EUROPEAN CHEMICALS AGENCY

~~Confidential~~

Helsinki, 04 June 2021

**Addressees**
Registrants of JS_C18 MDEA Esterq_Multicon listed in the last Appendix of this decision

**Date of submission of the dossier subject of a decision**
22/09/2020

**Registered substance subject to this decision, hereafter 'the Substance'**
Substance name: Reaction mass of Ethanaminium, 2-hydroxy-N,N-dimethyl-N-[2-[(1-oxooctadecyl)oxy]ethyl]-, chloride and Ethanaminium, N,N-dimethyl-2-[(1-oxohexadecyl)oxy]-N-[2-[(1-oxooctadecyl)oxy]ethyl]-, chloride
EC number: 951-974-7
CAS number: NS

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

### A. Testing proposal under Annex IX to REACH

1. Extended one-generation reproductive toxicity study (OECD TG 443) using analogue substance Ethanaminium, 2-hydroxy-N-(2-hydroxyethyl)-N,N-dimethyl-, esters with C16-18 and C18-unsatd. fatty acids, chlorides (EC No. 620-174-7, CAS No. 1079184-43-2)

Reasons for the rejection are explained in Appendix A.

For references used in this decision, please consult the Appendix entitled "Guidance on REACH and other supporting documents".

### 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 for the decision

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

## A. Reasons to reject testing proposal under Annex IX to REACH

1. Extended one-generation reproductive toxicity study

An extended one-generation reproductive toxicity (EOGRT) study (OECD 443) is an information requirement under Annex IX to REACH (Section 8.7.3.) if the available repeated dose toxicity studies indicate adverse effects on reproductive organs or tissues or reveal other concerns in relation with reproductive toxicity.

Your dossier contains

- OECD TG 407 study with the proposed source substance (CAS No. 1079184-43-2)
- OECD TG 407 study with the registered substance ('the Substance')
- OECD TG 408 study with the proposed source substance (CAS No. 1079184-43-2)
- OECD TG 414 study with the proposed source substance (CAS No. 1079184-43-2)

which do not indicate adverse effects on reproductive organs or tissues or reveal other concerns in relation with reproductive toxicity. Therefore, there is no need for an EOGRTS.

*1.1. Information provided to fulfil the information requirement*

You have submitted a testing proposal (based on read-across) for an EOGRTS according to OECD TG 443. Your testing proposal refers to a read-across justification document (provided in IUCLID section 13), and a compliance check decision on the proposed source substance Ethanaminium, 2-hydroxy-N-(2-hydroxyethyl)-N,N-dimethyl-, esters with C16-18 and C18-unsatd. fatty acids, chlorides (EC No. 620-174-7, CAS No. 1079184-43-2). You have not provided any justification why an EOGRT study would be an information requirement for the Substance at Annex IX.

ECHA considers that an EOGRTS 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**

This decision does not prevent ECHA from initiating compliance checks at a later stage on the registrations present.

ECHA received your testing proposal on 24 September 2020 and started the testing proposal evaluation in accordance with Article 40(1).

ECHA held a third party consultation for the testing proposal(s) from 23 November 2020 until 7 January 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.

In your comments you agreed to the draft decision. ECHA took your comments into account and did not amend the requests.

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 references - ECHA Guidance[2] and other supporting documents**

Evaluation of available information
Guidance on information requirements and chemical safety assessment, Chapter R.4 (version 1.1., December 2011), referred to as ECHA Guidance R.4 where relevant.

QSARs, read-across and grouping
Guidance on information requirements and chemical safety assessment, Chapter R.6 (version 1.0, May 2008), referred to as ECHA Guidance R.6 where relevant.

Read-across assessment framework (RAAF, March 2017)[3]

RAAF - considerations on multi-constituent substances and UVCBs (RAAF UVCB, March 2017)[4]

Physical-chemical properties
Guidance on information requirements and chemical safety assessment, Chapter R.7a (version 6.0, July 2017), referred to as ECHA Guidance R.7a in this decision.

Toxicology
Guidance on information requirements and chemical safety assessment, Chapter R.7a (version 6.0, July 2017), referred to as ECHA Guidance R.7a in this decision.

Guidance on information requirements and chemical safety assessment, Chapter R.7c (version 3.0, June 2017), referred to as ECHA Guidance R.7c in this decision.

Environmental toxicology and fate
Guidance on information requirements and chemical safety assessment, Chapter R.7a (version 6.0, July 2017), referred to as ECHA Guidance R.7a in this decision.

Guidance on information requirements and chemical safety assessment, Chapter R.7b (version 4.0, June 2017), referred to as ECHA Guidance R.7b in this decision.

Guidance on information requirements and chemical safety assessment, Chapter R.7c (version 3.0, June 2017), referred to as ECHA Guidance R.7c in this decision.

PBT assessment
Guidance on information requirements and chemical safety assessment, Chapter R.11 (version 3.0, June 2017), referred to as ECHA Guidance R.11 in this decision.

Guidance on information requirements and chemical safety assessment, Chapter R.16 (version 3.0, February 2016), referred to as ECHA Guidance R.16 in this decision.

Data sharing
Guidance on data-sharing (version 3.1, January 2017), referred to as ECHA Guidance on data sharing in this decision.

[2] https://echa.europa.eu/guidance-documents/guidance-on-information-requirements-and-chemical-safety-assessment
[3] https://echa.europa.eu/support/registration/how-to-avoid-unnecessary-testing-on-animals/grouping-of-substances-and-read-across
[4] https://echa.europa.eu/documents/10162/13630/raaf_uvcb_report_en.pdf/3f79684d-07a5-e439-16c3-d2c8da96a316

OECD Guidance documents[5]
Guidance Document on aqueous-phase aquatic toxicity testing of difficult test chemicals – No 23, referred to as OECD GD 23.

Guidance document on transformation/dissolution of metals and metal compounds in aqueous media – No 29, referred to as OECD GD 29.

Guidance Document on Standardised Test Guidelines for Evaluating Chemicals for Endocrine Disruption – No 150, referred to as OECD GD 150.

Guidance Document supporting OECD test guideline 443 on the extended one-generation reproductive toxicity test – No 151, referred to as OECD GD 151.

[5] http://www.oecd.org/chemicalsafety/testing/series-testing-assessment-publications-number.htm

**Appendix D: 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.