~~Confidential~~

Helsinki, 27 October 2021

Addressees
Registrants of JS_C11 amidoamine Me sulfate listed in the last Appendix of this decision

Date of submission of the dossier subject of a decision
18/06/2020

Registered substance subject to this decision, hereafter 'the Substance'
Substance name: Trimethyl-3-[(1-oxo-10-undecenyl)amino]propylammonium methyl sulphate
EC number: 304-990-8
CAS number: 94313-91-4

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 using an analogue substance methyl trimethyl-3-[(1-oxododecyl)amino]propylammonium sulphate (CAS 10595-49-0) 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 proposals 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

You have submitted a testing proposal for a PNDT study according to OECD TG 414 with an analogue substance methyl trimethyl-3-[(1-oxododecyl)amino]propylammonium sulphate (CAS 10595-49-0).

Your dossier contains a read-across justification document in IUCLID section 13.

ECHA requested your considerations for alternative methods to fulfil the information requirement for Developmental toxicity. You provided your considerations and you applied read-across to fulfil the respective information requirement, and no other alternative methods were available. ECHA has taken these considerations into account.

However, you have not provided any indication of serious concerns about the potential for adverse effects on development: your dossier contains no information on developmental toxicity, and the read-across justification document does not address developmental toxicity.

ECHA considers that, in the absence of indications of serious concerns about the potential for adverse effects on development, 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.

In the testing proposal examination, ECHA has only assessed the need for the test. This assessment resulted in the rejection of the testing proposal. Therefore, no assessment of the proposed read-across approach was performed as the information requirement is not triggered at this tonnage level.

Appendix B: Procedure

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

ECHA held a third party consultation for the testing proposal(s) from 16 December 2020 until 1 February 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]
[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.