~~Confidential~~

Helsinki, 03 November 2021

Addressees
Registrants of JS_Alkylphenyl ketone listed in the last Appendix of this decision

Date of submission of the dossier subject of a decision
05/01/2015

Registered substance subject to this decision, hereafter 'the Substance'
Substance name: 1-Propanone, 2-hydroxy-2-methyl-, 1-(4-C10-13-alkylphenyl) derivs.
EC number: 600-033-6
CAS number: 1001416-18-7

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), your proposed test is rejected, according to Article 40(3)(d):

Pre-natal developmental toxicity study (EU B.31./OECD TG 414)

Reasons for the rejection are explained in Appendix A.

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 reject testing proposal under Annex VIII to REACH

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

1. Pre-natal developmental toxicity study

A pre-natal developmental toxicity (PNDT) study may be proposed in case of serious concerns about the potential for adverse effects on development under Annex VIII to REACH (Section 8.7.1., column 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. You have not provided any further specifications on the test material, test species, or the route of exposure. You have not provided any justification for a serious concern about the potential for adverse effects on development.

ECHA requested your considerations for alternative methods to fulfil the information requirement for Developmental toxicity. You did not provide your considerations by the given deadline.

ECHA considers that a PNDT study is not necessary at this tonnage band.

1.2. Outcome

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

Appendix B: Procedure

ECHA started the testing proposal evaluation in accordance with Article 40(1) on 6 October 2020.

ECHA held a third party consultation for the testing proposal 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 C: Addressees of this decision

Registrant Name	Registration number	Highest REACH Annex applicable to you
[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.