EUROPEAN CHEMICALS AGENCY

~~Confidential~~

Helsinki, 26 May 2021

Addressees
Registrants of JS_Amphopropionate-C8 listed in the last Appendix of this decision

Date of submission of the dossier subject of a decision
15/05/2018

Registered substance subject to this decision, hereafter 'the Substance'
Substance name: N-(2-hydroxyethyl)-N-[2-[(1-oxooctyl)amino]ethyl]-β-alanine
EC number: 264-761-2
CAS number: 64265-45-8

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 originally proposed test using the Substance is rejected:

1. 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

Absence of serious concern

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:

"*In the Amphoacetates C8-C18 (EC number: 931-291-0) dossier, which has already been submitted to ECHA, a prenatal developmental toxicity study in the rat according to OECD guideline 414, testing by oral route, is proposed. A read-across from this study will be used to cover the endpoint toxicity to reproduction (REACH Regulation, Annex VII, 8.7.1). As soon as study data are available, a robust study summary will be prepared and submitted within an update of the dossier. Evaluation will be reconsidered based on the outcome of the prenatal developmental toxicity study. In conclusion, a prenatal developmental toxicity study will be conducted with the closely related source substance Amphoacetates C8-C18. Hence, a further testing proposal for a prenatal developmental toxicity study with the target substance itself is considered not justified.* "

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

In the absence of any serious concern, you have not demonstrated that the trigger for a pre-natal developmental toxicity study at Annex VIII was fulfilled.

Overall conclusion

Therefore we conclude that your testing proposal for a pre-natal developmental toxicity study has no legal basis and your testing proposal is rejected.

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

Appendix B: Procedure

ECHA started the testing proposal evaluation in accordance with Article 40(1) on 21 May 2018.

ECHA held a third party consultation for the testing proposal(s) from 25 May 2020 until 9 July 2020. ECHA did not receive information from third parties.

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: ECHA followed the procedure detailed in Articles 50 and 51 of REACH. Addressees 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.