EUROPEAN CHEMICALS AGENCY

Helsinki, 5 November 2018

Addressee:
[redacted]

Decision number: TPE-D-2114449823-42-01/F
Substance name: 1,4-phenylene bis[(4-phenoxyphenyl)-methanone]
EC number: 620-097-9
CAS number: 54299-17-1
Registration number: [redacted]
Submission number: [redacted]
Submission date: 19 September 2017
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 proposals are accepted and you are requested to carry out:

1. **Long-term toxicity testing on aquatic invertebrates (Annex IX, Section 9.1.5.; test method: Daphnia magna reproduction test, EU C.20./OECD TG 211) using the registered substance.**
2. **Long-term toxicity testing on fish (Annex IX, Section 9.1.6.1.; test method: Fish, early-life stage (FELS) toxicity test, OECD TG 210) using the registered substance.**
3. **Bioaccumulation in aquatic species (Annex IX, Section 9.3.2.; test method: Bioaccumulation in fish: aqueous and dietary exposure, OECD TG 305, aqueous/dietary exposure) using the registered substance. Aqueous exposure is preferred if technically feasible.**

You 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 to the REACH Regulation. To ensure compliance with the respective information requirement, any such adaptation will need to have a scientific justification, referring and conforming to the appropriate rules in the respective annex, and an adequate and reliable documentation.

You have to submit the requested information in an updated registration dossier by **12 November 2019**. 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 Kevin Pollard, Head of Unit, Evaluation E1

[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 testing on aquatic invertebrates (Annex IX, Section 9.1.5.)**

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

"Long-term toxicity testing on aquatic invertebrates" is a standard information requirement as laid down in Annex IX, Section 9.1.5. 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.

You have submitted a testing proposal for testing the registered substance for long-term toxicity testing on aquatic invertebrates (*Daphnia magna* reproduction test, EU C.20/OECD TG 211). You have not provided any justification for the proposed testing but you refer to the REACH regulation Annex VII, section 9.1.1., column 2, where it is specified that "*a long-term toxicity has to be considered if the substance is poorly soluble*". ECHA notes that the water solubility reported in the dossier is 0.005 mg/L indicating a poor solubility in water. ECHA considers that the proposed study is appropriate to fulfil the information requirement of Annex IX, Section 9.1.5 of the REACH regulation.

ECHA also notes that you have also submitted a testing proposal on a "Long-term toxicity testing on fish", which is a standard information requirement as laid down in Annex IX, Section 9.1.6. of the REACH Regulation.

According to ECHA *Guidance on information requirements and chemical safety assessment* (version 4.0, June 2017), Chapter R7b (Section R.7.8.5 including Figure R.7.8-4), if based on acute aquatic toxicity data neither fish nor invertebrates are shown to be substantially more sensitive, long-term studies may be required on both. There were no indications in the dossier from the short-term toxicity studies on aquatic species that substantial sensitivity differences would occur between fish and invertebrates as no effects were observed in the short-term toxicity studies up to limit of water solubility. Therefore, the Integrated Testing Strategy (ITS) outlined in ECHA *Guidance on information requirement and chemical safety assessment* (version 4.0, June 2017), Chapter R7b (Section R.7.8.5 including Figure R.7.8-4) above is not applicable in this case and the long-term toxicity studies on both invertebrates and fish are required to be conducted.

Therefore, pursuant to Article 40(3)(a) of the REACH Regulation, you are requested to carry out the proposed test using the registered substance subject to the present decision: Long-term toxicity testing on aquatic invertebrates (test method: *Daphnia magna* reproduction test, EU C.20/OECD TG 211).

2. Long-term toxicity testing on fish (Annex IX, Section 9.1.6.1.)

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

"Long-term toxicity testing on fish" is a standard information requirement as laid down in Annex IX, Section 9.1.6. 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.

You have submitted a testing proposal for testing the registered substance for long-term toxicity testing on fish (Fish, early-life stage toxicity test, OECD TG 210) with the following justification: "*Test substance is poorly soluble, no acute fish toxicity observed at water solubility limit, therefore long-term toxicity has to be proposed.*" ECHA considers that the proposed study is appropriate to fulfil the information requirement of Annex IX, Section 9.1.6 of the REACH Regulation.

As discussed under issue 1. above, the Integrated Testing Strategy (ITS) outlined in ECHA *Guidance on information requirement and chemical safety assessment* (version 4.0, June 2017), Chapter R7b (Section R.7.8.5 including Figure R.7.8-4) is not applicable in this case and the long-term toxicity studies on both invertebrates and fish are required to be conducted.

ECHA requested your considerations for alternative methods to fulfil the information requirement for long-term toxicity testing on fish. ECHA notes that you provided your considerations concluding that there were no alternative methods which could be used to adapt the information requirement for which testing is proposed. ECHA has taken these considerations into account.

Therefore, pursuant to Article 40(3)(a)of the REACH Regulation, you are requested to carry out the proposed test using the registered substance subject to the present decision: Fish, early-life stage (FELS) toxicity test (test method: Fish, early-life stage toxicity test, OECD TG 210).

Notes for your consideration for requests 1 and 2

Due to the low solubility of the substance in water you should consult OECD Guidance Document on Aquatic Toxicity Testing of Difficult Substances and Mixtures, ENV/JM/MONO (2000)6 and ECHA *Guidance on information requirements and chemical safety assessment* (version 4.0, June 2017), Chapter R7b, table R. 7.8-3 summarising aquatic toxicity testing of difficult substances for choosing the design of the requested long-term ecotoxicity tests and for calculation and expression of the result of this test.

3. Bioaccumulation in aquatic species (Annex IX, Section 9.3.2.)

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

"Bioaccumulation in aquatic species, preferably fish" is a standard information requirement as laid down in Annex IX, Section 9.3.2. 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.

You have submitted a testing proposal for testing the registered substance for a bioaccumulation in aquatic species (Bioaccumulation in Fish: Aqueous and Dietary Exposure, OECD TG 305-III: Dietary Exposure Bioaccumulation Fish Test) with the following justification: "*Data from logKow cannot discard bioaccumulation potential*". ECHA considers that the proposed study is appropriate to fulfil the information requirement of Annex IX, Section 9.3.2. of the REACH Regulation.

You indicate in your PBT assessment that the substance is not B/vB based on the reported log Kow of 2.9. On the other hand, you conclude in the technical dossier section 4.7 that this log Kow value (based on solubility in 1-octanol only) should be considered with care due to methodological difficulties in the experimental testing of partition coefficient and the high estimated log Kow of 8.41 obtained using the QSAR (KOWWIN 1.67) estimation. Therefore, the new experimental bioaccumulation information is needed for PBT/vPvB assessment to allow the definitive concluding on the potential B/vB properties.

In the testing proposal you have specified that the route to be used in the proposed OECD TG 305 bioaccumulation study is the dietary route (*i.e.* OECD TG 305-III) but you do not provide any specific justification to support the selection of this route. ECHA Guidance defines that results obtained from a test with aqueous exposure can be used directly for comparison with the B and vB criteria of Annex XIII of REACH Regulation and can be used for hazard classification and risk assessment. Comparing the results of a dietary study with the REACH Annex XIII B and vB criteria is more complex and has higher uncertainty. Therefore, the aqueous route of exposure is the preferred route and shall be used whenever technically feasible. As recommended in the OECD Guidance Document on Aspects of OECD TG 305 on Fish Bioaccumulation, ENV/JM/MONO (2017)16, before conducting the test via dietary route of exposure, you shall conduct the preliminary aquatic dosing experiment under test conditions without fish in order to investigate the solubility and stability of the test substance under aqueous exposure conditions. If the testing via aqueous route is not technically feasible and you finally decide to conduct the study using the dietary exposure route, you shall provide scientifically valid justification for your decision.

You shall also attempt to estimate the corresponding BCF value from the dietary test data by using the approaches given in Annex 8 of the OECD 305 TG and in OECD Guidance Document on Aspects of OECD TG 305 on Fish Bioaccumulation, ENV/JM/MONO (2017)16. In any case you shall report all data derived from the dietary test as listed in the OECD 305 TG.

ECHA requested your considerations for alternative methods to fulfil the information requirement for bioaccumulation in aquatic species. ECHA notes that you provided your considerations concluding that there were no alternative methods which could be used to adapt the information requirement for which testing is proposed. ECHA has taken these considerations into account.

Therefore, pursuant to Article 40(3)(a) of the REACH Regulation, you are requested to carry out the proposed study using the registered substance subject to the present decision: Aqueous or dietary exposure bioaccumulation fish test, OECD TG 305).

Notes for your consideration

With regards to the PBT assessment, you indicate that the substance is not readily biodegradable but no conclusion can be reached on persistency based on available biodegradation screening information. ECHA notes that the available biodegradation screening information indicates that the registered substance may have persistent or very persistent (P or vP) properties. ECHA reminds you that, depending on the results of the bioaccumulation study (i.e. if B/vB criteria are met), you may need to submit a testing proposal for a biodegradation simulation testing that is necessary for the definitive conclusion on potential P/vP properties of your registered substance.

You also indicate in your PBT assessment that the substance does not meet T criterion as there are no aquatic toxicity NOEC/EC_{10} values below 0.01 mg/L, no classification as carcinogenic (1A or 1B), germ cell mutagenic (1A or 1B) or toxic for reproduction (1A, 1B or 2) and there is no other evidence of chronic toxicity. However, ECHA reminds that there are ongoing testing proposals for the long-term toxicity to aquatic invertebrates and fish (issues 1 and 2 of this decision) and the new aquatic long-term toxicity data could potentially affect your conclusion on T.

Before conducting testing, you are advised to consult the ECHA *Guidance on information requirements and chemical safety assessment* (version 3.0, June 2017), Chapter R.11. PBT/vPvB assessment, in particular to first conclude on whether the registered substance is not persistent (P) and not very persistent (vP) or whether it may fulfil Annex XIII of the REACH Regulation criteria of being P or vP and to consult the PBT assessment for Weight-of-Evidence determination and the integrated testing strategy for bioaccumulation assessment. Also, you need to carefully consider the potential formation of stable degradation products with PBT/vPvB properties.

In addition, you are advised to consult the ECHA *Guidance on information requirements and chemical safety assessment*, Chapters R.4, 5, 6, R.7b and R.7c. If you decide to adapt the testing requested according to the specific rules outlined in Annexes VI to X and/or according to general rules contained in Annex XI of the REACH Regulation, you are referred to the advice provided in ECHA's Practical Guides on "How to use alternatives to animal testing to fulfil your information requirements for REACH registration" and on "How to use and report (Q)SARs".

Due to the low solubility of the substance in water and high octanol-water partition coefficient, you should consult OECD Guidance Document on Aquatic Toxicity Testing of Difficult Substances and Mixtures, ENV/JM/MONO (2000)6 and ECHA *Guidance on information requirements and chemical safety assessment* (version 4.0, June 2017), , Chapter R7b (table R.7.8-3 summarising aquatic toxicity testing of difficult substances) for choosing the design of the requested test and calculation and expression of the results of the test.

Appendix 2: Procedural history

ECHA received your registration containing the testing proposals for examination in accordance with Article 40(1) on 19 September 2017.

ECHA held a third party consultation for the testing proposals from 22 November 2017 until 8 January 2018. ECHA did not receive information from third parties.

This decision does not take into account any updates after **20 July 2018**, 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 proposals 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, or to otherwise fulfil the information requirements with a valid and documented adaptation, 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.