Helsinki, 1 April 2020

Addressees
Registrants of JS_ditolyl ether listed in the last Appendix of this decision

Date of submission for the jointly submitted dossier subject of a decision
12/07/2019

Registered substance subject to this decision, hereafter 'the Substance'
Substance name: Ditolyl ether
EC number: 248-948-6
CAS number: 28299-41-4

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 ***8 April 2021***.

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

1. Long-term toxicity on terrestrial invertebrates (Annex IX, Section 9.4.1., column 2; test method: Earthworm reproduction test (OECD TG 222) with the Substance;

2. 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) with the Substance;

3. Effects on soil micro-organisms (Annex IX, Section 9.4.2.; test method: EU C.21/OECD TG 216) with the Substance.

Conditions to comply with the requests

You are bound by the requests for information corresponding to the REACH Annexes applicable to your own registered tonnage of the Substance at the time of evaluation.

Therefore, you have to comply with the requirements of Annexes VII to X of REACH, if you have registered a substance at above 1000 tpa.

Appendix A states the reasons for the requests for information to fulfil the requirements set out in the respective Annexes 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 IX of REACH

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

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

Effects on terrestrial organisms is a standard information requirement in Annex IX, Section 9.4. to REACH. The requirement must be addressed for different taxonomic groups: invertebrates, soil micro-organisms and terrestrial plants. Column 2 of section 9.4 of Annex IX specifies that long-term toxicity testing must be considered instead of short-term, in particular for substances that have a high potential to adsorb to soil or that are very persistent.

You have submitted a testing proposal for a long-term toxicity test to terrestrial invertebrates (Earthworm reproduction test (*Eisenia fetida/Eisenia andrei*), OECD TG 222).

According to the provided information, the Substance has a high potential to adsorb to soil (logKow = 4.9) and is potentially very persistent (default setting for non-readily biodegradable substances when half-life in soil is not available, Section R.7.11.5.3 of ECHA Guidance R.7c).

ECHA agrees that a long-term testing is required and the proposed test is appropriate to fulfil the information requirement of Annex IX, Section 9.4.1.

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

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

The effects on terrestrial organisms is a standard information requirement in Annex IX, Section 9.4. to REACH. The requirement must be addressed for different taxonomic groups: invertebrates, soil micro-organisms and terrestrial plants. Column 2 of section 9.4 of Annex IX specifies that long-term toxicity testing must be considered instead of short-term, in particular for substances that have a high potential to adsorb to soil or that are very persistent.

You have submitted a testing proposal for a long-term toxicity test to terrestrial plants (Terrestrial Plants Test: Seedling Emergence and Seedling Growth Test, OECD TG 208).

According to the provided information, the Substance has a high potential to adsorb to soil and is potentially very persistent, as explained in section 1 above.

Therefore, ECHA agrees that a long-term testing is required and the proposed test is appropriate to fulfil the information requirement.

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

Test design

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 208 guideline.

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

Effects on terrestrial organisms is a standard information requirement in Annex IX, Section 9.4. to REACH. The requirement must be addressed for different taxonomic groups: invertebrates, soil micro-organisms and terrestrial plants.

You have submitted a testing proposal for soil micro-organisms test (Soil Microorganisms: Nitrogen Transformation Test, OECD TG 216).

Because your dossier does not contain the required information, ECHA agrees that the effects on soil microorganisms need to be ascertained by performing a relevant test and that the proposed test is appropriate to fulfil the information requirement of Annex IX, Section 9.4.2.

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

Appendix B: Procedural history

ECHA started the testing proposal evaluation in accordance with Article 40(1) on 15 July 2019.

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 did not receive any comments within the 30-day notification period.

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. The substance subject to the present decision is listed in the Community rolling action plan (CoRAP) and is under substance evaluation.

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

3. 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).

4. 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].

5. 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.

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

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

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

Environmental toxicology and fate
Guidance on information requirements and chemical safety assessment, Chapter R.7a (version 6.0, July 2017).

Guidance on information requirements and chemical safety assessment, Chapter R.7b (version 4.0, June 2017).

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).

[3] https://echa.europa.eu/manuals
[4] 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

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.