~~Confidential~~

Helsinki, 5 August 2020

Addressee
Registrant of 1,2,4,5,7,8-Hexoxonane, 3,6,9-trimethyl-, 3,6,9-tris(Ethyl and Propyl) derivatives (upper limit: 41% w/w; typical concentration: 38% w/w) listed in the last Appendix of this decision

Date of submission for the jointly submitted dossier subject of a decision
24/01/2019

Registered substance subject to this decision, hereafter 'the Substance'
Substance name: 1,2,4,5,7,8-Hexoxonane, 3,6,9-trimethyl-, 3,6,9-tris(Ethyl and Propyl) derivatives (upper limit: 41% w/w; typical concentration: 38% w/w)
EC number: [redacted]
CAS number: [redacted]

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 ***14 February 2022***.

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

1. Simulation testing on ultimate degradation in surface water (Annex IX, Section 9.2.1.2.; test method EU C.25./OECD TG 309) at a temperature of 12 °C;

2. Identification of degradation products (Annex IX, Section 9.2.3.) using an appropriate test method;

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 IX 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. **Simulation testing on ultimate degradation in surface water (Annex IX, Section 9.2.1.2.)**

Examination of the testing proposal

Simulation testing on ultimate degradation in surface water is a standard information requirement in Annex IX to REACH.

You have submitted a testing proposal for a surface water simulation test (OECD 309).

In the draft decision notified to you, ECHA considered that the proposed study fulfils the information requirement.

Study design

OECD TG 309 is an appropriate method for studying the degradation in surface water. However, when performing the OECD TG 309 test, the pelagic test option with natural surface water containing approximately 15 mg dw/L of suspended solids (acceptable concentration between 10 and 20 mg dw/L) shall be followed (ECHA Guidance R.11).

Annex XIII indicates that information used for PBT/vPvB assessment shall be obtained under relevant conditions. Therefore, simulation tests should be performed at the temperature of 12 °C, the average environmental temperature for the EU (ECHA Guidance R.16, Table R.16-8). Performing the test at this temperature is in line with the applicable test conditions of the OECD TG 309.

Quantification of non-extractable residues (NER) needs to be carried out in all simulation studies. The reporting of results shall include a scientific justification of the used extraction procedures and solvents. By default, total NER is regarded as non-degraded substance. However, if reasonably justified and analytically demonstrated, a certain part of NER may be differentiated and quantified as irreversibly bound or as degraded to biogenic NER. Such fractions could be regarded as removed when calculating the degradation half-life(s) (ECHA Guidance R.11).

Annex XIII requires assessment of relevant constituents of a substance for PBT/vPvB assessment. The biodegradation of each relevant constituent present in concentration at or above 0.1% (w/w) or, if not technically feasible, in concentrations as low as technically detectable shall be assessed. This can be done simultaneously during the same study. Alternatively, you shall provide a justification for why you consider these as not relevant for the PBT/vPvB assessment.

If you should encounter technical difficulties to perform the requested OECD TG 309 test, such difficulties and attempted solutions should be clearly demonstrated and documented.

Your comments on the draft decision

In your comments you indicated that you wish to withdraw your testing proposal for this study because you now consider that the study is not possible for technical reasons. Instead you request to discuss if there are alternatives to the OECD 309 or if the bioaccumulation should

be investigated instead.

ECHA understands from your comments that you intend to adapt the information requirement in accordance with Annex IX, Section 2 of REACH.

We have assessed your comment and identified the following issue:

Under Section 2 of Annex XI to REACH, a study may be omitted if it is technically not possible to conduct because of the properties of the substance. OECD TG 309, in particular its technical limitations, must always be respected.

As regards the technical difficulties you argue in your comments that:

1) You were advised by two laboratories that they cannot prepare a radiolabelled sample of the Substance because it is a triperoxide and there are safety concerns due to the instabililty and explosion risk. You indicate that you are not aware of any radiolabeling laboratory capable of handling such material.
2) It is not possible to devise an adequate analytical method for the non-radiolabelled substance to conduct the test at the maximum concentration of 100µg/l recommended in OECD 309, i.e. with a LoQ of at least 10% of the concentration tested.

As regards point 1) above, ECHA considers that it is in principle possible to prepare a sample of radiolabelled peroxide test material for simulation testing; for example this was done for Di-tert-butyl 3,3,5-trimethylcyclohexylidene diperoxide (EC 229-782-3), registered with a trade name Trigonox 29 (https://echa.europa.eu/registration-dossier/-/registered-dossier/13187/5/3/3).

As regards point 2), paragraph 5 of OECD TG 309 states: '*Higher concentrations of test substance (>100 µg/l and sometimes >1 mg/l) may be used for the identification and quantification of major transformation products or if a specific analysis method with a low detection limit is not available.*' Therefore the test guideline clearly allows for higher concentrations than 100µg/l in situations where the conduct of the study is limited by the available analytical methods.

Therefore, we reject the arguments in your comments that an OECD TG 309 is not technically possible.

Outcome

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

2. Identification of degradation products (Annex IX, 9.2.3.)

Identification of the degradation products is a standard information requirement in Annex IX to REACH.

You have not provided any information on the identification of degradation products, nor an adaptation in accordance with column 2 of Annex IX, Sections 9.2 or 9.2.3. or with the general rules of Annex XI for this standard information requirement.

Therefore, information on identification of degradation products is required.

Study selection and design

You should obtain this information from the simulation study also requested in this decision (Appendix C, section 1). If any other method is used for identification of the transformation/degradation products, you must provide a scientifically valid justification for the chosen method.

Identity, stability, behaviour, and molar quantity of the degradation/transformation products relative to the Substance shall be evaluated and reported, when analytically possible. In addition, degradation half-life, log Kow and potential toxicity of the metabolite must be investigated.

Your comments on the draft decision

In your comments you refer to the available modified Zahn-Wellens test (OECD 302B). You state that the theoretical degradants Methyl Ethyl Ketone (MEK) and methyl propyl ketone (MPK) were not detected and that no water soluble organic transformation products were detected by NMR in that study. You argue that it is probably impossible to develop an analytical method to detect degradants without knowing the identity of those degradants.

ECHA understands from your comments that you intend to adapt the information requirement in accordance with Annex IX, Section 2 of REACh.

As already explained in section A.1. above, we consider that it is possible to prepare radiolabelled test material and additionally according to OECD TG 309 it is possible to use concentrations of test substance (>100 µg/l and sometimes >1 mg/l) for the identification and quantification of major transformation products if a specific analysis method with a low detection limit is not available.

Outcome

Under Article 40(3)(c) of the REACH Regulation, you are requested to carry out the additional test, as indicated above.

Appendix B: Procedural history

ECHA started the testing proposal evaluation in accordance with Article 40(1) on 4 April 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

ECHA took into account your comments and did not amend the requests.

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]

Environmental toxicology and fate
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.

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.

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

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.