~~Confidential~~

Helsinki, 08 November 2021

Addressees
Registrants of JS_1879-09-0 listed in the last Appendix of this decision

Date of submission of the dossier subject of a decision
04/08/2020

Registered substance subject to this decision, hereafter 'the Substance'
Substance name: 6-tert-butyl-2,4-xylenol
EC number: 217-533-1
CAS number: 1879-09-0

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

DECISION ON TESTING PROPOSAL(S)

Based on Article 40 of Regulation (EC) No 1907/2006 (REACH), you must submit the information listed below by ***15 May 2023***.

The requested information must be generated using the Substance unless otherwise specified.

A. Information required from the Registrants subject to Annex IX of REACH

1. Pre-natal developmental toxicity study (Annex IX, Section 8.7.2.; test method: EU B.31./OECD TG 414) by oral route, in one species (rat or rabbit)

2. 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. Non-extractable residues (NER) must be quantified and a scientific justification of the selected extraction procedures and solvents must be provided.

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

4. Long-term toxicity testing on terrestrial invertebrates (triggered by Annex IX, Section 9.4.1., column 2; test method: OECD TG 222 or 220 or 232)

B. Reasons to reject testing proposals under Annex IX of REACH

1. Soil simulation testing (Annex IX, Section 9.2.1.3.; test method: EU C.23./OECD TG 307)

2. Sediment simulation testing (Annex IX, Section 9.2.1.4.; test method: EU C.24./OECD TG 308)

Reasons for the request(s) are explained in Appendix A entitled "Reasons to request information required under Annex IX of REACH". The reasons for the rejection of some of your testing proposal(s) are explained under Appendix B entitled "Reasons to reject testing proposal(s) under Annex IX of REACH". In case a testing proposal is rejected, no

assessment(s) of the adequacy of the proposed test(s) for the corresponding REACH information requirements(s) and/or of the proposed test material((s)) were performed.

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.

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 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 to request information required under Annex IX of REACH

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

1. Pre-natal developmental toxicity study

A pre-natal developmental toxicity (PNDT) study (OECD 414) in one species is an information requirement under Annex IX to REACH (Section 8.7.2.).

1.1. Information provided to fulfil the information requirement

You have submitted a testing proposal for a PNDT study according to OECD TG 414 with the Substance.

ECHA requested your considerations for alternative methods to fulfil the information requirement for Developmental toxicity. You provided your considerations concluding that there were no alternative methods which could be used to adapt the information requirement(s) for which testing is proposed. ECHA has taken these considerations into account.

ECHA agrees that a PNDT study in a first species is necessary.

1.2. Specification of the study design

You proposed testing in the rat as a first species. You may select between the rat or the rabbit because both are preferred species under the OECD TG 414 (ECHA Guidance R.7a, Section R.7.6.2.3.2.).

You did not specify the route for testing. The oral route of administration is the most appropriate to investigate reproductive toxicity (ECHA Guidance R.7a, Section R.7.6.2.3.2.).

1.3. Outcome

Your testing proposal is accepted under Article 40(3)(a) and you are requested to conduct the test with the Substance, as specified above.

2. Simulation testing on ultimate degradation in surface water

Simulation testing on ultimate degradation in surface water is an information requirement under Annex IX to REACH (Section 9.2.1.2.).

Under Article 40(3)(c) of REACH, ECHA may require a registrant to carry out one or more additional tests in case of non-compliance of the testing proposal with Annexes IX, X or XI of the REACH Regulation. The endpoint on Degradation (Section 9.2.) at Annex IX requires to provide information on Biotic degradation (Section 9.2.1.) on relevant environmental compartments (i.e., surface water, sediment and soil) and on the identity of degradation products (Section 9.2.3.) for the Substance. You have submitted a testing proposal for soil simulation testing (Section 9.2.1.3.) and sediment simulation testing (Section 9.2.1.4.) only. In case of data gap for Simulation testing on ultimate degradation in surface water, it is necessary to request this information as an additional test to ensure compliance with the endpoint.

2.1 Information needed to fulfil the information requirement

Your registration dossier does not include any information on simulation testing on ultimate degradation in surface water. Instead, you have provided the following justifications to omit the study:

i. an adaptation under Annex IX, Section 9.2.1.2, column 2, first indent with the following justification: *"the substance is of low solubility in water, and hence evaluation of this endpoint is considered to be technically unfeasible"*;
ii. a statement that "*further investigation of biodegradation in surface water and sediment is not required as these are not the main endpoint for exposure*".

We have assessed this information and identified the following issues:

A. Under Annex IX, Section 9.2.1.2, column 2, first indent, the study may be omitted if the substance is highly insoluble in water. This may be the case, for instance, if the saturation concentration of the substance is so low that the test may be practically difficult or impossible to conduct at concentrations below the water solubility limit of the substance (ECHA Guidance R.7.9.2.3.). Therefore, to demonstrate high insolubility, the specific technical limitations of the test method(s) referred to in Article 13(3) of REACH must always be respected. For a simulation testing on ultimate degradation in surface water in water, the OECD TG 309 specifies that:
   - for the determination of biodegradation kinetics, the concentrations of the test substance must be below its water solubility, and
   - the limit of quantification (LOQ) should be equal to or less than 10% of the applied concentration.

   Considering the above, a simulation testing on ultimate degradation in surface water according to OECD TG 309 is considered technically feasible if the LOQ of a sensitive analytical method is at least ten times lower to the water solubility of the substance.

   The saturation concentration of the Substance in water was determined to be 120 mg/L (OECD TG 105). You have not provided any justification as to why an analytical method with sufficiently low sensitivity to conduct a degradation simulation study in surface water cannot be developed for the Substance.

   On this basis, you have not demonstrated that the saturation concentration of the substance is so low that the test may be practically difficult or impossible to conduct at concentrations below the water solubility limit of the substance. Therefore, your adaptation is rejected.

B. A registrant may only adapt this information requirement based on the specific rules set out in Annex IX, Section 9.2.1.2., column 2 or the general rules set out in Annex XI.

   Under point ii. above, you state that this information may be omitted as surface water is not the main compartment of concern for the Substance.

   Your justification to omit this information does not refer to any legal ground for adaptation under Annex IX, Section 9.2.1.2., column 2 or under Annex XI to REACH. Therefore, you have not demonstrated that this information can be omitted.

On this basis, the information requirement is not fulfilled.

2.2 Test selection and study specifications

The proposed Aerobic mineralisation in Surface Water – Simulation biodegradation test (test method: OECD TG 309) is appropriate to cover the information requirement for degradation/biodegradation (ECHA Guidance R.7.9.4.1).

Simulation degradation studies must include two types of investigations (ECHA Guidance R.7.9.4.1.):

1) a degradation pathway study where transformation/degradation products are quantified and, if relevant, are identified, and
2) a kinetic study where the degradation rate constants (and degradation half-lives) of the parent substance and of relevant transformation/degradation products are experimentally determined.

You must perform the test, by following 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) (ECHA Guidance R.11.4.1.1.3.).

The required test temperature is 12°C, which corresponds to the average environmental temperature for the EU (ECHA Guidance R.16, Table R.16-8) and is in line with the applicable test conditions of the OECD TG 309.

As specified in ECHA Guidance R.7.9.4.1., the organic carbon (OC) concentration in surface water simulation tests is typically 2 to 3 orders of magnitude higher than the test substance concentration and the formation of non-extractable residues (NERs) may be significant in surface water tests. Therefore, non-extractable residues (NER) must be quantified. The reporting of results must 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.11.4.1.1.3.). Further recommendations may be found in the background note on options to address non-extractable residues in regulatory persistence assessment available on the ECHA website.

Relevant transformation/degradation products are at least those detected at ≥ 10% of the applied dose at any sampling time or those that are continuously increasing during the study even if their concentrations do not exceed 10% of the applied dose, as this may indicate persistence (OECD TG 309; ECHA Guidance R.11.4.1.).

2.3 Outcome

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

3. Identification of degradation products

Identification of degradation products is an information requirement under Annex IX to REACH (Section 9.2.3.).

3.1 Information provided to fulfil the information requirement

You have submitted a testing proposal for the identification of degradation products. You propose to use the EAWAG Biocatalysis/Biodegradation Database Pathway Prediction System to provide the corresponding information.

Your registration dossier does not include any information on identification of degradation products.

ECHA agrees that an appropriate information on the Identification of degradation product is needed.

3.2 Specification of the study design

ECHA Guidance R.7.9.3.1. specifies that qualitative information on the identity of degradations products may be generated from a number of biodegradation pathways, most notably the EAWAG (former University of Minnesota) Biocatalysis/Biodegradation Database. However, the suitability of this data for the purpose of the hazard, persistence and risk assessment needs careful consideration and may only contribute as part of the Weight of Evidence assessment if other data are available, which ideally should include experimental data on the Substance. Therefore, your proposal to use only the results of EAWAG Biocatalysis/Biodegradation Database Pathway Prediction System cannot be accepted.

In all cases, the selection of appropriate and suitable method(s) will have to be substance specific. Identity, stability, behaviour, and molar quantity of the degradation/transformation products relative to the Substance must be evaluated and reported, when analytically possible. In addition, degradation half-life, log K_{ow} and potential toxicity of the transformation/degradation may need to be investigated. You may obtain this information from the degradation study requested in Appendix A.2. (as this information is part of the mandatory requirements of the test guideline) or by some other measures. If any other method is used for the identification of the transformation/degradation products, you must provide a scientifically valid justification for the chosen method.

To determine the degradation rate of the Substance, the requested study according to OECD TG 309 (Appendix A.2.) must be conducted at 12°C and at a test material application rate reflecting realistic assumptions. However, to overcome potential analytical limitations with the identification and quantification of major transformation/degradation products, you may consider running a parallel test at higher temperature (but within the frame provided by the test guideline) and at higher application rate (*e.g.* 10 times).

3.3 Outcome

Under Article 40(3)(b) of REACH, your testing proposal is accepted under modified conditions as specified above.

4. Long-term toxicity testing on terrestrial invertebrates

Short-term toxicity to invertebrates is an information requirement under Annex IX to REACH (Section 9.4.1). Long-term toxicity testing must be considered (Annex IX, Section 9.4., column 2) if the substance has a high potential to adsorb to soil or is very persistent.

Under Annex IX, Section 9.4., column 2, for substances that have a high potential to adsorb to soil or that are very persistent, long-term toxicity testing must be considered instead of short-term. ECHA Guidance R.7.11.5.3. clarifies that a substance is considered to be very persistent in soil if it has a half-life >180 days. In the absence of specific soil data, high persistence is assumed unless the substance is readily biodegradable.

Under Section 5.2.1. of your technical dossier you report two OECD TG 301C conducted with the Substance. The Substance showed 0% and 3-5% biodegradation after 28 days, respectively, and therefore the Substance is concluded not to be readily biodegradable. Your technical dossier does not include any specific soil biodegradation data.

Therefore, the Substance is concluded to be highly persistent in soil and information on long-term toxicity on terrestrial organisms must be provided.

4.1 Information provided to fulfil the information requirement

You have submitted a testing proposal for an Earthworm Reproduction Test (test method: OECD TG 222).

ECHA agrees that an appropriate study on long-term toxicity to terrestrial invertebrates is needed.

4.2 Test selection and study specifications

The proposed Earthworm Reproduction Test (test method: OECD TG 222) is appropriate to cover the information requirement for long-term toxicity on terrestrial invertebrates (ECHA Guidance R.7.11.3.1).

4.3 Outcome

Your testing proposal is accepted under Article 40(3)(a) and you are requested to conduct the test with the Substance, as specified above.

Appendix B: Reasons to reject testing proposal(s) under Annex IX of REACH

1. Soil simulation testing

Soil simulation testing is an information requirement under Annex IX to REACH (Section 9.2.1.3.) for substances with a high potential for adsorption to soil.

Substances with a log Koc > 4 are considered to have a high potential for adsorption to soil (ECHA Guidance R.7.9.4.3.).

The log Kow of the Substance was determined to be 3.64 (OECD TG 117). In addition, you have provided a predicted log Koc estimate of 3.1 (KOCWIN v 2.00). On this basis, the Substance is concluded to be not highly adsorptive to soil.

1.1. Information provided to fulfil the information requirement

You have submitted a testing proposal for an Aerobic and Anaerobic Transformation study in Soil according to OECD TG 307 with the Substance.

ECHA considers that this study is not needed to meet the information requirement of Section 9.2.1.3. of Annex IX as the Substance is not highly adsorptive to soil.

1.2. Outcome

Under Article 40(3)(d) of REACH, the proposed test is rejected.

2. Sediment simulation testing

Sediment simulation testing is an information requirement under Annex IX to REACH (Section 9.2.1.4.) for substances with a high potential for adsorption to sediment.

Substances with a log Koc > 4 are considered to have a high potential for adsorption to sediment (ECHA Guidance R.7.9.4.3.).

The Substance is concluded to be not highly adsorptive to sediment for the same reasons as developed under Section B.1 above.

2.1 Information provided to fulfil the information requirement

You have submitted a testing proposal for an Aerobic and Anaerobic Transformation study in Aquatic Sediment Systems according to OECD TG 308 with the Substance.

ECHA considers that this study is not needed to meet the information requirement of Section 9.2.1.4. of Annex IX as the Substance is not highly adsorptive to sediment.

2.2 Outcome

Under Article 40(3)(d) of REACH, the proposed test is rejected.

Appendix C: 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 D: Procedure

ECHA started the testing proposal evaluation in accordance with Article 40(1) on 28 August 2020.

ECHA held a third party consultation for the testing proposal(s) from 18 February 2021 until 5 April 2021. ECHA did not receive information from third parties.

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

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

ECHA did not receive any comments within the commenting 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 E: 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 multi-constituent 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 F: Addressees of this decision and the corresponding information requirements applicable to them

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]

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.