ECHA
EUROPEAN CHEMICALS AGENCY

Decision number: TPE-D-0000002731-79-09/F Helsinki, 28 June 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 No 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 No 68937-96-2 (EC No 273-103-3), by [redacted] (Registrant):

- Long-term toxicity to sediment organisms. Test method: OECD Guideline 218 (Sediment-Water Chironomid Toxicity Test Using Spiked Sediment)

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 after 18 January 2013, 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.

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 present registration at a later stage.

The examination of the testing proposal was initiated upon the date when receipt of the complete registration dossier was confirmed on 7 May 2012.

On 27 September 2012 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 26 October 2012 ECHA received comments from the Registrant.

ECHA considered the Registrant's comments received. On the basis of these comments, only the deadline in Section II was amended. The Statement of Reasons (Section III) was changed accordingly.

On 18 January 2013 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, Competent Authorities of the Member States did not propose amendments to the draft decision and ECHA took the decision pursuant to Article 51(3) of the REACH Regulation.

II. Testing required

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

- Long-term toxicity to sediment organisms (Annex X, 9.5.1.), according to one of the following test methods:
  - Sediment-water Chironomid toxicity using spiked sediment (OECD 218); or
  - Sediment-water Lumbriculus toxicity test using spiked sediment (OECD 225); or
  - Sediment-water Chironomid life-cycle toxicity test using spiked water or spiked sediment (OECD 233).

Pursuant to Articles 40(4) and 22 of the REACH Regulation, the Registrant shall submit to ECHA by **2 January 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.

III. Statement of reasons

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

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

a) Examination of the testing proposal

The Registrant provided the following justification for conducting a long-term toxicity test to sediment organisms:
"No data are available for characterizing polysulfides, di-tert-bu possible impacts on sediment organisms. Based on the outcomes of the sediment risk assessment one can safely expect that sediment dwelling organisms are out of concerns when possibly exposed to polysulfides, di-tert-bu. Nevertheless, testing toxicity on this compartment, potential sink for a substance with such adsorptive properties, will allow not only to get knowledge on impact to sediment organisms, but also to investigate criticity of persistence behaviour in the compartment (and usefulness to launch a sediment biodegradation study), and to derive a NOECaqua making use of the Equilibrium Partitioning Method, as described in Guidance, R.11.1.3.3. This will help assessing the "T" criterion in PBT assessment".

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 of Annex X, section 9.5.1. of the REACH Regulation. The substance has been registered within the tonnage band of 100 to 1000 tonnes per year, but as is clarified by Step 4 of the Guidance Note on fulfilling the requirements of Annexes VI to XI (see Annex VI of the REACH Regulation) "*[i]n some cases the rules set out in Annexes VII to XI may require certain tests to be undertaken earlier than or in addition to the standard requirements*".

For substances that strongly adsorb or bind to particles, uptake from sediment or food may become more important than uptake from water. Furthermore, such substances may not necessarily exhibit a toxic effect when tested in water because equilibrium may not have been reached during the exposure phase, but they may nevertheless exert significant toxic effects in sediment tests. Therefore, gathering information on toxicity to sediment organisms should be considered for substances with such properties even at tonnages below 1000 tonnes per year.

The technical dossier indicates that the registered substance is highly hydrophobic (log Kow of 5.6 at 20°C) and is not readily biodegradable. The registered substance has thus potential to strongly adsorb to sediment and food particles. Furthermore, the information currently available in the dossier is not considered as sufficient to conclude on the long-term toxicity potential of the registered substance in sediment organisms. In accordance with the statement in Annex VI of the REACH Regulation, testing on sediment organisms can thus be undertaken in such a case.

In the technical dossier, the Registrant proposed a sediment-water Chironomid toxicity test using spiked sediment (OECD 218). He made reference both to test guidelines OECD 218 (Sediment-water Chironomid toxicity using spiked sediment) and OECD 225 (Sediment-water *Lumbriculus* toxicity test using spiked sediment). ECHA considers these two test guidelines adequate to cover information requirement of Annex X, 9.5.1. of the REACH Regulation. In addition, ECHA would like to point out that test guideline OECD 233 (Sediment-water Chironomid life-cycle toxicity test using spiked water or spiked sediment) using spiked sediment exposure is adequate as well. Test guideline OECD 233 has been recently adopted and is designed to assess the effects of life-long exposure of chemicals on Chironomids, fully covering the 1st generation and the early part of the 2nd generation. It is thus an extension of OECD test guideline 218 covering the full life-cycle of Chironomids and including all relevant reproductive endpoints. Therefore, test guideline OECD 233 offers a more complete level of information than test guidelines OECD 218 and 225.

The Registrant is advised to give special attention to the pathways by which the test organisms will be exposed to the substance. In order to cover the dietary exposure, OECD test guidelines 218 and 233 recommend that when testing strongly adsorbing substances (typically with log Kow > 5) food should be added to the formulated sediment before the stabilisation period (paragraph 31 of OECD test guidelines 218 or 233). As for OECD test guideline 225, the test protocol requires that the food be added prior to or during application of the test substance whatever the substance properties. Because the registered substance has potential to strongly adsorb to sediment and to food particles, the Registrant should specifically consider the feeding recommendations for testing strongly adsorbing substances established in paragraph 31 of test guidelines OECD 218 or 233 if he chooses to perform the test according to one of these two test guidelines.

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: long-term toxicity to sediment organisms (Annex X, 9.5.1.) according to one of the following test methods:

- Sediment-water Chironomid toxicity using spiked sediment (OECD 218);
  or
- Sediment-water Lumbriculus toxicity test using spiked sediment (OECD 225);
  or
- Sediment-water Chironomid life-cycle toxicity test using spiked water or spiked sediment (OECD 233), using spiked sediment exposure.

If the Registrant chooses to perform the test according to test guidelines OECD 218 or OECD 233, he should specifically consider the feeding recommendations for testing strongly adsorbing substances established in paragraph 31 of those test guidelines.

ECHA notes that the testing proposal is part of a strategy and linked with an adaptation argument for the standard information requirement of Annex IX, 9.1.5. of the REACH Regulation. ECHA wishes to highlight that it cannot assess the adaptation argument for the *Daphnia* study before the results of the proposed test have been submitted.

c) Deadline for submitting the information

In the draft decision communicated to the Registrant, the time indicated to provide the requested information was 12 months from the date of adoption of the decision. In his comments on the draft decision, the Registrant included a request for an extension of the deadline for submission of the long-term toxicity to sediment organisms data from 12 months to 18 months from the date of the final decision. The Registrant has indicated that he would need 18 months to carry out the study, 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 considers that the request made by the Registrant, substantiated by the detailed explanations regarding the substance specific technical constraints, is adequately justified. The decision was therefore modified accordingly.

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 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).

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]
Jukka Malm
Director of Regulatory Affairs