Helsinki, 18 May 2020

Addressees
Registrants of "C14-17 alkanes, sec-mono- and disulfonic acids, phenyl esters" listed in the last Appendix of this decision

Date of submission for the jointly submitted dossier subject of a decision
16 July 2018

Registered substance subject to this decision, hereafter 'the Substance'
Substance name: C14-17 alkanes, sec-mono- and disulfonic acids, phenyl esters
EC number: 701-257-8
CAS number: NS

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 ***25 May 2022***.

A. Requirements applicable to all the Registrants subject to Annex X of REACH[1]

1. Pre-natal developmental toxicity study (Annex X, Section 8.7.2.; test method OECD TG 414) in a second species (rabbit), oral route.

Conditions to comply with the request

You have registered the Substance at more than 1000 tonnes per year, and therefore you have to comply with the requirements of Annexes VII to X of REACH.

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

The test material used to perform the required study must be selected and reported in accordance with the specifications prescribed in Appendix C.

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.

[1] Testing required under this Annex can only be started or performed after the decision has been adopted according to Article 51.

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[2] under the authority of Christel Schilliger-Musset, Director of Hazard Assessment

[2] 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 requirement applicable to all the Registrants subject to Annex X of REACH

This decision is based on the examination of the testing proposal you submitted. The ECHA Guidance documents referred to in this decision are listed in Appendix C of this decision.

1. **Pre-natal developmental toxicity study (Annex X, Section 8.7.2., column 2) in a second species;**

Pre-natal developmental toxicity (PNDT) studies on two species are part of the standard information requirements for substance registered for 1000 tonnes or more per year (Annex IX, Section 8.7.2., column 1, Annex X, Section 8.7.2., column 1, and sentence 2 of introductory paragraph 2 of Annex X of the REACH Regulation).

You have submitted a testing proposal for a PNDT study to be conducted according to OECD TG 414.

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.

You did not specify the second species to be used for testing. The test in the first species was carried out using rats. According to the test method OECD TG 414, the rat is the preferred rodent species and the rabbit the preferred non-rodent species. On the basis of this default consideration, testing should be performed with the rabbit as a second species.

You did not specify the route for testing. The oral route is the most appropriate route of administration to investigate reproductive toxicity as indicated in ECHA Guidance R.7a. The study must be performed using the oral route.[3]

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

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 18 months from the date of adoption of the decision. In your comments on the draft decision you requested ECHA to extend the standard granted time to a total of 24 months based on the complex nature of the study with your Substance and limited laboratory capacities.

ECHA agreed with your request and the deadline was extended to 24 months.

[3] ECHA Guidance R.7a, Section R.7.6.2.3.2.

Appendix B: Procedural history

ECHA started the testing proposal evaluation in accordance with Article 40(1) on 20 July 2018.

ECHA held a third party consultation for the testing proposal from 10 August 2018 until 24 September 2018. 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 of the draft decision according to Article 50(1) of the REACH.

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.

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 on the present registrations 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 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, 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'[4].

4. Test material

   Selection of the test material(s) for UVCB substances

   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 in 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 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. Any constituent that has a harmonised classification and labelling, according to the CLP Regulation (Regulation (EC) No 1272/2008) must be identified and quantified using the appropriate analytical methods.

   The OECD Series on Principles of Good Laboratory Practice and Compliance Monitoring, Number 11 [ENV/MC/CHEM(98)16] requires a careful identification of the test material and description of its characteristics. The Test Methods Regulation (EU) 440/2008, as amended by Regulation (EU) 2016/266, requires that "*if the test method is used for the testing of a* [...] *UVCB* [...], *sufficient information on its composition should be made available, as far as possible, e.g. by the chemical identity of its constituents, their quantitative occurrence, and relevant properties of the constituents*".

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

In order to meet this requirement, all the constituents of the test material used for each test shall be identified as far as possible. For each constituent the concentration value in the test material shall be reported in the Test material section of the endpoint study record.

Technical reporting of the test material for UVCB substances

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" on the ECHA website[5].

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

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.

[5] https://echa.europa.eu/manuals
[6] 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 of the corresponding information requirements applicable to them

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