EUROPEAN CHEMICALS AGENCY

Decision number: TPE-D-2114312121-74-01/F

Helsinki, 23 November 2015

DECISION ON TESTING PROPOSAL(S) SET OUT IN A REGISTRATION PURSUANT TO ARTICLE 40(3) OF REGULATION (EC) NO 1907/2006

For Polysulfides, di-tert-dodecyl, EC No 270-335-7 (CAS No 68425-15-0), 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)(e) thereof for Polysulfides, di-tert-dodecyl, EC No 270-335-7 (CAS No 68425-15-0), submitted by [redacted] (Registrant).

- Bioaccumulation in aquatic species (OECD 305) according to a fish feeding test
- Sediment-water chironomid toxicity test using spiked sediment (OECD 218)

This decision is based on the registration as submitted with submission number [redacted], for the tonnage band of 1000 tonnes or more per year. This decision does not take into account any updates after 18 June 2015, i.e. 30 calendar days after the end of the commenting period.

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 updated registration dossier containing the above-mentioned testing proposals for further examination pursuant to Article 40(1) on 6 November 2014.

ECHA held a third party consultation for the testing proposals from 16 February 2015 until 2 April 2015. ECHA did not receive information from third parties.

On 9 April 2015 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 15 May 2015 ECHA received comments from the Registrant agreeing to ECHA's draft decision.

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. Bioaccumulation in aquatic species (Annex IX, Section 9.3.2.; test method Bioaccumulation in Fish: Dietary Exposure Bioaccumulation Fish Test, OECD 305-III);
2. Long-term toxicity to sediment organisms (Annex X, Section 9.5.1.; test method: Sediment-water Chironomid toxicity using spiked sediment, OECD 218).

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 requests in this decision, or to fulfil otherwise the information requirements 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 **30 November 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. Bioaccumulation in aquatic species (Annex IX, Section 9.3.2.)

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.

"Bioaccumulation in aquatic species, preferably fish" is a standard information requirement as laid down in Annex IX, Section 9.3.2. 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 testing the registered substance for bioaccumulation in aquatic species (Bioaccumulation in Fish: Aqueous and Dietary Exposure, OECD 305) with the following justification:
"*No experimental data are available for characterizing bioaccumulation potential for polysulfides, di-tert-dodecyl. No modeled data can eventually invalidate the potential bioaccumulation potential described through Log Pow measured. Further to the results of the OECD 308 biodegradation in water/sediment system, the registrant proposes a testing on the registered substance through an OECD 305 feeding study*".

ECHA considers that the proposed study is appropriate to fulfil the information requirement of Annex IX, Section 9.3.2. of the REACH regulation.

In the testing proposal, the Registrant has indicated that "*based on intrinsic properties of the test substance (high sorption potential), a fish feeding test is foreseen*". The REACH Guidance recommends dietary exposure for the bioaccumulation fish test for certain types of substances with specific physical chemical properties (e.g. low water solubility, high Log Kow value). The substance subject to the present decision has a very low water solubility (< 1µg/L) and a very high log Kow (>12). Therefore the Registrant's proposal to perform a test via dietary exposure to estimate bioaccumulation is acceptable to ECHA. The approach to deriving a bioconcentration factor from the fish dietary accumulation test should follow the recommendations given at Annex 8 of OECD Guideline 305 as adopted on 2 October 2012, and Chapter R.11 of the REACH Guidance.

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: Bioaccumulation in aquatic species, preferably fish (Annex IX, 9.3.2.; test method: Bioaccumulation in Fish: Dietary Exposure Bioaccumulation Fish Test, OECD 305-III).

2. Long-term toxicity to sediment organisms (Annex X, Section 9.5.1.)

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 to sediment organisms" is a standard information requirement as laid down in Annex X, Section 9.5.1. 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 sediment organisms Sediment-water Chironomid toxicity test using spiked sediment (OECD 218) with the following justification:
"*No data are available for characterizing polysulfides, di-tert-dodecyl possible impacts on sediment dwelling organisms. As the substance is not toxic to aquatic species, no PNEC aquatic can be derived and therefore Equilibrium Partitioning Method (EPM) cannot be applied. Therefore at the moment no PNEC is proposed until hazard profile is better*

characterized. Further to the results of biodegradation in sediment study (OECD 308), showing a half life of about 169 days in this compartment, an OECD 218 is proposed in order to identify if a toxicity to sediment organisms study [occurs]".

ECHA considers that the proposed study is appropriate to further investigate long-term toxicity to sediment organisms (Annex X, Section 9.5.1. 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 to sediment organisms (Annex X, 9.5.1.; test method: Sediment-water Chironomid toxicity using spiked sediment, OECD 218).

Notes for consideration by the Registrant

Due to substance properties, the Registrant is advised to consider the feeding recommendations given in OECD test guideline 218. The guideline recommends that when testing strongly adsorbing substances (typically with log Kow > 5) in order to cover the dietary exposure food should be added to the formulated sediment before the stabilisation period (paragraph 31 of OECD test guideline 218).

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, or the information submitted by other registrants of the same substance, has not been checked for compliance with the substance identity requirements set out in Section 2 of Annex VI of the REACH Regulation.

In relation to the proposed tests, the sample of substance used for the new studies must be suitable for use by all the joint registrants. Hence, the sample should have a composition that is within the specifications of the substance composition that are given by the joint registrants. It is the responsibility of all joint registrants of the same substance to agree to the tests proposed (as applicable to their tonnage level) and to document the necessary information on their substance composition.

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 by each registrant. If the registration of the substance by any registrant covers different grades, the sample used for the new studies 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 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.

Authorised[1] 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.