~~Confidential~~

Helsinki, 19 January 2023

Addressee
Registrant of CEM JS 732-26-3 as listed in Appendix 3 of this decision

Date of submission of the dossier subject to this decision
20/04/2021

Registered substance subject to this decision ("the Substance")
Substance name: 2,4,6-tri-tert-butylphenol
EC/List number: 211-989-5

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

DECISION ON TESTING PROPOSAL(S)

Under Article 40(3)(d) of Regulation (EC) No 1907/2006 (REACH), the testing proposal listed below is rejected:

Testing proposal(s) under Annex IX to REACH

1. Pre-natal developmental toxicity study (OECD TG 414) using the Substance.

Reasons for the rejection(s) are explained in Appendix 1.

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.

Approved[1] under the authority of Mike Rasenberg, Director of Hazard Assessment

Appendix 1: Reasons for the decision
Appendix 2: Procedure
Appendix 3: Addressees of the decision and their individual information requirements

[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 1: Reasons to reject testing proposal under Annex IX to REACH

Contents

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Testing proposal under Annex IX to REACH

1. Pre-natal developmental toxicity study

1 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

2 Data on pre-natal developmental toxicity (PNDT) study (OECD 414) in one species is not available from the registration dossier under evaluation.

3 You have submitted a testing proposal for a PNDT study according to OECD TG 414 in rats by the oral route.

4 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.

1.2. Consideration of the need for testing

5 According to Annex IX, Section 8.7, Column 2, '*if a substance is known to cause developmental toxicity, meeting the criteria for classification in the hazard class reproductive toxicity (category 1A or 1B: May damage the unborn child (H360D)), and the available data are adequate to support a robust risk assessment, then no further testing shall be necessary*'.

6 The Substance is known to cause developmental toxicity, meeting the criteria for classification in the hazard class reproductive toxicity (Repr. 1B (H360D); as found by Commission Delegated Regulation (EU) 2022/692[2] which will amend Annex VI to the CLP Regulation). A NOAEL is available in order to derive a DNEL. This information is sufficient to enable the registrants to perform a robust risk assessment.

7 ECHA therefore considers that a PNDT study in a first species is not necessary.

1.3. Outcome

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

[2] https://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:32022R0692&from=EN

References

The following documents may have been cited in the decision.

Guidance on information requirements and chemical safety assessment (Guidance on IRs & CSA)

Chapter R.4 Evaluation of available information; ECHA (2011).
Chapter R.6 QSARs, read-across and grouping; ECHA (2008).
Appendix to Chapter R.6 for nanoforms; ECHA (2019).
Chapter R.7a Endpoint specific guidance, Sections R.7.1 – R.7.7; ECHA (2017).
Appendix to Chapter R.7a for nanomaterials; ECHA (2017).
Chapter R.7b Endpoint specific guidance, Sections R.7.8 – R.7.9; ECHA (2017).
Appendix to Chapter R.7b for nanomaterials; ECHA (2017).
Chapter R.7c Endpoint specific guidance, Sections R.7.10 – R.7.13; ECHA (2017).
Appendix to Chapter R.7a for nanomaterials; ECHA (2017).
Appendix R.7.13-2 Environmental risk assessment for metals and metal compounds; ECHA (2008).
Chapter R.11 PBT/vPvB assessment; ECHA (2017).
Chapter R.16 Environmental exposure assessment; ECHA (2016).

Guidance on data-sharing; ECHA (2017).
Guidance for monomers and polymers; ECHA (2012).
Guidance on intermediates; ECHA (2010).
All guidance documents are available online: https://echa.europa.eu/guidance-documents/guidance-on-reach

Read-across assessment framework (RAAF)

RAAF, 2017 Read-across assessment framework (RAAF); ECHA (2017).
RAAF UVCB, 2017 Read-across assessment framework (RAAF) – considerations on multi- constituent substances and UVCBs; ECHA (2017).

The RAAF and related documents are available online:
https://echa.europa.eu/support/registration/how-to-avoid-unnecessary-testing-on-animals/grouping-of-substances-and-read-across

***OECD Guidance documents* (OECD GDs)**

OECD GD 23 Guidance document on aquatic toxicity testing of difficult substances and mixtures; No. 23 in the OECD series on testing and assessment, OECD (2019).
OECD GD 29 Guidance document on transformation/dissolution of metals and metal compounds in aqueous media; No. 29 in the OECD series on testing and assessment, OECD (2002).
OECD GD 150 Revised guidance document 150 on standardised test guidelines for evaluating chemicals for endocrine disruption; No. 150 in the OECD series on testing and assessment, OECD (2018).
OECD GD 151 Guidance document supporting OECD test guideline 443 on the extended one-generation reproductive toxicity test; No. 151 in the OECD series on testing and assessment, OECD (2013).

Appendix 2: Procedure

ECHA started the testing proposal evaluation in accordance with Article 40(1) on 30 April 2021.

ECHA held a third party consultation for the testing proposal(s) from 1 July 2021 until 16 August 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 3: Addressee of this decision

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.