~~Confidential~~

Helsinki, 02 February 2022

Addressees
Registrants of JS_tert-butyl hydroperoxide as listed in the last Appendix of this decision

Date of submission of the dossier subject to this decision
02/07/2021

Registered substance subject to this decision ("the Substance")
Substance name: tert-butyl hydroperoxide
EC number: 200-915-7
CAS number: 75-91-2

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

DECISION ON A COMPLIANCE CHECK

Under Article 41 of Regulation (EC) No 1907/2006 (REACH), you must submit the information listed below, by the deadline of ***7 November 2023***.

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

A. Information required from 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.; test method: OECD TG 210)

Reasons for the request(s) are explained in the following appendix entitled "Reasons to request information required under Annex IX of REACH".

Information required depends on your tonnage band

You must provide the information listed above for all REACH Annexes applicable to you, and in accordance with Articles 10(a) and 12(1) of REACH:

- the information specified in Annexes VII, VIII and IX to REACH, for registration at 100-1000 tpa;
- the information specified in Annexes VII to X to REACH, for registration at more than 1000 tpa.

You are only required to share the costs of information that you must submit to fulfil your information requirements.

How to comply with your information requirements

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

You must follow the general testing and reporting requirements provided under the Appendix entitled "Requirements to fulfil when conducting and reporting new tests for REACH purposes". For references used in this decision, please consult the Appendix entitled "List of references".

Appeal

This decision, when adopted under Article 51 of REACH, may be appealed to the Board of Appeal of ECHA within three months of its notification to you. Please refer to http://echa.europa.eu/regulations/appeals for further information.

Failure to comply

If you do not comply with the information required by this decision by the deadline indicated above, ECHA will notify the enforcement authorities of your Member State.

Authorised[1] under the authority of Mike Rasenberg, 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 to request information required under Annex IX of REACH

1. Long-term toxicity testing on aquatic invertebrates

Long-term toxicity testing on aquatic invertebrates is an information requirement under Annex IX to REACH (Section 9.1.5.).

You have provided the following information:

i. a justification to omit the study which you consider to be based on Annex IX, Section 9.1., Column 2. In support of your adaptation, you provided the following justification: "*In accordance with column 2 of REACH annex IX, long-term toxicity testing in aquatic invertebrates is not required as the chemical safety assessment does not indicate the need to investigate further effects on aquatic organisms.*"

We have assessed this information and identified the following issue:

Annex IX, Section 9.1., Column 2 does not allow omitting the need to submit information on long-term toxicity to aquatic invertebrates under Column 1. It must be understood as a trigger for providing further information on aquatic invertebrates if the chemical safety assessment according to Annex I indicates the need (Decision of the Board of Appeal in case A-011-2018).

Your adaptation is therefore rejected.

In the comments to the draft decision, you propose to adapt this information requirement by means of grouping and read-across approach according to Annex XI, section 1.5 of the REACH Regulation. You indicate your intention to "*update the dossier with a read-across rationale to structurally similar substances*" and you state that "*If this rationale is rejected*", you agree to conduct the requested study.

However, the information in your comments is not sufficient for ECHA to make an assessment, because while you have described your intention to provide a read-across adaptation, you have not provided any new scientific information addressing the information requirement. Please note that this decision does not take into account updates of the registration dossiers after the date on which you were notified of the draft decision according to Article 50(1) of REACH (see section 5.4. of ECHA's Practical Guide "How to act in Dossier Evaluation"). You remain responsible for complying with this decision by the set deadline.

On this basis, the information requirement is not fulfilled.

2. Long-term toxicity testing on fish

Long-term toxicity testing on fish is an information requirement under Annex IX to REACH (Section 9.1.6.).

You have provided the following information in the dossier:

i. a justification to omit the study which you consider to be based on Annex IX, Section 9.1., Column 2. In support of your adaptation, you provided the following justification: "*In accordance with column 2 of REACH annex IX, long-term toxicity testing in fish is not required as the chemical safety assessment does not indicate the need to investigate further effects on aquatic organisms.*"

We have assessed this information and identified the following issue:

Annex IX, Section 9.1., Column 2 does not allow omitting the need to submit information on long-term toxicity to fish under Column 1. It must be understood as a trigger for providing

further information on long-term toxicity to fish if the chemical safety assessment according to Annex I indicates the need (Decision of the Board of Appeal in case A-011-2018).

Your adaptation is therefore rejected.

In the comments to the draft decision, you state that " *registrants have an obligation under REACH Article 13 and Annex VI to consider all available sources of information before committing to conduct of vertebrate animal testing"*. Therefore, you indicate that before conducting the requested study, you will "*conduct a full evaluation of other data sources*".

First, you propose to adapt this information requirement by means of grouping and read-across approach according to Annex XI, section 1.5 of the REACH Regulation. You indicate your intention to "*update the dossier with a read-across rationale to structurally similar substances*" and to use "*existing long-term aquatic vertebrate tests with structural analogues*".

Second, you state that "*If this rationale is rejected*", you agree to conduct the requested study sequentially to the long-term toxicity to aquatic invertebrates study (request A.1). You consider that it is "*premature to issue a decision on this endpoint before a read-across proposal has been considered or testing has been concluded on the non-vertebrate studies such as Annex IX, Section 9.1.5.*"

ECHA has assessed the information provided in the comments and identified the following issue(s):

(i) regarding your claim on the need to consider other sources of information before proceeding with vertebrate animal testing

ECHA notes that Annex VI and also Article 25(1) of REACH indicate that testing on vertebrate animals must be undertaken only as a last resort. According to Article 13(1), information on intrinsic properties of substances may be generated by means other than tests, provided that the conditions set out in Annex XI are met.

However, the information provided in the comments does not meet the conditions set out in Annex XI, as explained in points (ii) and (iii) below. When the conditions for an adaptation are not met and there is a data gap, ECHA has the duty to request the missing study, which is a standard information requirement and ECHA does not breach the principle of testing as last resort in Article 25(1) and Annex VI of the REACH Regulation by requesting the study.

(ii) regarding your proposal to adapt this information requirement under Annex XI, section 1.5

The information in your comments is not sufficient for ECHA to make an assessment, because while you have indicated your intention to provide a read-across adaptation, you have not provided any new scientific information addressing the information requirement. Please note that this decision does not take into account updates of the registration dossiers after the date on which you were notified of the draft decision according to Article 50(1) of REACH (see section 5.4. of ECHA's Practical Guide "How to act in Dossier Evaluation"). You remain responsible for complying with this decision by the set deadline.

(iii) regarding your claim that the decision on long-term fish testing should be taken only after long-term testing to aquatic invertebrates

A registrant may only adapt this information requirement based on the general rules set out in Annex XI. As explained above, the Column 1 information requirement cannot be adapted based on the Column 2 referring to the Chemical Safety Assessment.

In your comments to the draft decision, you indicate that you will consider conducting the requested study only after performing the long-term toxicity study to aquatic invertebrates (request A.1). On this basis, you request to perform the long-term toxicity to fish study conditionally to the long-term toxicity to aquatic invertebrates study. You also indicate that sequential testing is needed "*to support study design (e.g., dose selection) in the long term aquatic vertebrate test.*"

While you have not specified how you intend to use information on long-term toxicity to aquatic invertebrates to conclude on this standard information requirement, ECHA notes that this argument does not correspond to any adaptation possibility under Annex XI.

In addition, ECHA considers that your claim that long-term toxicity to aquatic invertebrates is needed to support study design (e.g. dose selection) of the long-term toxicity to fish study is not a valid justification for sequential testing. As explained in par. 22 of OECD TG 210, selecting the range of test concentrations should be based on information on short-term toxicity to fish (which is provided in the dossier for the Substance) and/or range-finding studies, and also on other available information on fish toxicity. Therefore there is no need for information on long-term toxicity to aquatic invertebrates for the dose selection of the long-term toxicity to fish study.

In conclusion, in your comments you have not provided any acceptable reason why long-term toxicity to fish should be conducted conditionally to long-term toxicity to aquatic invertebrates (request A.1). Since there is a data gap for both endpoints, ECHA requests that these studies are conducted in parallel.

On this basis, the information requirement is not fulfilled.

Appendix B: Requirements to fulfil when conducting and reporting new tests for REACH purposes

A. Test methods, GLP requirements and reporting

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

2. 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.

3. 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 on How to report robust study summaries[2].

B. Test material

Before generating new data, you must agree within the joint submission on the chemical composition of the material to be tested (Test Material) which must be relevant for all the registrants of the Substance.

1. Selection of the Test material(s)

   The Test Material used to generate the new data must be selected taking into account the following:
   - the variation in compositions reported by all members of the joint submission,
   - the boundary composition(s) of the Substance,
   - 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.

2. Information on the Test Material needed in the updated dossier
   - You must report the composition of the Test Material selected for each study, under the "Test material information" section, for each respective endpoint study record in IUCLID.
   - The reported composition must include all constituents of each Test Material and their concentration values and other parameters relevant for the property to be tested.

This information is needed to assess whether the Test Material is relevant for the Substance and whether it is suitable for use by all members of the joint submission.

Technical instructions on how to report the above is available in the manual on How to prepare registration and PPORD dossiers[3].

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

Appendix C: Procedure

This decision does not prevent ECHA from initiating further compliance checks at a later stage on the registrations present.

ECHA followed the procedure detailed in Articles 50 and 51 of REACH.

The compliance check was initiated on 01 February 2021.

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

ECHA took into account your comments and did not amend the request(s).

Deadline to provide the information

In the comments to the draft decision, you requested an extension of the deadline to provide the information from 12 to 24 months from the date of adoption of the decision. You considered that the extension of 12 months is needed for completion of the testing and data submission. Specifically, you considered that additional time is needed a) for the development of a sufficiently sensitive analytical method; b) due to the limited capacity of testing laboratories; c) for the submission of the final studies using "*the most recent IUCLID version*" and d) for conducting long-term toxicity to fish (request A.2) sequentially to long-term toxicity to aquatic invertebrates (request A.1).

ECHA acknowledges that extra time may be needed to develop a suitable analytical method and providing an additional six months is considered as sufficient for that purpose. Further extension of the deadline is considered not justified because: a) you have not provided any documentary evidence as requested by ECHA to substantiate your request based on the limited capacity of the laboratory; b) the deadline already included time for the submission of the information in an updated registration dossier; c) long-term toxicity to fish must be run in parallel to long-term toxicity to aquatic invertebrates, as explained in request A.2. On this basis, ECHA has extended the deadline to 18 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 D: List of references - ECHA Guidance[4] and other supporting documents

Evaluation of available information
Guidance on information requirements and chemical safety assessment, Chapter R.4 (version 1.1., December 2011), referred to as ECHA Guidance R.4 where relevant.

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 where relevant.

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

RAAF - considerations on multiconstituent substances and UVCBs (RAAF UVCB, March 2017)[6]

Physical-chemical properties
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.

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.

Data sharing
Guidance on data-sharing (version 3.1, January 2017), referred to as ECHA Guidance on data sharing in this decision.

OECD Guidance documents[7]

[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
[6] https://echa.europa.eu/documents/10162/13630/raaf_uvcb_report_en.pdf/3f79684d-07a5-e439-16c3-d2c8da96a316
[7] http://www.oecd.org/chemicalsafety/testing/series-testing-assessment-publications-number.htm

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

Guidance document on transformation/dissolution of metals and metal compounds in aqueous media – No 29, referred to as OECD GD 29.

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

Guidance Document supporting OECD test guideline 443 on the extended one-generation reproductive toxicity test – No 151, referred to as OECD GD 151.

Appendix E: Addressees of this decision and their corresponding information requirements

You must provide the information requested in this decision for all REACH Annexes applicable to you.

Registrant Name	Registration number	Highest REACH Annex applicable to you
[redacted]	[redacted]	[redacted]
[redacted]	[redacted]	[redacted]
[redacted]	[redacted]	[redacted]

Where applicable, the name of a third party representative (TPR) may be displayed in the list of recipients whereas ECHA will send the decision to the actual registrant.