ECHA
EUROPEAN CHEMICALS AGENCY

Decision number: CCH-D-2114292327-43-01/F Helsinki, 23 November 2015

DECISION ON A COMPLIANCE CHECK OF A REGISTRATION PURSUANT TO ARTICLE 41(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 41(1) of the REACH Regulation ECHA has performed a compliance check of the registration for Polysulfides, di-tert-dodecyl, CAS No 68425-15-0 (EC No 270-335-7), submitted by [redacted] (Registrant). The scope of this compliance check is limited to the standard information requirements of Annex IX, Sections 9.1.5. and 9.1.6. relating to aquatic toxicity, of the REACH Regulation and related environmental hazard assessment. ECHA stresses that it has not checked the information provided by the Registrant and other joint registrants for compliance with requirements regarding the identification of the substance (Section 2 of Annex VI).

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 submitted after 4 September 2014, 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 compliance check decision does not prevent ECHA from initiating further compliance checks on the present registration at a later stage.

The compliance check was initiated on 15 May 2013.

On 29 July 2013 ECHA sent the draft decision to the Registrant and invited him to provide comments within 30 days of the receipt of the draft decision. That draft decision was based on submission number [redacted].

On 27 August 2013 ECHA received comments from the Registrant on the draft decision.

On 20 September 2013 the Registrant updated his registration dossier [redacted]. A further update with submission number AF481369-39 has been made on 17 March 2014.

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

On 4 September 2014 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.

Subsequently, a proposal for amendment to the draft decision was submitted.

On 10 October 2014 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.

The ECHA Secretariat reviewed the proposal for amendment received and amended the draft decision.

On 20 October 2014 ECHA referred the draft decision to the Member State Committee.

By 10 November 2014 the Registrant did not provide any comments on the proposal for amendment. However, the Registrant provided comments on the draft decision. The Member State Committee did not take into account the Registrant's comments on the draft decision as they were not related to the proposal for amendment made and are therefore considered outside the scope of Article 51(5).

A unanimous agreement of the Member State Committee on the draft decision was reached on 24 November 2014 in a written procedure launched on 13 November 2014.

ECHA took the decision pursuant to Article 51(6) of the REACH Regulation.

II. Information required

Pursuant to Articles 41(1)(a) and (b), 41(3), 10(a)(vii), 12(1)(e), 13 and Annex IX of the REACH Regulation the Registrant shall submit the following information using the indicated test methods and the registered substance subject to the present decision:

1. Long-term toxicity testing on aquatic invertebrates (Annex IX, 9.1.5.; test method: *Daphnia magna* reproduction test, EU C.20./OECD 211);

2. Long-term toxicity testing on fish (Annex IX, 9.1.6.1.; test method: Fish, early-life stage (FELS) toxicity test, OECD 210).

Pursuant to Articles 41(1)(c), 41(3), 10(b) and 14 as well as Annex I of the REACH Regulation, once the results of the above long-term aquatic studies are available to the Registrant, he shall revise the chemical safety assessment as necessary according to Annex I of the REACH Regulation, including the derivation of the aquatic PNECs.

Pursuant to Article 41(4) of the REACH Regulation the Registrant shall submit the information in the form of an updated registration to ECHA by **30 November 2016**.

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.

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.

III. Statement of reasons

A. Information in the technical dossier derived from the application of Annex IX, Sections 9.1.5. and 9.1.6.

Pursuant to Article 41(3) of the REACH Regulation, ECHA may require the Registrant to submit any information needed to bring the registration into compliance with the relevant information requirements. The scope of the present decision covers Annex IX, 9.1.5. and 9.1.6. as well as related environmental hazard assessment. In accordance with Articles 10(a)(vii), (b), 12(1) and 14(1) of the REACH Regulation, the registration is required to contain this information.

1. and 2. Long-term aquatic toxicity testing on invertebrates and fish

According to column 1 of Sections 9.1.5. and 9.1.6. of Annex IX of the REACH Regulation, long-term toxicity testing on invertebrates and on fish is required to fulfil the standard information requirements. Regarding long-term toxicity testing on fish, the information shall be provided for one of the following: Fish early-life stage (FELS) toxicity test (Annex IX, 9.1.6.1), fish short-term toxicity test on embryo and sac-fry stages (Annex IX, 9.1.6.2), or Fish, juvenile growth test (Annex IX, 9.1.6.3).

Pursuant to Articles 10(b) and 14(1) of the REACH Regulation the registration shall contain a chemical safety report which shall document the chemical safety assessment conducted in accordance with Article 14(2) to (7) and with Annex I of the REACH Regulation.

Annex I, Section 3.3. of the REACH Regulation requires the registrant to establish, based on the available information, predicted no effect concentrations (PNEC(s)) for the registered substance, covering each environmental sphere, including the aquatic compartment.

ECHA notes that the Registrant has waived the long-term testing on fish using the following justification: "Polysulfides, di-tert-dodecyl is not toxic or harmful to aquatic species (whatever the species considered) up to its water solubility limit. Therefore notifiers considered that additional testing for characterizing aquatic impacts is not necessary especially considering vertebrates." ECHA further notes that the Registrant has waived the long-term testing on aquatic invertebrates with the following justification: "Polysulfides, di-tert-dodecyl is not toxic or harmful to aquatic species (whatever the species considered) up to its water solubility limit. Therefore notifiers considered that additional testing for characterizing aquatic impacts is not necessary."

ECHA points out the justification for waiving provided by the Registrant does not meet the criteria of the general adaptation rules of Annex XI to the REACH Regulation.

The ECHA Guidance on information requirements and chemical safety assessment (Version 1.2, November 2012), Chapter R7b, page 32, indicates that the need to conduct further testing according to column 2 of Annex IX, section 9.1., may be triggered e.g. when due to low water solubility of a substance, short term toxicity tests do not reveal any toxicity. The absence of toxicity observed in the short-term tests with the registered substance having a low water solubility cannot, therefore be used as an argument for adaptation of long-term tests.

Therefore, the adaptations proposed by the Registrant cannot be accepted.

In his comments to the draft decision the Registrant agreed with ECHA that the justification for waiving the long-term testing on fish and long-term testing on aquatic invertebrates is not sufficient, but further stated that neither testing is required taking into account the intrinsic properties of the substance (water solubility, Octanol-water partition coefficient and aquatic toxicity).

In his comments the Registrant also refers to one of the registered substance's main raw materials [redacted] CAS No [redacted] (EC No [redacted]). Due to similarities of the two substances the Registrant states that "*we can consider that the two substances share structural properties and that information on environmental fate and effects of* [redacted] *is valuable for the assessment of Polysulfides, di-tert-dodecyl.*" ECHA notes that in the updated dossier the Registrant has not submitted any further evidence for the read-across referred to in the comments. According to Annex XI, Section 1.5. of the REACH Regulation, "*substances whose physicochemical, toxicological and ecotoxicological properties are likely to be similar or follow a regular pattern as a result of structural similarity may be considered as a group*" and that the "*application of the group concept requires that physicochemical properties, human health effects and environmental effects or environmental fate may be predicted [...] by interpolation*". It continues by stating that the results should "*have adequate and reliable coverage of the key parameters addressed in the corresponding test method referred to in Article 13(3)*", "*cover an exposure duration comparable to or longer than the corresponding test method referred to in Article 13(3) if exposure duration is a relevant parameter*" and "*adequate and reliable documentation of the applied method shall be provided*". ECHA notes that the Registrant has not provided and documented a read-across justification assessing the structural similarity and a systematic comparison of ecotoxicological properties and thus, the requirements in Annex XI, Section 1.5. have not been fulfilled. Therefore ECHA is not able to assess the read-across at this stage.

In his comments the Registrant refers also to aquatic toxicity and water solubility data on [redacted] CAS No [redacted] (EC No [redacted]) to justify why no further aquatic testing on the registered substance is required. However, in addition to the point raised above, as no robust study summaries for these studies have been provided in the technical dossier for the substance subject to the present decision, it is not possible for ECHA to evaluate this information at this stage.

In a subsequent update (submission number [redacted]) the Registrant has modified the adaptations for both aquatic long-term endpoints to the following: "*Polysulfides, di-tert-dodecyl has a very low water solubility (calculated to be in the range 10-7 to 10-8 mg/L). Being a complex UVCB no 14C material can be prepared to circumvent analytical difficulties, therefore no further testing of pelagic species is proposed, further sediment compartment*

investigation is on-going."

ECHA notes that advice on how to deal with a difficult to test substance is given at the end of this section. This information was already available in the initial draft decision. ECHA notes furthermore that neither low water solubility nor substance being a complex UVCB are acceptable justifications for adapting the standard information requirements of Annex IX sections 9.1.5. and 9.1.6. Neither does this justification for waiving meet the criteria of the general adaptation rules of Annex XI to the REACH Regulation.

In the modified adaptations the Registrant has also stated that "further sediment compartment investigation is on-going ", clarifying that they are currently in the process of carrying out a sediment simulation study according to OECD 308 as requested in ECHA decision TPE-D-0000003039-76-05/F. ECHA notes that long-term aquatic testing is a standard information requirement under REACH Annex IX sections 9.1.5 and 9.1.6. These information requirements are not linked to the requirement of carrying out simulation studies. Moreover, simulation studies do not provide for an acceptable justification for adapting the standard information requirements of Annex IX sections 9.1.5. and 9.1.6., neither does this justification for waiving meet the criteria of the general adaptation rules of Annex XI to the REACH Regulation.

As the submitted information does not fulfil the above information requirements, there are information gaps and it is necessary to provide information for the endpoints in order to bring the registration dossier into compliance with the relevant information requirements.

Regarding the long-term toxicity testing on fish pursuant to Annex IX, section 9.1.6.1, ECHA considers that the FELS toxicity test according to OECD 210 is the most sensitive of the standard fish tests available as it covers several life stages of the fish from the newly fertilised egg, through hatch to early stages of growth and should therefore be used (see ECHA *Guidance on information requirements and chemical safety assessment* (version 1.2., November 2012), Chapter R7b, Figure R.7.8-4 page 26). The test method OECD 210 is also the only suitable test currently available for examining the potential toxic effects of bioaccumulation (ECHA Guidance R7b, version 1.2., November 2012, p. 26). For these reasons, ECHA considers the FELS toxicity test using the test method OECD 210 as appropriate and suitable.

As for the test method for the long-term toxicity testing on aquatic invertebrates, ECHA considers the standard recommended test method EU C.20./OECD 211 to be the most appropriate and suitable.

Therefore, pursuant to Article 41(1)(a) and (b) and (3) of the REACH Regulation, the Registrant is requested to submit the following information derived with the registered substance subject to the present decision:

- Daphnia magna reproduction test (test method: EU C.20./OECD 211); and
- Fish, early-life stage (FELS) toxicity test (test method: OECD 210).

Once the results of the above long-term aquatic studies are available to the Registrant, he shall revise the chemical safety assessment as necessary according to Annex I of the REACH Regulation, including a derivation of the aquatic PNECs.

ECHA notes that as effects were observed in the limit test submitted for the Annex VIII section 9.1.3. endpoint of Short-term toxicity testing on fish, fish can be considered to be more sensitive than aquatic invertebrates. Consequently the integrated testing strategy outlined in ECHA *Guidance on information requirements and chemical safety assessment* (version 1.2., November 2012), Chapter R7b, Figure R.7.8-4 page 56, is not applicable and long-term tests are required on both.

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. This period of time took into account the fact that the draft decision also included the integrated testing strategy which allows the Registrant to test Daphnia first and fish only if necessary. As the integrated testing strategy is not addressed in the present decision and long-term tests are required on both species, ECHA considers that a reasonable time period for providing the required information in the form of an updated IUCLID5 dossier is 12 months from the date of the adoption of the decision. The decision was therefore modified accordingly.

IV. Adequate identification of the composition of the tested material

ECHA stresses that the information submitted by the Registrant and other joint registrants for identifying the substance has not been checked for compliance with the substance identity requirements set out in Section 2 of Annex VI of the REACH Regulation. The Registrant is reminded of his responsibility and that of joint Registrants to ensure that the joint registration covers one substance only and that the substance is correctly identified in accordance with Annex VI, Section 2 of the REACH Regulation.

In relation to the information required by the present decision, 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 who manufacture or import the same substance to agree on the appropriate composition of the test material 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 an appeal shall be lodged within three months of receiving notification of this decision. Further information on the appeal procedure can be found on 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.

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.