

Helsinki, 15 May 2020

**Addressees**

Registrants of JS\_benzyltoluene listed in the last Appendix of this decision

**Date of submission for the jointly submitted dossier subject of a decision**

11/04/2019

**Registered substance subject to this decision, hereafter 'the Substance'**

Substance name: Benzyltoluene

EC number: 248-654-8

CAS number: 27776-01-8

**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 **22 November 2021**.

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

1. Long-term toxicity testing on aquatic invertebrates (Annex IX, Section 9.1.5.; test method EU C.20./OECD TG 211)
2. Long-term toxicity testing on fish (Annex IX, Section 9.1.6.1.; test method OECD TG 210)

**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 to IX of REACH, if you have registered a substance at 100-1000 tpa;
- you have to comply with the requirements of Annexes VII to X of REACH, if you have registered a substance at above 1000 tpa.

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

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>.

Authorised<sup>1</sup> under the authority of Christel Schilliger-Musset, Director of Hazard Assessment

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<sup>1</sup> 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 IX of REACH**

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

**1. Long-term toxicity testing on aquatic invertebrates (Annex IX, Section 9.1.5.)**

Long-term toxicity testing on aquatic invertebrates is a standard information requirement in Annex IX to the REACH Regulation.

You have submitted a testing proposal for a *Daphnia magna* Reproduction Test (OECD TG 211).

To support the testing proposal, you indicate that there is currently no GLP study available on long-term toxicity to aquatic invertebrates for the Substance.

ECHA agrees with your assessment and that OECD TG 211 is an appropriate method to study long-term toxicity to aquatic invertebrates. Consequently, under Article 40(3)(a) of the REACH Regulation, you are required to carry out the proposed test.

*Study design*

Due to the low solubility of the substance in water, you need to consult the OECD Guidance Document (GD) 23/ OECD GD 23 and ECHA Guidance, Chapter R7b, Table R.7.8-3 relating to the aquatic toxicity testing of difficult substances, so that you choose the most appropriate design of the requested ecotoxicity test and you best calculate and report the results of the test.

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

Long-term toxicity testing on fish is a standard information requirement in Annex IX to REACH.

You have submitted a testing proposal for Fish, Early-life Stage Toxicity Test (OECD TG 210).

To support the testing proposal, you indicate that there is currently no GLP study available on long-term toxicity to fish for the Substance.

ECHA agrees with your assessment and that OECD TG 210 is an appropriate method to study long-term toxicity to fish. Consequently, under Article 40(3)(a) of the REACH Regulation, you are required to carry out the proposed test.

*Study design*

Due to the low solubility of the substance in water, you need to consult the OECD Guidance Document (GD) 23/ OECD GD 23 and ECHA Guidance, Chapter R7b, Table R.7.8-3 relating to the aquatic toxicity testing of difficult substances, so that you choose the most appropriate design of the requested ecotoxicity test and you best calculate and report the results of the test.

**Appendix B: Procedural history**

ECHA started the testing proposal evaluation in accordance with Article 40(1) on 11 April 2019.

ECHA held a third party consultation for the testing proposals from 25 June 2019 until 9 August 2019. 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 within 30 days of the notification.

ECHA took into account your comments and amended the deadline.

The timeline indicated in the draft decision to provide the information requested is 10 months from the date of adoption of the decision. In your comments on the draft decision, you requested an extension of the timeline to 15 months. You justified your request stating that you anticipate technical difficulties for testing this poorly water soluble substance and provided a statement supporting this timeline from the test laboratory.

Therefore, ECHA has modified the deadline of the decision 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'<sup>2</sup>.

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"<sup>3</sup>.

<sup>2</sup> <https://echa.europa.eu/practical-guides>

<sup>3</sup> <https://echa.europa.eu/manuals>

5. List of references of the ECHA Guidance and other guidance/ reference documents<sup>4</sup>

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.

OECD Guidance documents

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

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<sup>4</sup> <https://echa.europa.eu/guidance-documents/guidance-on-information-requirements-and-chemical-safety-assessment>

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

<b>Registrant Name</b>	<b>Registration number</b>	<b>(Highest) Data requirements to be fulfilled</b>
[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.