November 2015

DECISION ON TESTING PROPOSAL(S) SET OUT IN A REGISTRATION PURSUANT TO ARTICLE 40(3) OF REGULATION (EC) NO 1907/2006**For calcium bis(di C8-C10, branched, C9 rich, alkylnaphthalenesulphonate), EC No 939-717-7, registration number: [REDACTED]****Addressee:** [REDACTED]

The European Chemicals Agency (ECHA) has taken the following decision in accordance with the procedure set out in Articles 50 and 51 of Regulation (EC) No 1907/2006 concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH Regulation).

I. Procedure

Pursuant to Article 40(1) of the REACH Regulation, ECHA has examined the following testing proposals submitted as part of the registration dossier in accordance with Articles 10(a)(ix) and 12(1)(d) thereof for calcium bis(di C8-C10, branched, C9 rich, alkylnaphthalenesulphonate), EC No 939-717-7, submitted by [REDACTED] (Registrant).

- 90-day oral toxicity study (OECD 408)
- Long-term toxicity testing to invertebrates (OECD 211)

This decision is based on the registration dossier as submitted with submission number [REDACTED], for the tonnage band of 100 to 1000 tonnes per year. This decision does not take into account any updates submitted after the deadline for updating (15 March 2015) communicated to the Registrant by ECHA on 6 February 2015.

This decision does not imply that the information provided by the Registrant in his 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.

ECHA received the registration dossier containing the above-mentioned testing proposals for further examination pursuant to Article 40(1) on 30 May 2013.

ECHA held a third party consultation for the testing proposals from 2 June 2014 until 17 July 2014. ECHA did not receive information from third parties.

On 21 October 2014 ECHA sent the draft decision to the Registrant and invited him to provide comments within 30 days of the receipt of the draft decision.

On 21 November 2014 ECHA received comments from the Registrant on the draft decision.

The ECHA Secretariat considered the Registrant's comments. The information is reflected in the Statement of Reasons (Section III) whereas no amendments to the Information Required (Section II) were made.

On 3 September 2015 ECHA notified the Competent Authorities of the Member States of its draft decision and invited them pursuant to Article 51(1) of the REACH Regulation to submit proposals for amendment of the draft decision within 30 days of the receipt of the notification.

As no proposal for amendment was submitted, ECHA took the decision pursuant to Article 51(3) of the REACH Regulation.

II. Testing required

A. Tests required pursuant to Article 40(3)

The Registrant shall carry out the following proposed tests pursuant to Article 40(3)(a) and 13(4) of the REACH Regulation using the indicated test methods and the registered substance subject to the present decision:

1. Sub-chronic toxicity study (90-day), oral route (Annex IX, Section 8.6.2.; test method: EU B.26/OECD 408) in rats;
2. Long-term toxicity testing on aquatic invertebrates (Annex IX, Section 9.1.5.; test method: *Daphnia magna* reproduction test, EU C.20/OECD 211).

Note for consideration by the Registrant:

The Registrant 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 to and conforming with the appropriate rules in the respective Annex, and an adequate and reliable documentation.

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 the Member States.

B. Deadline for submitting the required information

Pursuant to Articles 40(4) and 22(2) of the REACH Regulation, the Registrant shall submit to ECHA by **1 June 2017** an update of the registration dossier containing the information required by this decision, including, where relevant, an update of the Chemical Safety Report.

III. Statement of reasons

The decision of ECHA is based on the examination of the testing proposals submitted by the Registrant for the registered substance.

A. Tests required pursuant to Article 40(3)

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

a) Examination of the testing proposal

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.

The Registrant has submitted a testing proposal for a sub-chronic toxicity study (90 day) via the oral route (EU B.26/OECD 408) with the following justification: *"In the OECD 422 study, side effects were seen at 298 mg/kg bw/d (mid dose group) whereas no effects occurred at 95 mg/kg bw/d (low dose group). The most prominent effects were the mortalities at 893 mg/kg/day (4 males and 1 female) and at 298 mg/kg/day (1 female). Surviving animals in both treatments showed some of the same clinical signs as those in the animals sacrificed. Thus, the NOAEL was set to 95 mg/kg bw/d. As a result, a testing proposal for a 90 day oral repeated dose toxicity study was made in order to further investigate the effects seen in the LOAEL treatment of 298 mg/kg/day"*.

ECHA considers that the proposed study is appropriate to fulfil the information requirement of Annex IX, Section 8.6.2. of the REACH Regulation.

ECHA notes that, amongst other uses, the substance is used for industrial spraying (PROC 7; "Coating application by spraying" and "Coating application by manual spraying"). However, due to the high viscosity, inhalation exposure is excluded by the registrant. Furthermore, ECHA observes that in the endpoint study record for a 14-day oral dose-range finding study, the registrant stated that *"The oral route was selected as it is a possible route of human exposure during manufacture, handling or use of the test substance."* Furthermore, the registrant explained that the OECD 408 study is proposed to follow up on the adverse effects seen in the provided oral OECD 422 screening study. In his comments to the draft decision the Registrant indicated that this study was conducted on the parent acid, "di C8-C10, branched, C9 rich, alkylnaphthalenesulphonic acid" (DNNSA).

Therefore, ECHA considers that testing by the oral route is most appropriate.

The Registrant did not specify the species to be used for testing. According to the test method EU B.26/OECD 408 the rat is the preferred species. ECHA considers this species as being appropriate and testing should be performed with the rat.

The Registrant is reminded that this decision does not take into account any updates submitted after 15 March 2015. All the new information in the later update(s) of the registration dossier will however be assessed for compliance with the REACH requirements in the follow-up evaluation pursuant to Article 42 of the REACH Regulation.

b) Outcome

Therefore, pursuant to Article 40(3)(a) of the REACH Regulation, the Registrant is 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: EU B.26/OECD 408).

2. Long-term toxicity testing on aquatic invertebrates (Annex IX, Section 9.1.5.)

a) Examination of the testing proposal

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

"Long-term toxicity testing on aquatic invertebrates" is a standard information requirement as laid down in Annex IX, Section 9.1.5. 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.

The Registrant has submitted a testing proposal for testing the registered substance for long-term toxicity testing on aquatic invertebrates *Daphnia magna* reproduction test, EU C.20/OECD 211 with the following justification: "*As the water solubility of the test substance is poor, the long-term toxicity test to daphnia is proposed*". ECHA considers that the proposed study is appropriate to fulfil the information requirement of Annex IX, Section 9.1.5 of the REACH Regulation.

According to ECHA *Guidance on information requirements and chemical safety assessment* (version 1.2., November 2012), Chapter R7b (Section R.7.8.5 including Figure R.7.8-4), if based on acute aquatic toxicity data neither fish nor invertebrates are shown to be substantially more sensitive, long-term studies may be required on both. There were no indications in the dossier from the short-term toxicity studies on aquatic species that the fish would be substantially more sensitive than aquatic invertebrates.

In such case, according to the integrated testing strategy, the *Daphnia* study is to be conducted first. If based on the results of the long-term *Daphnia* study and the application of a relevant assessment factor no risks are observed ($PEC/PNEC < 1$), no long-term fish testing may need to be conducted. However, if a risk is indicated, long-term fish testing may need to be conducted.

The Registrant outlined in the comments to the draft decision that he plans to commence the chronic aquatic study (OECD 211), once the final decision is published by ECHA.

The Registrant is reminded that this decision does not take into account any updates submitted after 15 March 2015. All the new information in the later update(s) of the registration dossier will however be assessed for compliance with the REACH requirements in the follow-up evaluation pursuant to Article 42 of the REACH Regulation.

b) Outcome

Therefore, pursuant to Article 40(3)(a) of the REACH Regulation, the Registrant is required to carry out the proposed study using the registered substance subject to the present decision: Long-term toxicity testing on aquatic invertebrates (Annex IX, 9.1.5.; test method: *Daphnia magna* reproduction test, EU C.20/OECD 211).

Notes for consideration by the Registrant

Once results of the proposed test on long-term toxicity to aquatic invertebrates are available, the Registrant shall revise the chemical safety assessment as necessary according to Annex I of the REACH Regulation. If the revised chemical safety assessment indicates the need to investigate further the effects on aquatic organisms, the Registrant shall submit a testing proposal for a long-term toxicity test on fish in order to fulfil the standard information requirement of Annex IX, 9.1.6. If the Registrant comes to the conclusion that no further investigation of effects on aquatic organisms is required, he shall update his technical dossier by clearly stating the reasons for adapting the standard information requirement of Annex IX, 9.1.6.

Due to the low solubility of the substance in water OECD Guidance Document on Aquatic Toxicity Testing of Difficult Substances and Mixtures, ENV/JM/MONO (2000)6 and ECHA

Guidance, Chapter R7b, table R. 7.8-3 summarising aquatic toxicity testing of difficult substances should be consulted by the Registrant for choosing the design of the requested long-term ecotoxicity tests and for calculation and expression of the result of this test.

B. Deadline for submitting the required information

In the draft decision communicated to the Registrant, the time indicated to provide the requested information was 18 months from the date of adoption of the decision. In his comments on the draft decision of 24 November 2014, the Registrant requested an extension of the timeline to 40 months or, alternatively, to postpone the adoption until the end of 2016. He sought to justify this request by referring to the economic difficulties he is facing as a result of the global economic crisis, the issue of test laboratory capacity (with regards to the repeated-dose toxicity study, OECD 408), as well as substance specific considerations in relation to the available OECD 422 study on a read-across substance. In relation to the first point, while recognising the current global economic situation, ECHA considers the argument as generic and not appropriate to justify an extension of the deadline, particularly in the interest of equal treatment of other potentially affected Registrants. Regarding the issue of laboratory capacity, following a request to the Registrant from ECHA to provide evidence in support of this argument, ECHA notes that the Registrant has not provided any evidence in support of this argument that would justify its request. Lastly, the Registrant refers to the results of the OECD 422 screening test on the parent acid and claims that toxicity of the registered substance is expected to be low. ECHA considers these arguments as not valid to extend the deadline to 40 months from adoption of the decision or, alternatively, to postpone the adoption until the end of 2016. In fact, these arguments seem to contradict the information provided by the Registrant in his dossier and the testing proposal submitted for the 90-day study (see Section III above). Therefore, ECHA has not modified the deadline of the decision.

IV. Adequate identification of the composition of the tested material

The process of examination of testing proposals set out in Article 40 of the REACH Regulation aims at ensuring that the new studies meet real information needs. Within this context, the Registrant's dossier was sufficient to confirm the identity of the substance to the extent necessary for examination of the testing proposal. The Registrant must note, however, that this information has not been checked for compliance with the substance identity requirements set out in Section 2 of Annex VI of the REACH Regulation.

In addition, it is important to ensure that the particular sample of substance tested in the new studies 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. If the registration of the substance covers different grades, the sample used for the new studies must be suitable to assess these.

Finally, there must be adequate information on substance identity for the sample tested and the grade(s) registered to enable the relevance of the studies to be assessed.

V. Information on right to appeal

An appeal may be brought against this decision to the Board of Appeal of ECHA under Article 51(8) of the REACH Regulation. Such appeal shall be lodged within three months of receiving notification of this decision. Further information on the appeal procedure can be found on the ECHA's internet page at <http://www.echa.europa.eu/regulations/appeals>. The notice of appeal will be deemed to be filed only when the appeal fee has been paid.

Authorised¹ by Ofelia Bercaru, Head of Unit, Evaluation E3

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.