EUROPEAN CHEMICALS AGENCY

Decision number: TPE-D-0000002783-70-06/F Helsinki, 31 May 2013

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

For Bis(4-chlorophenyl) sulphone, CAS 80-07-9 (EC No 201-247-9), 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 set out in the registration dossier in accordance with Articles 10(a)(ix) and 12(1)(e) thereof for (bis(4-chlorophenyl) sulphone), CAS No 80-07-9 (EC No 201-247-9) submitted by [redacted] (Registrant).

- Biodegradation in water and sediment (OECD Guideline 308 (Aerobic and Anaerobic Transformation in Aquatic Sediment Systems))
- Sediment toxicity (OECD Guideline 218 (Sediment-Water Chironomid Toxicity Test Using Spiked Sediment)
- Pre-natal developmental toxicity study (EU Method B.31 (Prenatal Developmental Toxicity Study)) Test species: Rabbit

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 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 dossier at a later stage.

On 17 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 15 April 2011 until 30 May 2011. ECHA did receive information from third parties (see section III below).

On 29 October 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.

By 28 November 2012 the Registrant did not provide any comments on the draft decision to ECHA.

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

On 21 February 2013 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 4 March 2013 ECHA referred the draft decision to the Member State Committee.
By 25 March 2013 the Registrant did not provide any comments on the proposal for amendment but only comments on the draft decision that were not requested at this stage of the decision making.

A unanimous agreement of the Member State Committee on the draft decision was reached on 8 April 2013 in a written procedure launched on 27 March 2013. ECHA took the decision pursuant to Article 51(6) of the REACH Regulation.

II. Testing required

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

1. Pre-natal developmental toxicity study in rats or rabbits, oral route (Annex IX, 8.7.2., EU Method B.31/OECD 414);

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

3. Long-term toxicity to sediment organisms (Annex X, 9.5.1.; test method: Sediment-water Chironomid toxicity using spiked sediment, OECD 218).

Pursuant to Articles 40(4) and 22 of the REACH Regulation, the Registrant shall submit to ECHA by **31 May 2014** an update of the registration dossier containing the information required by this decision.

Data from a second pre-natal developmental toxicity study on another species is a standard information requirement according to Annex X, 8.7.2. of the REACH Regulation, subject to the Annex IX, 8.7.2. column 2 requirements. If the Registrant considers that testing is necessary to fulfil this information requirement taking into account the outcome of the pre-natal developmental toxicity study on a first species and all other relevant and available data, he should include in the update of his dossier a testing proposal for a pre-natal developmental toxicity study on a second species. However, as the registered substance

subject to the present decision is currently listed on the draft Community rolling action plan for Substance Evaluation, the Registrant shall discuss his further envisaged testing needs with the evaluating Competent Authority before submitting further testing proposals in that regard.

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 proposals submitted by the Registrant for the registered substance and scientific information submitted by third parties.

1. Pre-natal developmental toxicity study

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.

A pre-natal developmental toxicity study for a first species is a standard information requirement as laid down in Annex IX, section 8.7.2. 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 proposed the test to be carried out with rabbit via oral administration route. According to the test method EU B.31/OECD 414, the rat is the preferred rodent species, the rabbit the preferred non-rodent species and the test substance is usually administered orally. ECHA considers these default parameters appropriate and testing should be performed by the oral route with the rat or rabbit as a first species to be used.

b) Consideration of the information received during third party consultation

ECHA received third party information concerning the testing proposal during the third party consultation. For the reasons explained further below the information provided by third parties is not sufficient to fulfil this information requirement.

The third party provided information using a nonlinear ANN QSAR model. It indicated that their information was "private". Therefore ECHA will not provide it to the Registrant.

ECHA has examined the information submitted. The third party presented a quantitative structure-activity relationship model (QSAR) for prenatal developmental toxicity study in rodents.

ECHA concludes that on this occasion, the information submitted does not meet the conditions for the adaptation on the basis of QSAR models set out in Annex XI, Section 1.3. of the REACH Regulation. Therefore, it cannot constitute an acceptable adaptation to standard information requirements.

c) Outcome

Therefore, pursuant to Article 40(3)(a) of the REACH Regulation, the Registrant is required to carry out the proposed study: Pre-natal developmental toxicity study in rats or rabbits, oral route (test method: EU B.31/OECD 414) using the registered substance (bis(4-chlorophenyl) sulphone).

When considering the need for a testing proposal for a prenatal developmental toxicity study in a second species, the Registrant should take into account the outcome of the pre-natal developmental toxicity study on the first species and all available data to determine if the conditions are met for adaptations according to Annex X, 8.7. column 2, or according to Annex XI; for example if the substance meets the criteria for classification as toxic for reproduction Category 1B: May damage the unborn child (H360D), and the available data are adequate to support a robust risk assessment, or alternatively, if Weight of Evidence assessment of all relevant available data provides scientific justification that the study in a second species is not needed.

2. Sediment simulation testing

Pursuant to Article 40(3)(a) of the REACH Regulation, ECHA may require the Registrant to carry out the proposed test.

According to column 1 of Section 9.2.1.4. of Annex IX of the REACH Regulation, sediment simulation testing is a standard information requirement for substances with a high potential for adsorption to sediment.

The Registrant notes in the Chemical Safety Report that final conclusions on the persistence of the registered substance in the environment are not possible based on the available information, and that further investigations on environmental persistence and biomagnification of the substance are indicated.

The information on this endpoint is not available for the registered substance, but needs to be present in the technical dossier for persistency assessment. Consequently, there is an information gap and it is necessary to provide information for this endpoint.

The Registrant has submitted a testing proposal for an aerobic and anaerobic transformation in aquatic sediment systems simulation biodegradation study (OECD 308 / EU C.24) to cover the endpoint.

ECHA notes that the proposed test can be used to fulfil the information requirement for sediment simulation testing.

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 (bis(4-chlorophenyl) sulphone): Sediment simulation testing (Annex IX, 9.2.1.4.; test method: Aerobic and anaerobic transformation in aquatic sediment systems, EU C.24/OECD 308).

3. Long-term toxicity testing on sediment organisms

Pursuant to Article 40(3)(a) of the REACH Regulation, ECHA may require the Registrant to carry out the proposed test.

According to column 1 of Section 9.5.1. of Annex X of the REACH Regulation, long-term toxicity to sediment organisms is a standard information requirement. 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 proposed a sediment-water Chironomid toxicity test using spiked sediment (OECD 218).

The Registrant provided the following justification for conducting the proposed test: *'The study is proposed in case the DT50 of DCDPS in sediment is determined >180 days in the as well proposed study according to OECD TGD 308, which will be performed earlier. Only under the provision that DCDPS is then placed in the soil/sediment Hazard Category 3 according to Table R.7.11-2 in ECHA (2008a Guidance on information requirements and chemical safety assessment, Chapter R.7c: Endpoint specific guidance, p 131) this chironomid confirmatory long-term study is planned as a confirmatory assay for the applicability of the equilibrium partitioning method.'*

ECHA notes that the above mentioned guidance does not support conditional toxicity testing on sediment based on soil hazard category and DT50 values in sediment. The substance is adsorptive (log Koc 3.5) and exposure to sediment cannot be excluded. Potential long-term effects to the sediment should be investigated.

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 and thus it is necessary to generate additional data for this endpoint.

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 (bis(4-chlorophenyl) sulphone): Long-term toxicity to sediment organisms (Annex X, 9.5.1.; test method: Sediment-water Chironomid toxicity using spiked sediment, OECD 218).

IV. Adequate identification of the composition of the tested material

The process of evaluation 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 evaluation 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 grades registered to enable the relevance of the studies 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.

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