EUROPEAN CHEMICALS AGENCY

Helsinki, 16 April 2019

Addressee: [redacted]

Decision number: TPE-D-2114465982-36-01/F
Substance name: Bumetrizole
EC number: 223-445-4
CAS number: 3896-11-5
Registration number: [redacted]
Submission number: [redacted]
Submission date: 17/04/2018
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. **Bioaccumulation in aquatic species (Annex IX, Section 9.3.2.; test method: Bioaccumulation in fish: aqueous and dietary exposure, OECD TG 305, aqueous exposure/dietary exposure) using the registered substance.**

You have to submit the requested information in an updated registration dossier by **25 May 2020**. You shall also 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 **Claudio Carlon**, 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. 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 available information on this endpoint for the registered substance is not considered reliable. 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) with the following justifications:

For the assessment of the bioaccumulative potential of CAS 3896-11-5 one experimental study according to OECD TG 305C is available. You have considered this study unreliable due to the the fact that the two of the three concentration levels used in the test are above the water solubility limit for the substance. In order to avoid an underestimation of the bioaccumulative potential you deem it neccessary to conduct a new test at concentrations below the water solubility.

You also note that in order to avoid an underestimation of the BCF (bioconcentration factor), the concentration of test substance in fish used for the calculation of the BCF must be the concentration at steady state. According to the latest OECD 305 test guideline a steady state is reached when three successive analyses of the concentration in fish made on samples taken at intervals of at least two days are within ±20% of each other. As the available study does not report any data on the concentration in fish it cannot be verified if steady state was reached. Therefore, the reported BCF values might underestimate the true steady state BCF. As no depuration phase was included in the study the kinetic BCF cannot be derived and used as comparison/alternative. In conclusion, the available study has deficiencies and delivers only limited information on the bioaccumulative potential of the registered substance compound which could lead to an underestimation of the bioaccumulative potential.

With regards to the PBT assessment, you indicate that the substance is considered as poorly biodegradable and should be regarded as potentially persistent or even very persistent in the environment. You further specified in your justification that no degradation is expected and no relevant metabolites could be identified. ECHA notes that the available biodegradation screening information indicates that the registered substance may have persistent or very persistent (P or vP) properties. Consequently, information on bioaccumulation is highly relevant in the context of PBT assessement.

ECHA has considered the available information submitted in the technical dossier and agrees that the available information does not meet the conditions set out in Annex XI, Section 1.2. of the REACH Regulation, i.e. the results obtained do not allow an assumption/conclusion that the registered substance subject to the present decision has or has not bioaccumulation potential in aquatic species. Hence the available data are not adequate for the purpose of classification and labelling and/or risk assessments.

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.

The study is proposed to be conducted according to OECD TG 305.

ECHA considers that the proposed study is appropriate to fulfil the information requirement of Annex IX, Section 9.3.2. of the REACH Regulation.

In the testing proposal you have specified that the aqueous exposure route will be used in the proposed OECD TG 305 bioaccumulation study. 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. However, ECHA notes that in the case of substances with low or very water solubility, as is the case for the registered substance, it may be difficult to conduct a study via the aqueous route of exposure due to the detection limits of the available analytical methods. You indicated that would consider using radioactively labeled test material in order to perform the test via the aqueous route. ECHA advises you to consider performing a feasibility test with such a radiolabelled substance to verify that the substance can be monitored accurately and quantitatively when performing the fish bioaccumulation test via flow-through.

If the outcome of such a feasibility test or other information would lead you to conduct the study using the dietary exposure route instead, you shall provide a 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 III.

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

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/REV1 (6 July 2018) 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.

Deadline to submit the requested information in this decision

In your comments on the draft decision, you requested an extension of the deadline to 16 months from the original 9 months. In order to justify the extension request, you provided documents detailing the technical challenges involved in testing of the substance due to its physico-chemical properties and indicating the timeframe and steps needed to synthesize radiolabelled test material.

ECHA-S acknowledges that there are technical challenges in testing the substance and that radiolabelling may be required.

Nevertheless, ECHA highlights that the standard 9 month deadline for performance of an OECD TG 305 test already allows time for test design/setup and associated administrative steps. Additionally, feasibility studies and other preparatory work including test material preparation can already be planned and carried out during the ongoing decision making process before the decision is adopted. Therefore significant extension of the 9 month deadline to 16 months is not considered necessary or justified. Given all of the above considerations, ECHA concludes that an extension of the deadline by 4 months is warranted.

Hence, ECHA-S extended the deadline in the draft decision, to 13 months from the date of the final decision.

Appendix 2: Procedural history

ECHA received your registration containing the testing proposals for examination in accordance with Article 40(1) on 17 April 2018.

ECHA notes that the tonnage band for several members of the joint submission is 100 to 1 000 tonnes per year per year.

ECHA held a third party consultation for the testing proposals from 18 June 2018 until 02 August 2018. ECHA did not receive information from third parties.

This decision does not take into account any updates after **17 December 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 took into account your comments and amended the deadline.

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 will result in a notification to the enforcement authorities of the Member States.

3. In relation to the information required by the present decision, the sample of the substance used for the new tests must be suitable for use by all the joint registrants. Hence, the sample should have a composition that is suitable to fulfil the information requirement for the range of substance compositions manufactured or imported 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 the substance tested in the new tests 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 by each registrant.

   If the registration of the substance by any registrant covers different grades, the sample used for the new tests 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 tests to be assessed.