Helsinki, 28 May 2019

Addressee: [redacted]

Decision number: TPE-D-2114471585-40-01/F
Substance name: Reaction products of 3,4,5,6-tetrabromobenzene-1,2-dicarboxylate with 2,2'-oxy-diethanol and 2-epoxypropane
EC number: 616-436-5
CAS number: 77098-07-8
Registration number: [redacted]
Submission number: [redacted]
Submission date: 26 June 2018
Registered tonnage band: 100-1000

DECISION ON A TESTING PROPOSAL

Based on Article 40 of Regulation ((EC) No 1907/2006) (the REACH Regulation), ECHA examined your testing proposal(s) and decided as follows.

Your testing proposal is accepted and you are requested to carry out:

1. **Long-term toxicity to terrestrial plants (Annex IX, Section 9.4.3., column 2; test method: Terrestrial plant test: seedling emergence and seedling growth test, OECD TG 208 with at least six species tested (with as a minimum two monocotyledonous species and four dicotyledonous species)) using the registered substance.**
2. **Effects on soil micro-organisms (Annex IX, Section 9.4.2.; test method: Soil microorganisms: nitrogen transformation test, EU C.21/OECD TG 216) using the registered substance.**

You are requested to perform as additional test:

3. **Long-term toxicity to terrestrial invertebrates (Annex IX, Section 9.4.1., column 2; test method: Earthworm reproduction test (OECD TG 222) *or* Enchytraeid reproduction test (OECD TG 220) *or* Collembolan reproduction test in soil (OECD TG 232)) using the registered substance.**

You have to submit the requested information in an updated registration dossier by **4 June 2020**. You also have to update the chemical safety report, where relevant.

The reasons for this decision are set out in Appendix 1. The procedural history is described in Appendix 2 and advice and further observations are provided in Appendix 3.

Appeal

This decision can be appealed to the Board of Appeal of ECHA within three months of its notification. An appeal, together with the grounds thereof, has to be submitted to ECHA in writing. An appeal has suspensive effect and is subject to a fee. Further details are described under: http://echa.europa.eu/regulations/appeals.

Authorised[1] by Ofelia Bercaru, Head of Unit, Hazard Assessment

[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

The decision of ECHA is based on the examination of the testing proposals submitted by you.

1. Long-term toxicity to terrestrial plants (Annex IX, Section 9.4.3., column 2)

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

"Effects on terrestrial organisms" is a standard information requirement as laid down in Annex IX, Section 9.4. of the REACH Regulation. The Registrant must address the standard information requirements set out in Annex IX, Section 9.4., for different taxonomic groups: short-term toxicity testing on invertebrates (Annex IX, Section 9.4.1.), effects on soil micro-organisms (Annex IX, Section 9.4.2.), and short-term toxicity testing on plants (Annex IX, Section 9.4.3.). Furthermore, Annex IX, Section 9.4., column 2 specifies that long-term toxicity testing shall be considered by the Registrant instead of short-term, in particular for substances that have a high potential to adsorb to soil or that are very persistent.

The information on "long-term toxicity to plants" 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.

You have submitted a testing proposal for a long-term toxicity test to plants (*Terrestrial plant test: Seedling Emergence and Seedling Growth Test*, OECD TG 208) with the justification that "*accoring to REACH guidance R7.c this test is the most suitable for industrial chemicals that may eventually released to soil*".

Based on the substance properties reported in your technical dossier (not readily biodegradable based on QSAR estimation and no reliable experimental biodegradation half-life available for soil), ECHA considers that the substance is potentially very persistent which is the default setting for not readily biodegradable substances when reliable value for the half-life in soil is not available. Furthermore, only QSAR predicted values are reported for partition coefficient (LogKow 3.83) and adsorption/desorption (Koc 10). In the absence of reliable experimentally derived LogKow and Koc parameters ECHA considers that the potential for high adsorption to soil cannot be ruled out. Therefore ECHA agrees that a long-term testing is indicated and the proposed test is appropriate to fulfil the information requirement of Annex IX, Section 9.4.3., column 2.

OECD guideline 208 (Terrestrial plants, growth test) considers the need to select the number of test species according to relevant regulatory requirements, and the need for a reasonably broad selection of species to account for interspecies sensitivity distribution. For long-term toxicity testing, ECHA considers six species as the minimum to achieve a reasonably broad selection. Testing shall be conducted with species from different families, as a minimum with two monocotyledonous species and four dicotyledonous species, selected according to the criteria indicated in the OECD TG 208 guideline. You should consider if testing on additional species is required to cover the information requirement.

You have indicated in your testing proposal that "*The test substance concentration will need to be based on the nominal concentration. The study will be conducted if technically feasible*" and you also state that "*Analytical monitoring* will *probably not be possible based*

on the nature of the substance as UVCB". In this regard, ECHA reminds you that the OECD TG 208 requires that the concentrations/rates of application must be confirmed by an appropriate analytical verification. For soluble substances, verification of all test concentrations can be confirmed by analysis of the highest concentration test solution with the documentation on subsequent dilution. For insoluble substances, verification of compound material must be provided with weights of the test substance added to the soil.

Therefore, pursuant to Article 40(3)(a) of the REACH Regulation, you are required to carry out one of the proposed study using the registered substance subject to the present decision: Terrestrial plants, growth test (OECD 208), with at least six species tested (with as a minimum two monocotyledonous species and four dicotyledonous species).

2. Effects on soil micro-organisms (Annex IX, Section 9.4.2.)

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

"Effects on terrestrial organisms" is a standard information requirement as laid down in Annex IX, Section 9.4. of the REACH Regulation. The Registrant must address the standard information requirements set out in Annex IX, Section 9.4., for different taxonomic groups: short-term toxicity testing on invertebrates (Annex IX, Section 9.4.1.), effects on soil micro-organisms (Annex IX, Section 9.4.2.), and short-term toxicity testing on plants (Annex IX, Section 9.4.3.).

You have submitted a testing proposal for an Soil microorganisms: nitrogen transformation test (OECD TG 216). ECHA considers that the proposed test is appropriate to fulfil the information requirement of Annex IX, Section 9.4.2.

ECHA notes that the proposed test accepted under point (1) above is not sufficient to address this standard information requirement. ECHA concludes that the effects on soil microorganisms need to be ascertained by performing a relevant test.

To address this endpoint, either a nitrogen transformation test (test method: EU C.21/OECD TG 216) or a carbon transformation test (test method: EU C.22/OECD TG 217) could be performed. According to Section R.7.11.3.1, Chapter R.7c of the ECHA *Guidance on information requirements and chemical safety assessment* (version 3.0, June 2017), ECHA considers the nitrogen transformation test (EU C.21/OECD TG 216) suitable for non-agrochemicals.

Therefore, pursuant to Article 40(3)(a) of the REACH Regulation, you are requested to carry out one of the proposed study using the registered substance subject to the present decision: Soil microorganisms: nitrogen transformation test, EU C.21/OECD TG 216.

3. Long-term toxicity to terrestrial invertebrates (Annex IX, Section 9.4.1., column 2)

Pursuant to Article 40(3)(c) of the REACH Regulation, ECHA may require the Registrant to carry out one or more additional tests in case of non-compliance of the testing proposal with Annexes IX, X or XI of the REACH Regulation.

"Effects on terrestrial organisms" is a standard information requirement as laid down in Annex IX, Section 9.4. of the REACH Regulation. The Registrant must address the standard

information requirements set out in Annex IX, Section 9.4., for different taxonomic groups: short-term toxicity testing on invertebrates (Annex IX, Section 9.4.1.), effects on soil micro-organisms (Annex IX, Section 9.4.2.), and short-term toxicity testing on plants (Annex IX, Section 9.4.3.). Furthermore, Annex IX, Section 9.4., column 2 specifies that long-term toxicity testing shall be considered by the Registrant instead of short-term, in particular for substances that have a high potential to adsorb to soil or that are very persistent.

The proposed tests accepted by ECHA under points 1 and 2 above are not sufficient by themselves to address the standard information requirement of Annex IX, section 9.4.1. Furthermore, based on the available aquatic toxicity information and information on stability and biodegradation of the substance, ECHA considers that currently there are not sufficient data for hazard assessment or assigning substance to any soil Hazard Category according to section R.7.11.6 of ECHA Guidance on Information Requirements and Chemical Safety Assessment Chapter R7.C (version 3.0, June 2017"). Therefore, in the context of an integrated testing strategy for soil toxicity, you need to conduct long-term soil toxicity tests according to standard information requirements.

ECHA notes that the registration dossier does not contain reliable data for the long-term toxicity to terrestrial invertebrates. You have sought to adapt the standard information requirement of Annex IX, section 9.4.1. by using a QSAR prediction (Annex XI, Section 1.3.) for the selected component of the registered UVCB substance, and provided a QSAR Model Reporting Formats (QMRF) for the several predictions performed with ECOSAR version 1.11. and OECD QSAR Toolbox version 4.2. ECHA considers that the predictions do not fulfil the requirements set in Annex XI section 1.3. because the scientific validity of the models have not been fully established for the soil ecotoxicology. Furthermore, according to Section R.7.11.4.1, Chapter R.7c of the ECHA *Guidance on information requirements and chemical safety assessment* (version 3.0, June 2017) the terrestrial endpoint predictions using QSARs should only be used as supportive evidence and to advise on how to proceed with further testing.

Based on above, the reliable information on "long-term toxicity to invertebrates" 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.

ECHA considers that based on the currently available information and the uncertainty related to the estimated values, the substance may adsorb to soil particles and hence the exposure of terrestrial organisms via ingested soil particles may be relevant. The earthworm reproduction testing allows potential uptake via all uptake routes, i.e. surface contact, soil particle ingestion and porewater.

As indicated above under point 1, ECHA considers that the substance is also potentially very persistent. High absorbance potential and persistence of the substance indicates the need for long-term testing to be performed (Column 2 of Section 9.4. of Annex IX). Therefore ECHA concludes that only a long-term toxicity test on invertebrates (and not the short-term) will provide the necessary useful information.

The earthworm reproduction test (OECD TG 222), Enchytraeid reproduction test (OECD TG 220), and Collembolan reproduction test (OECD TG 232) are each considered capable of generating information appropriate for the fulfilment of the information requirements for long-term toxicity testing to terrestrial invertebrates. ECHA is not in a position to determine

the most appropriate test protocol, since this decision is dependent upon species sensitivity and substance properties.

Therefore, pursuant to Article 40(3)(c) of the REACH Regulation, you are required to carry out one of the following additional studies using the registered substance subject to the present decision: Earthworm reproduction test (*Eisenia fetida/Eisenia andrei*) OECD 222, or Enchytraeid reproduction test OECD 220, or Collembolan reproduction test in soil OECD 232).

Appendix 2: Procedural history

ECHA received your registration containing the testing proposals for examination in accordance with Article 40(1) on 26 June 2018.

This decision does not take into account any updates after **14 January 2019**, 30 calendar days after the end of the commenting period.

The decision making followed the procedure of Articles 50 and 51 of the REACH Regulation, as described below:

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

ECHA did not receive any comments by the end of the commenting period.

ECHA notified the draft decision to the competent authorities of the Member States for proposal(s) for amendment.

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

Appendix 3: Further information, observations and technical guidance

1. This decision does not imply that the information provided in your 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.

2. Failure to comply with the requests in this decision will result in a notification to the enforcement authorities of the Member States.

3. In carrying out the tests required by the present decision, it is important to ensure that the particular sample of substance tested 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 or imported. If the registration of the substance covers different grades, the sample used for the new tests 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 tests to be assessed.