

Decision number: TPE-D-0000003039-76-05/F

Helsinki, 19 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-dodecyl, CAS No 68425-15-0 (EC No 270-335-7), 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 proposal submitted as part of the registration dossier in accordance with Articles 10(a)(ix) and 12(1)(e) thereof for Polysulfides, di-tert-dodecyl, CAS No 68425-15-0 (EC No 270-335-7), by [REDACTED] (Registrant).

- Biodegradation in water and sediment: Aerobic and anaerobic transformation in aquatic sediment systems (OECD 308)

This decision is based on the registration dossier 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 2 November 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

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.

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 for the substance mentioned above.

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 6 June 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 5 July 2012 ECHA received comments from the Registrant agreeing to ECHA's draft decision with regard to the sediment simulation testing.

On 15 October 2012 the Registrant updated his registration dossier removing six of the seven originally submitted testing proposals including the Biodegradation in water and sediment: simulation tests Aerobic Sewage Treatment (OECD 303 A). The remaining testing proposal concerns Biodegradation sediment simulation testing (OECD 308).

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

On 2 November 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 5 December 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 the proposal for amendment within 30 days of the receipt of the notification.

ECHA reviewed the proposal for amendment received and decided not to amend the draft decision.

On 17 December 2012 ECHA referred the draft decision to the Member State Committee.

On 20 December 2012 the Registrant provided comments on the proposed amendment. The Member State Committee took the comments of the Registrant into account.

In addition to his comments on the proposed amendment, the Registrant included a request for extension of the deadline for providing the information required by this decision. On the basis of this request, the deadline in Section II was not amended. The Statement of Reasons (Section III) was changed accordingly.

A unanimous agreement of the Member State Committee on the draft decision was reached on 21 January 2013 in a written procedure launched on 11 January 2013. ECHA took the decision pursuant to Article 51(6) of the REACH Regulation.

II. Testing required

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

- Sediment simulation testing (Annex IX, 9.2.1.4.; test method: Aerobic and anaerobic transformation in aquatic sediment systems, EU C.24/OECD 308)

Pursuant to Articles 40(4) and 22 of the REACH Regulation, the Registrant shall submit to ECHA by **19 March 2014** 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.

Sediment simulation testing

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.

Sediment simulation testing is a standard information requirement as laid down in Annex IX, 9.2.1.4 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 generate the data for this endpoint.

The Registrant initially proposed an OECD test guideline 303A study and provided the following justification for conducting another simulation test in soil: "Polysulfides, di-tert-dodecyl is expected to be mainly traced in soil and sediment when released in the environment. Therefore simulation testing in water is not considered as a relevant approach for characterizing biodegradation potential and sediment and soil tests are proposed for addressing the biodegradation issue based on both expected behaviour and uses of the substance".

ECHA considers that the substance is highly adsorptive, not readily biodegradable and exposure to sediment cannot be excluded. Therefore, potential persistence in the sediment compartment should be investigated. The information currently available in the dossier is not considered as sufficient to conclude on the persistence/biodegradation potential of the registered substance in sediment compartment and thus it is necessary to generate additional data for this endpoint.

The initial draft decision of 6 June 2012 sent to the registrant rejected the use of the OECD test guideline 303 A and required the use of OECD test guideline 308 for the following reasons: OECD Test Guideline 303A test cannot be used to cover the simulation biodegradation endpoint, as indicated in the Guidance on Information requirements (R7b, version 1.1, May 2008). This Guidance (R.7.9.5.1, page 193) states that "*Results from tests simulating the conditions in a sewage treatment plant (STP) (e.g. the OECD 303) cannot be used for assessing the degradation in the aquatic environment*". The results from the OECD 303A test cannot be used for classification purposes either (R.7.9.5.1, page 192), especially as it cannot apply to classification on aquatic and sediment compartment, whereas the preferred test method: aerobic and anaerobic transformation in aquatic sediment systems - Sediment simulation testing (OECD 308) both covers biodegradation in sediment compartment and its results can be used for the CLP environmental classification. Furthermore, according to the guidance document the OECD 303 studies are not included in the relevant tests to assess persistence in the environment (R.7.9.5.2, page 194).

In the updated dossier submitted by the Registrant on 15 October 2012, submission number [REDACTED], responding to the ECHA's draft decision, it was stated: "Polysulfides, di-tert-dodecyl is expected to be mainly traced in soil when released in the environment. Therefore simulation testing in water is not considered as a relevant approach for characterizing biodegradation potential and sediment test is proposed for addressing the biodegradation issue based on both expected behaviour and uses of the substance".

Consequently the Registrant proposed to follow OECD Guideline 308 (Aerobic and Anaerobic Transformation in Aquatic Sediment Systems) as required by ECHA in the initial draft decision.

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:

Sediment simulation testing (Annex IX, 9.2.1.4.; test method: Aerobic and anaerobic transformation in aquatic sediment systems, EU C.24/OECD 308).

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 addition to his comments on proposals for amendment, the Registrant included a request for an extension of the deadline for submission of the OECD 308 data from 12 months to 18 months from the date of the final decision. To substantiate the request, the Registrant referred to the challenge to set up an analytical method for sediment testing of the registered substance subject to the present decision. ECHA considers that the request made by the Registrant is not justified as no further explanation has been provided why the study period would need to be extended and a 12-month time period should be sufficient to establish analytical methods. The decision was therefore not modified.

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 study meets 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 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.

Finally 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. 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.



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