~~Confidential~~

Helsinki, 11 November 2021

Addressees
Registrants of CEM JS 79-74-3 listed in the last Appendix of this decision

Date of submission of the dossier subject of a decision
03/09/2020

Registered substance subject to this decision, hereafter 'the Substance'
Substance name: 2,5-di-tert-pentylhydroquinone
EC number: 201-222-2
CAS number: 79-74-3

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 ***18 August 2022***.

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. 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)

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

3. Long-term toxicity to terrestrial plants (triggered by Annex IX, Section 9.4.3., column 2; test method: EU C.31./OECD TG 208 with at least six species or ISO 22030)

Your following proposed test using the Substance is rejected, according to Article 40(3)(d):

Short-term toxicity to terrestrial invertebrates (Annex IX, Section 9.4.1.; test method: OECD TG 207)

Reasons for the requests are explained in Appendix entitled "Reasons to request information required under Annexes 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.

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 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. 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 (Section 9.4., column 2) if the substance has a high potential to adsorb to soil or is very persistent.

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. A substance is considered highly adsorptive to soil when e.g. it has a log Koc or log Kow > 5.

Under Section 5.2.1. of your technical dossier, you report 1% degradation after 38 days based on OECD TG 301B. Your technical dossier does not include any specific soil biodegradation data.

Under Section 4.7. of your technical dossier, you report a log Kow of 2.1 based on OECD TG 123. This study was requested in a previous substance evaluation decision. On 04 June 2020, you sent a communication to ECHA alerting that the value currently reported in your dossier is erroneous. In particular you stated the following: "*Following some questions raised by the UK Environment Agency, as the final report on substance evaluation was being compiled, we duly went back to the test laboratory to seek answers on the questions raised. The laboratory through this process discovered an issue whereby they reported an erroneous value for the Log Pow determined via the slow stir method. Root cause investigation is ongoing at the laboratory but this was most likely due to the use of an erroneous calculation factor due to multiple human errors independent from the registrant's sphere and knowledge. The log Pow reported was at 2.1 but now may be as high as 5.1*". This information indicates that the log Kow of the Substance is above 5.

Based on the above, the Substance is concluded to be potentially highly persistent in soil and has a high potential to adsorb to soil. Therefore, information on long-term toxicity on terrestrial organisms must be provided.

1.1. Information provided to fulfil the information requirement

You have submitted a testing proposal for an Earthworm, Acute Toxicity Test (test method: OECD TG 207) with the following justification: "*Long term toxicity data only became available for Fish at the end of July 2018. As such, it was determined that the PNEC aquatic was very low. In the absence of terrestrial data, the soil PNEC is derived using the equilibrium partitioning method which is based on the PNEC aquatic. However, in accordance with Table R.7.11-2 of Chapter R.7c – Endpoint Specific Guidance, the substance meets the specification of Hazard Category 2. It is considered by the registrant that the soil PNEC derived using the PNEC aquatic is very low, and requires refinement in order to adequately assess the risk to the soil compartment. The registrant therefore intends to conduct a confirmatory short term soil toxicity test in order to further refine the risk and re-evaluate the PNEC*".

We have assessed this information and identified the following issue:

> Under Annex IX, Section 9.4., column 2, in the absence of toxicity data to soil organisms, the equilibrium partitioning method (EPM) may be applied to assess the

hazard to soil organisms. The choice of the appropriate tests depends on the outcome of the chemical safety assessment.

In this context, ECHA Guidance R.7.11.6. describes an integrated testing strategy (ITS) for soil toxicity, which rely on the assignment of the Substance to a "soil hazard category" and on an initial screening assessment using the EPM, in order to decide the information needed for the chemical safety assessment. Substances that have a high potential to adsorb to soil or are very persistent and that are very toxic to aquatic organisms (i.e. lowest short-term EC/LC50 < 1 mg/L and/or long-term NOEC < 0.1 mg/L) fall under Hazard Category 4. For such substances, long-term toxicity tests according to the standard information requirement of Annex X, Section 9.4 must be provided.

As already explained above, the Substance is concluded to be highly persistent in soil and has a high potential to adsorb to soil.

Under Section 6.1.1. of your technical dossier, you report a short-term toxicity to fish study similar to OECD TG 203 on *Lepomis macrochirus* ([redacted], 1983). The 96h-LC50 was determined to be 0.013 mg/L. Under Section 6.1.2. of your technical dossier, you report a long-term toxicity to fish study according to OECD TG 210 ([redacted], 2018). The 28d-NOEC was determined to be 0.002 mg/L (based on post-hatch survival). On this basis the Substance is concluded to be very toxic to aquatic organisms.

The information from your dossier indicates that the Substance belongs to Hazard Category 4 as described in the ITS for soil toxicity. For such substances the screening assessment based on the EPM is not recommended and information on long-term toxicity to terrestrial invertebrates and terrestrial plants (as described in Annex X, Section 9.4) must be provided.

On this basis, ECHA concludes that an appropriate study on long-term toxicity to terrestrial invertebrates is needed.

1.2. Test selection and study specifications

The Earthworm Reproduction Test (test method: OECD TG 222), the Enchytraeid Reproduction Test (OECD TG 220) and the Collembolan Reproduction Test in Soil (OECD TG 232) are appropriate to cover the information requirement for long-term toxicity on terrestrial invertebrates (ECHA Guidance R.7.11.3.1).

1.3. Outcome

Your testing proposal for a Short-term toxicity test on invertebrates is rejected under Article 40(3) (d) of REACH. Under Article 40(3)(c) you are requested to carry out the additional test with the Substance, as specified above.

2. Effects on soil micro-organisms

Effects on soil microorganisms is a standard information requirement under Annex IX to REACH (Section 9.4.2).

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 information requirement on Effects on terrestrial organisms at

Annex IX covers short-term toxicity on invertebrates (Section 9.4.1.) and on plants (Section 9.4.3.) and effects on soil micro-organisms (9.4.2.). However, you have not provided a testing proposal for effects on soil micro-organisms. In case of data gap for effects on soil micro-organisms, it is necessary to request this information as an additional test to ensure compliance with the endpoint.

2.1. Information provided to fulfil the information requirement

Your registration dossier does not include any information on effects on soil micro-organisms. Instead you provided the following statement: "*This information will be submitted later based on ECHA decision number SEV-D-2114321096-58-01/F*".

ECHA note that the corresponding substance evaluation decision does not include a request for effects on soil micro-organisms.

On this basis, the information requirement is not fulfilled.

2.2. Test selection and study specifications

ECHA Guidance R.7.11.3.1. specifies that the nitrogen transformation test (EU C.21/OECD TG 216) is considered suitable for assessing long-term adverse effects on soil microorganisms for most non-agrochemicals.

2.3. Outcome

Under Article 40(3)(c), you are therefore requested to conduct the additional test with the Substance, as specified above.

3. Long-term toxicity to terrestrial plants

Short-term toxicity to terrestrial plants is an information requirement under Annex IX to REACH (Section 9.4.3). Long-term toxicity testing must be considered (Section 9.4., column 2) if the substance has a high potential to adsorb to soil or is very persistent.

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.

As already explained under Appendix A.1 the Substance is concluded to be potentially highly persistent in soil and has a high potential to adsorb to soil. Therefore, information on long-term toxicity on terrestrial organisms must be provided.

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 information requirement on Effects on terrestrial organisms at Annex IX covers short-term toxicity on invertebrates (Section 9.4.1.) and on plants (Section 9.4.3.) and effects on soil micro-organisms (9.4.2.). However, you have not provided a testing proposal for toxicity to terrestrial plants. In case of data gap for toxicity to terrestrial plants, it is necessary to request this information as an additional test to ensure compliance with the endpoint.

3.1. Information provided to fulfil the information requirement

Your registration dossier does not include any information on effects on long-term toxicity to terrestrial plants. Instead you provided the following statement for short-term toxicity to terrestrial plants: "*This information will be submitted later based on ECHA decision number SEV-D-2114321096-58-01/F*".

ECHA note that the corresponding substance evaluation decision does not include a request for short-term or long-term toxicity to terrestrial plants.

On this basis, the information requirement is not fulfilled.

3.2. Test selection and study specifications

The Terrestrial Plant Test (test method: OECD TG 208) is appropriate to cover the information requirement for long-term toxicity on terrestrial plants.

The OECD TG 208 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 must 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 TG 208.

3.3. Outcome

Under Article 40(3)(c), you are therefore requested to conduct the additional test with the Substance, as specified above.

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

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 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.

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

The Substance is listed in the Community rolling action plan (CoRAP) where substance evaluation started in 2014.

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

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 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 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.

[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

OECD Guidance documents[7]
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.

[7] http://www.oecd.org/chemicalsafety/testing/series-testing-assessment-publications-number.htm

Draft decision notified to the registrant under Article 50 of REACH for comments

Appendix E: 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.