EUROPEAN CHEMICALS AGENCY

Decision number: TPE-D-0000002731-79-07/F Helsinki, 13 March 2013

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

For Polysulfides, di-tert-Bu, CAS 68937-96-2 (EC No 273-103-3), 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 proposal submitted as part of the registration dossier in accordance with Articles 10(a)(ix) and 12(1)(d) thereof for Polysulfides, di-tert-Bu, CAS 68937-96-2 (EC No 273-103-3) submitted by [redacted]

- Bioaccumulation in aquatic species according to a fish feeding test.

This decision is based on the registration dossier as submitted with submission number [redacted], for the tonnage band of 100 to 1000 tonnes or more per year. However, this decision does not take into account any new testing proposals submitted after 30 November 2011, the date upon which ECHA notified its draft decision to the Registrant pursuant to Article 50(1) of the REACH Regulation. Any new testing proposals submitted after that date will be addressed in a separate decision. Furthermore, the present decision does not take into account any updates after 6 September 2012, the date upon which ECHA notified its draft decision to the Competent Authorities of the Member States pursuant to Article 51(1) of the REACH Regulation.

The present decision does not imply that the information provided by the Registrant in his registration dossier is in compliance with the requirements of the REACH Regulation. This decision does not prevent ECHA to initiate a compliance check on the present dossier at a later stage.

On 23 November 2010, pursuant to Article 40(1) of the REACH Regulation, ECHA initiated the examination of the testing proposals set out by the Registrant in the registration dossier (submission number: [redacted]) for the substance mentioned above. This registration dossier contained testing proposals on the registered substance for:

- Sediment simulation testing (Annex IX, 9.2.1.4., test method: EU C.24/OECD 308);
- Soil simulation testing (Annex IX, 9.2.1.3., test method: EU C.23/OECD 307);
- Bioaccumulation in aquatic species (Annex IX, 9.3.2. according to a test method such as the Fish Dietary Accumulation test);
- Long-term toxicity on invertebrates (Daphnia sp.) (Annex IX, 9.1.5., test method: EU C.20/OECD 211)

ECHA held a third party consultation for the testing proposals from 1 July 2011 until 15 August 2011. ECHA did not receive information from third parties.

On 30 November 2011 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 22 December 2011 ECHA received comments from the Registrant.

On 7 May 2012 the Registrant updated his registration dossier (submission number [redacted]) removing three out of four initially submitted testing proposals. The remaining testing proposal is for Bioaccumulation in aquatic species (Annex IX, 9.3.2. according to a test method such as the Fish Dietary Accumulation test).

ECHA considered the Registrant's comments and the updated dossier. On basis of the comments and of the updated dossier, Section II was amended and the Statement of Reasons (Section III) was changed accordingly.

On 6 September 2012 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 to amend the draft decision within 30 days of the receipt of the notification.

Subsequently, one Competent Authority of a Member State submitted a proposal for amendment to the draft decision.

On 10 October 2012 ECHA notified the Registrant of the proposal for amendment to the draft decision and invited him pursuant to Article 51(5) of the REACH Regulation to provide comments on that proposal for amendment within 30 days of the receipt of the notification.

ECHA reviewed the proposal for amendment received and decided to amend the draft decision.

On 22 October 2012 ECHA referred the draft decision to the Member State Committee.

On 26 October 2012, the Registrant provided comments on the proposed amendment. The Member State Committee took the comments of the Registrant into account.

A unanimous agreement of the Member State Committee on the draft decision was reached on 26 November 2012 in a written procedure launched on 14 November 2012. ECHA took the decision pursuant to Article 51(6) of the REACH Regulation.

II. Testing required

Pursuant to Article 40(3)(a) of the REACH Regulation, the Registrant shall carry out the following test on the registered substance using the indicated test method:

- Bioaccumulation in aquatic species, dietary exposure route (Annex IX, 9.3.2.; test method Bioaccumulation in Fish: Aqueous and Dietary Exposure, OECD 305, adopted on 2 October 2012)

Pursuant to Articles 40(4) and 22 of the REACH Regulation, the Registrant shall submit to ECHA by **13 March 2015** an update of the registration dossier containing the information required by this decision.

At any time, the Registrant shall take into account that there may be an obligation to make every effort to agree on sharing of information and costs with other registrants, if relevant.

III. Statement of reasons

a) Examination of the testing proposal

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

The proposed test referred to in Section II above is part of the information requirements as laid down in Annex IX, 9.3.2. of the REACH Regulation. The registered substance has a high potential for bioaccumulation and direct or indirect exposure of the aquatic compartment cannot be excluded. Therefore, and as the registration dossier does not contain information on this endpoint, information on bioaccumulation in aquatic species needs to be provided.

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). For substances with a high Log K_{OW} value, a test via dietary exposure to estimate bioaccumulation is recommended. The substance subject to the present decision has water solubility of 7 mg/L at 20°C and high log Kow (5.6 at 20°C). Therefore the Registrant's proposal to perform a fish dietary accumulation test is acceptable to ECHA. This test needs to be performed to meet the information requirements of Annex IX 9.3.2. of the REACH Regulation.

Accordingly, a bioaccumulation test in aquatic species via the dietary exposure route is required using test method "Bioaccumulation in Fish: Aqueous and Dietary Exposure", OECD Guideline 305 as adopted on 2 October 2012. The approach to deriving a bioconcentration factor from the fish dietary accumulation test should follow the recommendations given at Annex 8 of the OECD Guideline 305 as adopted on 2 October 2012, and Chapter R.11 of the REACH Guidance..

The relevant constituents and/or transformation/degradation products meeting the persistence (P) or the very persistence (vP) criteria (as specified in Annex XIII of the REACH Regulation) should be identified before being tested for bioaccumulation.

When performing the above mentioned tests and interpreting the results, the Registrant is advised to take into account the fact that the substance contains many components (UVCB) and is highly volatile. For that purpose, the Registrant can refer to Appendix 7.8-1 of ECHA Guidance on information requirements and chemical safety assessment Chapter R.7b: Endpoint specific guidance - November 2012 (Version 1.2).

b) Deadline for submitting the information

In the first version of the draft decision communicated to the Registrant on 30 November 2011, the time indicated to provide the requested information was 18 months from the date of adoption of the decision. In his comments submitted on 22 December 2011 the Registrant included a request for an extension of this deadline to 30 months from the date of the final decision. The Registrant has indicated that he would need 30 months to provide the requested information, taking into account the time needed to get radio-labelled substance (if possible) or to set up an analytical method for the registered substance.

ECHA acknowledged the testing difficulties inherent in the substance properties and decided to extend the deadline. However, since the Registrant updated his dossier on 7 May 2012

and withdrew testing proposals for the sediment simulation test, the soil simulation test and the long-term toxicity test to *Daphnia*, the number of tests the Registrant will have to perform became substantially lower. Therefore ECHA accepts to grant additional time to the Registrant for providing the requested information, but believes that 24 months for the bioaccumulation study is sufficient.

IV. Adequate identification of the composition of the tested material

It is important to ensure that the particular sample of substance tested in the new study 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 study 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 study to be assessed.

V. General requirements for the generation of information and Good Laboratory Practice

ECHA always reminds registrants of the requirements of Article 13(4) of the REACH Regulation that ecotoxicological and toxicological tests and analyses shall be carried out in compliance with the principles of good laboratory practice (GLP). National authorities monitoring GLP maintain lists of test facilities indicating the relevant areas of expertise of each facility.

According to Article 13(3) of the REACH Regulation, tests that are required to generate information on intrinsic properties of substances shall be conducted in accordance with the test methods laid down in a Commission Regulation or in accordance with other international test methods recognised by the Commission or the European Chemicals Agency as being appropriate. Thus, the Registrant shall refer to Commission Regulation (EC) No 440/2008 laying down test methods pursuant to Regulation (EC) No 1907/2006 as adapted to technical progress or to other international test methods recognised as being appropriate and use the applicable test methods to generate the information on the endpoints indicated above.

VI. 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://echa.europa.eu/appeals/app_procedure_en.asp. The notice of appeal will be deemed to be filed only when the appeal fee has been paid.

[redacted]
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