~~Confidential~~

Helsinki, 8 March 2022

Addressees
Registrant of 4,4'-sulfonylbisphenol, polymer with ammonium chloride(NH4Cl), pentachlorophosphorane and phenol as listed in Appendix 3 of this decision

Date of submission of the dossier subject to this decision
22/02/2021

Registered substance subject to this decision ("the Substance")
Substance name: 4,4'-sulfonylbisphenol, polymer with ammonium chloride(NH4Cl), pentachlorophosphorane and phenol
EC number: 439-270-3

Decision number: Please refer to the REACH-IT message which delivered this communication (in format TPE-D-XXXXXXXXXX-XX-XX/F)

DECISION ON TESTING PROPOSAL(S)

Based on Article 40 of Regulation (EC) No 1907/2006 (REACH), you must submit the information listed below by **15 December 2022**.

Requested information must be generated using the Substance unless otherwise specified.

Information required from all the Registrants subject to Annex VIII of REACH

1. Long-term toxicity testing on terrestrial invertebrates (triggered by Annex I, section 0.5 in conjunction with Annex VI; test method: EU C.33/OECD TG 222)

The reasons for the decision(s) are explained in Appendix 1.

Information required depends on your tonnage band

You must provide the information listed above for all REACH Annexes applicable to you in accordance with Articles 10(a) and 12(1) of REACH. The addressees of the decision and their corresponding information requirements based on registered tonnage band are listed in Appendix 3.

You are only required to share the costs of information that you must submit to fulfil your information requirements.

How to comply with your information requirements

To comply with your information requirements, you must submit the information requested by this decision in an updated registration dossier by the deadline indicated above. You must also **update the chemical safety report, where** relevant, including any changes to classification and labelling, based on the newly generated information.

You must follow the general requirements for testing and reporting new tests under REACH, see Appendix 4.

Appeal

This decision, when adopted under Article 51 of REACH, may be appealed to the Board of Appeal of ECHA within three months of its notification to you. Please refer to http://echa.europa.eu/regulations/appeals for further information.

Failure to comply

If you do not comply with the information required by this decision by the deadline indicated above, ECHA will notify the enforcement authorities of your Member State.

Authorised[1] under the authority of Mike Rasenberg, Director of Hazard Assessment

Appendix 1: Reasons for the decision
Appendix 2: Procedure
Appendix 3: Addressees of the decision and their individual information requirements
Appendix 4: Conducting and reporting new tests under REACH

[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.

Appendix 1: Reasons for the decision

Contents

Reasons for the decision(s) related to the information under Annex VIII of REACH

1. Long-term toxicity testing on terrestrial invertebrates

1 Long-term toxicity to invertebrates is an information requirement under Annex X to REACH (Section 9.4.4.).

2 Nevertheless, according to Article 12(1) of and Annex VI to REACH, Annexes VI to XI stipulate minimum information requirements and, for each registration, the precise information requirements will differ under consideration of the Annexes as a whole and the overall requirements of registration, evaluation, and duty of care.

3 Annex VI, step 4 of the 'Guidance note on fulfilling the requirements of Annexes VI to XI' provides that 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. Furthermore, in accordance with Annex I, certain additional information may have to be generated if it is necessary for producing the chemical safety report (CSR). According to the last subparagraph of Section 0.5. of Annex I of REACH, if the manufacturer or importer considers that further information is necessary for producing his CSR and that this information can only be obtained by performing tests in accordance with Annex IX and X, he shall submit a proposal for a testing strategy, explaining why he considers that additional information is necessary and record this in the CSR under the appropriate heading.

4 The Guidance on IRs and CSA, Section R.7.11.16. describes an integrated testing strategy (ITS) for Effects on Terrestrial Organisms. For the soil compartment there are currently no criteria for classification and PBT assessment, therefore the ITS for soil is especially focussed on generating data for the chemical safety assessment. This approach relies on the assignment of the Substance to a "soil hazard category" and on an initial screening assessment using the EPM, in order to decide on the information needed for the chemical safety assessment (CSA).

The following information indicates that Substance falls into the soil hazard category 3 (HC3):

- the Substance is not considered very toxic to aquatic organisms as no effects were observed up to the water solubility limit of the substance in a long-term toxicity study on fish according to OECD TG 210 and a long-term toxicity study on aquatic invertebrates according to OEDC TG 211;
- the Substance is considered to be potentially highly persistent in soil as it is considered not readily biodegradable based on an OECD 301 study that indicated 2% degradation in 28 days;
- the Substance is considered to have high adsorption potential to soil as you report a log Pow value of > 6.2 based on OECD TG 117 and a QSAR calculated log Koc of >5.12.

5 However, in the absence of any acute and chronic effects observed up to the limit of water solubility in available aquatic toxicity studies on the Substance, a robust PNEC for the purpose of a soil screening assessment using the EPM cannot be derived.

6 In such case, where the substance is highly adsorptive (e.g., log Kow/Koc >5) and/or the substance is potentially very persistent in soil such as the Substance, a long-term test on effects to terrestrial organisms from those set out under Annex X is needed to meet the requirements of the CSA (Guidance on IRs and CSA, Section R.7.11.5.3.). Under Guidance on IRs and CSA, Section R.7.11.5.3. in the absence of a clear indication of the most

sensitive organism group as indicated by the available aquatic toxicity data, an invertebrate (earthworm or collembolan) test is preferred.

1.1. Information provided to fulfil the information requirement

7 You have submitted a testing proposal for Long-term toxicity testing on terrestrial invertebrates, Earthworm Reproduction Test (OECD TG 222) with the following justification "[T]*he PNECs for soil and sediment cannot be established by applying the equilibrium partitioning method (EPM) since there is no hazard identified to the aquatic environment. The low water solubility, high log* K_{ow} *and high log* K_{oc} *of the substance indicates that the substance has the potential for adsorption to sediment/soil and concern for soil/sediment organisms cannot be excluded. After consulting the ECHA help desk it was advised to perform the long-term terrestrial toxicity test to clarify the concern, while the results of this study can be used in a weight of evidence approach together with the absence of long-term effects in aquatic organism up to the solubility limit of the substance to conclude on the PNEC soil and sediment. This approach would allow to assess the risk of the substance to terrestrial organism, ensure its safe use and prepare the CSR*."

8 Your registration dossier does not include any information on Effects on terrestrial organisms.

9 ECHA agrees that the proposed test is necessary, within the context of Annex I, section 0.5. and Annex VI of REACH, to assess the risk of the Substance to terrestrial organisms, ensure its safe use and prepare the CSR.

1.2. Test selection and study specifications

10 The proposed Long-term toxicity testing on terrestrial invertebrates, Earthworm Reproduction Test (test method: OECD TG 222) is appropriate to provide relevant information on long-term effects on terrestrial organisms (ECHA Guidance R.7.11.6.) for the purpose of CSA.

1.3. Outcome

11 Your testing proposal is accepted under Article 40(3)(a) and you are requested to conduct the test with the Substance, as specified above.

References

The following documents may have been cited in the decision.

Guidance on information requirements and chemical safety assessment (Guidance on IRs & CSA)

Chapter R.4 Evaluation of available information; ECHA (2011).
Chapter R.6 QSARs, read-across and grouping; ECHA (2008).
Appendix to Chapter R.6 for nanoforms; ECHA (2019).
Chapter R.7a Endpoint specific guidance, Sections R.7.1 – R.7.7; ECHA (2017).
Appendix to Chapter R.7a for nanomaterials; ECHA (2017).
Chapter R.7b Endpoint specific guidance, Sections R.7.8 – R.7.9; ECHA (2017).
Appendix to Chapter R.7b for nanomaterials; ECHA (2017).
Chapter R.7c Endpoint specific guidance, Sections R.7.10 – R.7.13; (ECHA 2017).
Appendix to Chapter R.7a for nanomaterials; ECHA (2017).
Appendix R.7.13-2 Environmental risk assessment for metals and metal compounds; ECHA (2008).
Chapter R.11 PBT/vPvB assessment; ECHA (2017).
Chapter R.16 Environmental exposure assessment; ECHA (2016).

Guidance on data-sharing; ECHA (2017).

All Guidance on REACH is available online: https://echa.europa.eu/guidance-documents/guidance-on-reach

Read-across assessment framework (RAAF)

RAAF, 2017 Read-across assessment framework (RAAF), ECHA (2017)
RAAF UVCB, 2017 Read-across assessment framework (RAAF) – considerations on multi- constituent substances and UVCBs), ECHA (2017).

The RAAF and related documents are available online:
https://echa.europa.eu/support/registration/how-to-avoid-unnecessary-testing-on-animals/grouping-of-substances-and-read-across

***OECD Guidance documents* (OECD GDs)**

OECD GD 23 Guidance document on aquatic toxicity testing of difficult substances and mixtures; No. 23 in the OECD series on testing and assessment, OECD (2019).
OECD GD 29 Guidance document on transformation/dissolution of metals and metal compounds in aqueous media; No. 29 in the OECD series on testing and assessment, OECD (2002).
OECD GD 150 Revised guidance document 150 on standardised test guidelines for evaluating chemicals for endocrine disruption; No. 150 in the OECD series on testing and assessment, OECD (2018).
OECD GD 151 Guidance document supporting OECD test guideline 443 on the extended one-generation reproductive toxicity test; No. 151 in the OECD series on testing and assessment, OECD (2013).

Appendix 2: Procedure

ECHA started the testing proposal evaluation in accordance with Article 40(1) on 4 May 2021.

ECHA followed the procedure detailed in Articles 50 and 51 of REACH.

ECHA notified you of the draft decision and invited you to provide comments.

ECHA did not receive any comments within the commenting period.

ECHA notified the draft decision to the competent authorities of the Member States for proposals for amendment.

As no amendments were proposed, ECHA took the decision according to Article 51(3) of the REACH Regulation.

Appendix 3: Addressees of this decision and their corresponding information requirements

In accordance with Articles 10(a) and 12(1) of REACH, the information requirements for individual registrations are defined as follows:

- the information specified in Annexes VII and VIII to REACH, for registration at 10-100 tpa.

Registrant Name	Registration number	Highest REACH Annex applicable to you
[redacted]	[redacted]	[redacted]

Where applicable, the name of a third-party representative (TPR) may be displayed in the list of recipients whereas ECHA will send the decision to the actual registrant.

Appendix 4: Conducting and reporting new tests for REACH purposes

1. Requirements when conducting and reporting new tests for REACH purposes

1.1. Test methods, GLP requirements and reporting

(1) Under Article 13(3) of REACH, all new data generated as a result of this decision must be conducted according to the test methods laid down in a European Commission Regulation or to international test methods recognised by the Commission or ECHA as being appropriate.

(2) Under Article 13(4) of REACH, ecotoxicological and toxicological tests and analyses must be carried out according to the GLP principles (Directive 2004/10/EC) or other international standards recognised by the Commission or ECHA.

(3) Under Article 10(a)(vi) and (vii) of REACH, all new data generated as a result of this decision must be reported as study summaries, or as robust study summaries, if required under Annex I of REACH. See ECHA Practical Guide on How to report robust study summaries[2].

1.2. Test material

(1) Selection of the Test material(s)
The Test Material used to generate the new data must be selected taking into account the following:
- the impact of each constituent/ impurity on the test results for the endpoint to be assessed. For example, if a constituent/ impurity of the Substance is known to have an impact on (eco)toxicity, the selected Test Material must contain that constituent/ impurity.

(2) Information on the Test Material needed in the updated dossier
- You must report the composition of the Test Material selected for each study, under the "Test material information" section, for each respective endpoint study record in IUCLID.
- The reported composition must include all constituents of each Test Material and their concentration values and other parameters relevant for the property to be tested.

This information is needed to assess whether the Test Material is relevant for the Substance.

Technical instructions on how to report the above is available in the manual on How to prepare registration and PPORD dossiers[3].

[2] https://echa.europa.eu/practical-guides
[3] https://echa.europa.eu/manuals