~~Confidential~~

Helsinki, 21 August 2020

Addressees
Registrants of JS_226-122-6 listed in the last Appendix of this decision

Date of submission for the jointly submitted dossier subject of a decision
19 June 2019

Registered substance subject to this decision, hereafter 'the Substance'
Substance name: 4,4'-methylenebis[N-sec-butylaniline]
EC number: 226-122-6
CAS number: 5285-60-9

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

DECISION ON A TESTING PROPOSAL

Based on Article 40 of Regulation (EC) No 1907/2006 (REACH), ECHA requests that you submit the information listed below by the deadline of ***28 February 2022***.

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

A. Requirements applicable to all the Registrants subject to Annex VIII of REACH

1. Bioaccumulation in aquatic species (triggered by Annex I, Sections 0.6.1. and 4. in conjunction with Annex XIII, Section 2.1.; test method OECD TG 305, aqueous exposure);

Conditions to comply with the requests

Each addressee of this decision is bound by the requests for information corresponding to the REACH Annexes applicable to their own registered tonnage of the Substance at the time of evaluation of the jointly submitted dossier. To identify your legal obligations, please refer to the following:

- you have to comply with the requirements of Annexes VII and VIII of REACH, if you have registered a substance at 10-100 tpa.

Registrants are only required to share the costs of information they are required to submit to fulfil the information requirements for their registration.

Appendix A states the reasons for the request for information to fulfil the requirements set out in Annex VIII of REACH.

The Appendix entitled Observations and technical guidance addresses the generic approach for the selection and reporting of the test material used to perform the required studies and provides generic recommendations and references to ECHA guidance and other reference documents.

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

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.

Approved[1] under the authority of Christel Schilliger-Musset, Director of 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 A: Reasons for the requirements applicable to all the Registrants subject to Annex VIII of REACH

This decision is based on the examination of the testing proposals you submitted.

1. Bioaccumulation in aquatic species (Annex I, Sections 0.6.1. and 4.; Annex XIII, Section 2.1.)

Bioaccumulation in aquatic species is required for the purpose of PBT/vPvB assessment (Annex I, Sections 0.6.1. and 4. to REACH).

Annex I, Section 4 requires that the CSA includes the PBT (persistent, bioaccumulative and toxic) and vPvB (very persistent and very bioaccumulative) assessments.
In accordance with Annex XIII, Section 2.1., if the results of the screening tests or other information indicate that the substance may have PBT or vPvB properties, further testing on bioaccumulation as set out in Section 3.2. is required. In case the generation of relevant additional information would require information listed in Annexes IX or X, the registrant must submit a testing proposal.

You have submitted a testing proposal for a Bioaccumulation in aquatic species test (OECD TG 305-I: Aqueous Exposure Bioconcentration Fish Test) with the Substance with the following justification: "*In order to come to an unequivocal conclusion on the PBT properties of the substance, further information is needed. The BCF study is proposed to generate the necessary information to come to an unequivocal conclusion*".

Screening information demonstrating potential PBT or vPvB properties include the following (ECHA Guidance R.11, and Annex XIII):

- The Substance is not readily biodegradable and thus potentially persistent;
- The Substance is hydrophobic and thus potentially bioaccumulative (log Kow greater than 4.5);
- The Substance has high potential for aquatic toxicity (E(L)C50 < 0.1 mg/L) or NOEC or EC10 < 0.01 mg/L, or is classified as carcinogenic (category 1A or 1B), germ cell mutagenic (category 1A or 1B), or toxic for reproduction (category 1A, 1B, or 2), or is classified as specific target organ toxicity after repeated exposure (STOT RE category 1 or 2) according to Regulation EC No 1272/2008

Screening information provided in your dossier indicates that the Substance may have PBT/vPvB properties:

- the Substance is potentially P/vP since it is not readily biodegradable (2% degradation after 28 days in OECD TG 301B); and
- the Substance is potentially B/vB since the Log Kow is above the threshold of 4.5 (logKow 5.4)
- the Substance is T (classified as STOT RE2)

In the assessment of PBT/vPvB properties of the Substance in section 8 of your CSR you also indicate that the Substance may have PBT/vPvB properties. The Substance was concluded T, potentially P/vP and potentially B/vB.

The available screening information is not sufficient to conclude on the B/vB properties of the Substance, and therefore further testing is required.

ECHA requested your considerations for alternative methods to fulfil the information requirement for Bioaccumulation: aquatic. ECHA notes that you provided your considerations concluding that there were no alternative methods which could be used to adapt the

information requirement(s) for which testing is proposed. ECHA has taken these considerations into account.

Under Article 40(3)(a) of the REACH Regulation, you are requested to carry out the proposed test.

Study selection and design
Bioaccumulation in fish: aqueous and dietary exposure (test method EU C.13. / OECD TG 305) is the preferred test to investigate bioaccumulation (ECHA Guidance R.7c, R.7.10.3.1). Whenever technically feasible, the aqueous route of exposure (OECD TG 305-I) must be used as the results obtained can be used directly for comparison with the B and vB criteria of Annex XIII of REACH. If testing through aquatic exposure is technically not possible, you must provide scientifically valid justification for the infeasibility. In case you conduct the study using the dietary exposure route (OECD 305-III), you must also attempt to estimate the corresponding BCF value from the dietary test data according to Annex 8 of the OECD 305 TG and OECD Guidance Document on Aspects of OECD TG 305 on Fish Bioaccumulation, ENV/JM/MONO (2017)16. In any case you must report all data derived from the dietary test as listed in the OECD TG 305-III.

Appendix B: Procedural history

ECHA received your registration containing the testing proposals for examination on 20 June 2019.

ECHA held a third party consultation for the testing proposals from 27 January 2020 until 12 March 2020. ECHA did not receive information from third parties.

For the purpose of the decision-making, this decision does not take into account any updates of registration dossiers after the date on which you were notified the draft decision according to Article 50(1) of REACH.

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

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

In your comments you agreed to perform the test and asked for extension of the deadline. ECHA took your comments into account and amend the deadline as explained below.

Deadline to submit the requested information in this decision

In the draft decision communicated to you, the time indicated to provide the requested information was 9 months from the date of adoption of the decision. In your comments on the draft decision the Lead registrant (LR) agreed to perform the requested test and asked ECHA to extend the standard granted time to a total of 16 months to ensure adequate time to synthesize the test material, perform the bioaccumulation study and update the registration dossier including the chemical safety assessment (CSA). Furthermore, a member of the Joint Submission [redacted] requested an additional 3 months extension to the timeline proposed by the Lead registrant for a total of 19 months based on possible delays by CROs arising from current Covid-19 circumstances as well as due to possible technical difficulties arising if substance metabolises and therefore identification of metabolites is needed.

ECHA acknowledges difficulties arising from the synthesis of the radiolabelled test material and the development of analytical method for identification of metabolites as described in your comments to this decision. ECHA took into account the reasoning for extension of deadlines provided by the registrants. Balancing all arguments brought forward, ECHA believes that a deadline 15 months from the adoption of the decision is sufficient to enable performing and submitting the study under the current circumstances.

Therefore, ECHA has only partially granted the request and set the deadline to 15 months.

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

As no amendments were proposed, ECHA adopted the decision under Article 51(3) of REACH.

Appendix C: Observations and technical guidance

1. This testing proposal examination decision does not prevent ECHA from initiating compliance checks at a later stage on the registrations present.

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 your Member State(s).

3. Test guidelines, GLP requirements and reporting

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

   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.

   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: 'How to report robust study summaries'[2].

4. Test material

   Selection of the test material(s)

   The registrants of the Substance are responsible for agreeing on the composition of the test material to be selected for carrying out the tests required by the present decision. The test material selected must be relevant for all the registrants of the Substance, i.e. it takes into account the variation in compositions reported by all members of the joint submission. The composition of the test material(s) must fall within the boundary composition(s) of the Substance.

   While selecting the test material you must take into account the impact of each constituent/impurity is known to have or could have 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.

   Technical reporting of the test material

   The composition of the selected test material must be reported in the respective endpoint study record, under the Test material section. The composition must include all constituents of the test material and their concentration values. Without such detailed reporting, ECHA may not be able to confirm that the test material is relevant for the Substance and to all the registrants of the Substance.

   Technical instructions are available in the manual "How to prepare registration and PPORD dossiers"[3].

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

5. List of references of the ECHA Guidance and other guidance/ reference documents[4]

QSARs, read-across and grouping
Guidance on information requirements and chemical safety assessment, Chapter R.6 (version 1.0, May 2008), referred to as ECHA Guidance R.6 in this decision.

ECHA Read-across assessment framework (RAAF, March 2017)[5]

Toxicology
Guidance on information requirements and chemical safety assessment, Chapter R.7a (version 6.0, July 2017), referred to as ECHA Guidance R.7a in this decision.

Guidance on information requirements and chemical safety assessment, Chapter R.7c (version 3.0, June 2017), referred to as ECHA Guidance R.7c in this decision.

Environmental toxicology and fate
Guidance on information requirements and chemical safety assessment, Chapter R.7a (version 6.0, July 2017), referred to as ECHA Guidance R.7a in this decision.

Guidance on information requirements and chemical safety assessment, Chapter R.7b (version 4.0, June 2017), referred to as ECHA Guidance R.7b in this decision.

Guidance on information requirements and chemical safety assessment, Chapter R.7c (version 3.0, June 2017), referred to as ECHA Guidance R.7c in this decision.

PBT assessment
Guidance on information requirements and chemical safety assessment, Chapter R.11 (version 3.0, June 2017), referred to as ECHA Guidance R.11 in this decision.

Guidance on information requirements and chemical safety assessment, Chapter R.16 (version 3.0, February 2016), referred to as ECHA Guidance R.16 in this decision.

OECD Guidance documents
Guidance Document on aqueous-phase aquatic toxicity testing of difficult test chemicals – No 23, referred to as OECD GD 23.

Guidance Document on Standardised Test Guidelines for Evaluating Chemicals for Endocrine Disruption – No 150, referred to as OECD GD 150.

[4] https://echa.europa.eu/guidance-documents/guidance-on-information-requirements-and-chemical-safety-assessment
[5] https://echa.europa.eu/support/registration/how-to-avoid-unnecessary-testing-on-animals/grouping-of-substances-and-read-across

Appendix D: List of the registrants to which the decision is addressed and the corresponding information requirements applicable to them

Registrant Name	Registration number	(Highest) Data requirements to be fulfilled
[redacted]	[redacted]	[redacted]

Note: where applicable, the name of a third party representative (TPR) may be displayed in the list of recipients whereas the decision is sent to the actual registrant.