EUROPEAN CHEMICALS AGENCY

~~Confidential~~

Helsinki, 20 January 2021

Addressees
Registrants of JS_SMG_ZS listed in the last Appendix of this decision

Date of submission for the jointly submitted dossier subject of a decision
06/12/2018

Registered substance subject to this decision, hereafter 'the Substance'
Substance name: Sodium hydrogen N-(1-oxotetradecyl)-L-glutamate
EC number: 253-981-4
CAS number: 38517-37-2

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

DECISION ON A TESTING PROPOSAL

Your proposed test using an analogue substance L-Glutamic acid, N-coco acyl derivs., disodium salts / EC number: 269-085-1 is rejected, according to Article 40(3)(d):

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

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: Reasoning

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

Pre-natal developmental toxicity study in one species

A registrant may propose a pre-natal developmental toxicity study (OECD TG 414) instead of a screening study (OECD TG 421/422) in case of serious concerns about the potential for adverse effects on development (Section 8.7.1., column 2, last paragraph, Annex VIII to REACH).

You have submitted a testing proposal for a pre-natal developmental toxicity study (PNDT) according to OECD TG 414 with the following justification:

"*Refer to the section 13 of the IUCLID dataset for details on the read across justification. The planned pre-natal developmental toxicity study with the read across substance is considered sufficient to fulfil the information requirements as further explained in the provided endpoint summary*".

Your dossier does not contain reproductive or developmental toxicity studies or any discussion or indication of (serious) concern for adverse effects on development.

In the absence of demonstration of such a serious concern, we conclude that your testing proposal for a pre-natal developmental toxicity study at your registered tonnage is not justified.

In your comments on the initial draft decision you express your intentions to adapt the information requirement by providing a pre-natal developmental toxicity study (OECD TG 414) performed with an analogue substance, instead of a screening study (OECD TG 421/422).

You do not substantiate your intentions with any new data. It is in your discretion to generate and provide the necessary supporting information in order to justify your read-across adaptation or any other adaptation. If you do so, you are responsible for demonstrating the fulfilment of the requirements of the relevant Annex(es) of REACH.

Under Article 40(3)(d) of REACH, your proposal is therefore rejected.

Appendix B: Procedural history

ECHA started the testing proposal evaluation in accordance with Article 40(1) on 7 December 2018.

ECHA held a third party consultation for the testing proposals from 17 December 2019 until 31 January 2020. ECHA did not receive information from third parties.

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

ECHA took into account your comments and did not amend the request(s).

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: List of registrants to which the decision is addressed

Registrant Name	Registration number	(Highest) Data requirements to be fulfilled
[redacted]	[redacted]	[redacted]

Note: where applicable, the name of a third party representative (TPR) may be displayed in the list of recipients whereas the decision is sent to the actual registrant.