~~Confidential~~

Helsinki, 15 September 2022

**Addressee**
Registrant of 263-196-9_JS as listed in Appendix 3 of this decision

**Date of submission of the dossier subject to this decision**
21/04/2018

**Registered substance subject to this decision ("the Substance")**
Substance name: Amines, N-coco alkyltrimethylenedi-, acetates
EC number: 263-196-9

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

## DECISION ON A COMPLIANCE CHECK

Under Article 41 of Regulation (EC) No 1907/2006 (REACH), you must submit the information listed below, by the deadline of ***23 September 2024***.

Requested information must be generated using the Substance unless otherwise specified.

**Information required from all the Registrants subject to Annex VII of REACH**

1. Surface tension (Annex VII, Section 7.6.; test method: EU A.5./OECD TG 115)

2. Skin sensitisation (Annex VII, Section 8.3.):
   i. *in vitro/in chemico* skin sensitisation information on molecular interactions with skin proteins (OECD TG 442C), inflammatory response in keratinocytes (OECD TG 442D) and activation of dendritic cells (EU B.71/OECD TG 442E)(Annex VII, Section 8.3.1.); and
   ii. Only if the *in vitro/in chemico* test methods specified under point i.) are not applicable for the Substance or the results obtained are not adequate for classification and risk assessment, *in vivo* skin sensitisation (Annex VII, Section 8.3.2.; test method: EU B.42./OECD TG 429);

3. In vitro gene mutation study in bacteria (Annex VII, Section 8.4.1.; test method: OECD TG 471, 2020)

4. Short-term toxicity testing on aquatic invertebrates (Annex VII, Section 9.1.1.; test method: EU C.2./OECD TG 202)

5. Growth inhibition study aquatic plants (Annex VII, Section 9.1.2.; test method: EU C.3./OECD TG 201)

6. Ready biodegradability (Annex VII, Section 9.2.1.1.; test method: EU C.4. C/D/E/F/OECD TG 301B/C/D/F or EU C.29./OECD TG 310) on relevant constituent(s)/fraction(s) of the Substance, as described under the corresponding appendix on reasons for the request.

The reasons for the decision(s) are explained in Appendix 1.

**Information required depends on your tonnage band**

You must provide the information listed above for all REACH Annexes applicable to you in accordance with Articles 10(a) and 12(1) of REACH.

**How to comply with your information requirements**

To comply with your information requirements, you must submit the information requested by this decision in an updated registration dossier by the deadline indicated above. You must also **update the chemical safety report, where** relevant, including any changes to classification and labelling, based on the newly generated information.

You must follow the general requirements for testing and reporting new tests under REACH, see Appendix 4.

**Appeal**

This decision, when adopted under Article 51 of REACH, may be appealed to the Board of Appeal of ECHA within three months of its notification to you. Please refer to http://echa.europa.eu/regulations/appeals for further information.

**Failure to comply**

If you do not comply with the information required by this decision by the deadline indicated above, ECHA will notify the enforcement authorities of your Member State.

Authorised[1] under the authority of Mike Rasenberg, Director of Hazard Assessment

Appendix 1: Reasons for the decision
Appendix 2: Procedure
Appendix 3: Addressees of the decision and their individual information requirements
Appendix 4: Conducting and reporting new tests under REACH

[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 1: Reasons for the decision

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**Reasons related to the information under Annex VII of REACH**

## 1. Surface tension

1 Surface tension is an information requirement under Annex VII to REACH (Section 7.6.).

*1.1. Information provided to fulfil the information requirement*

2 You have provided the following statement: "*Data describing potential surface activity of the substance is not available*".

*1.2. Assessment of the information provided*

3 As you have provided no information or adaptation for this endpoint, the information requirement is not fulfilled.

## 2. Skin sensitisation

4 Skin sensitisation is an information requirement under Annex VII, Section 8.3. Under Section 8.3., Column 1, the registrants must submit information allowing (1) a conclusion whether the substance is a skin sensitiser and (2) whether it can be presumed to have the potential to produce significant sensitisation in humans (Cat. 1A).

*2.1. Information provided*

5 You have provided the following statement: "*Investigation of skin sensitisation in vitro is ongoing. The results of two concordant studies will determine the overall prediction and, the substance is classified for skin sensitisation as a precaution until results become available*".

*2.2. Assessment of the information provided*

*2.2.1. Assessment whether the Substance causes skin sensitisation*

*2.2.1.1. Your justification to omit the study has no legal basis*

6 A registrant may only adapt this information requirement based on the specific rules of Annex VII Section 8.3.1, Column 2 or the general rules set out in Annex XI.

7 Your statement that the studies are currently ongoing does not refer to any legal ground for adaptation under Annex VII, Section 8.3.1., column 2 or Annex XI to REACH.

8 Therefore, as you do not have any data in your dossier, you have not demonstrated that this information can be omitted.

*2.2.2. No assessment of potency*

9 To be considered compliant and enable a conclusion in cases where the substance is considered to cause skin sensitisation, the information provided must also allow a conclusion whether it can be presumed to have the potential to produce significant sensitisation in humans (Cat. 1A).

10 As the currently available data does not allow to conclude whether the Substance causes skin sensitisation (see section 2.2.1. above), this condition cannot be assessed.

11 On this basis, the information requirement is not fulfilled.

*2.3. Specification of the study design*

12 To fulfil the information requirement for the Substance, information on molecular interaction with skin proteins and inflammatory response in keratinocytes and activation of dendritic cells (OECD TG 442C and OECD TG 442D and EU B.71/OECD TG 442E) must be provided. Furthermore an appropriate risk assessment is required if a classification of the Substance as a skin sensitiser (Cat 1A or 1B) is warranted.

13 In case no conclusion on the skin sensitisation potency can be made for the Substance based on the existing in vitro/in chemico data or newly generated in vitro/in chemico data, in vivo skin sensitisation study must be performed and the murine local lymph node assay (EU Method B.42/OECD TG 429) is considered as the appropriate study for the potency estimation.

## 3. In vitro gene mutation study in bacteria

14 An in vitro gene mutation study in bacteria is an information requirement under Annex VII, Section 8.4.1.

*3.1. Information provided*

15 You have provided the following statement: "*The bacterial reverse mutation assay is ongoing. Interim results show that the substance is cytotoxic to five bacterial strains but non-mutagenic*."

*3.2. Assessment of the information provided*

*3.2.1. Your justification to omit the study has no legal basis*

16 A registrant may only adapt this information requirement based on the specific rules of Annex VII, Section 8.4.1, column 2 or the general rules set out in Annex XI.

17 Your statement that the study is currently ongoing does not refer to any legal ground for adaptation under Annex VII, Section 8.4.1, column 2 or Annex XI to REACH.

18 Therefore, you have not demonstrated that this information can be omitted.

19 On this basis, the information requirement is not fulfilled.

*3.3. Specification of the study design*

20 To fulfil the information requirement for the Substance, the in vitro gene mutation study in bacteria (OECD TG 471, 2020) is considered suitable.

## 4. Short-term toxicity testing on aquatic invertebrates

21 Short-term toxicity testing on aquatic invertebrates is an information requirement under Annex VII to REACH (Section 9.1.1.).

*4.1. Information provided*

22 You have provided the following statement: "*Investigation of short-term toxicity to Daphnia magna is ongoing and relevant publicly available data are not available. PNECs required for risk assessment are therefore based on current company prediction (LC50 0.032 mg/L)*".

*4.2. Assessment of the information provided*

*4.2.1. Your justification to omit the study has no legal basis*

23 A registrant may only adapt this information requirement based on the specific rules of Annex VII, Section 9.1.1., column 2 or the general rules set out in Annex XI.

24 Your statement that the study is currently ongoing does not refer to any legal ground for adaptation under Annex VII, Section 9.1.1., column 2 or Annex XI to REACH. It is also noted that, while you refer to "*current company prediction*", you have provided no further information or documentation on what this prediction refers to.

25 Therefore, you have not demonstrated that this information can be omitted.

26 On this basis, the information requirement is not fulfilled.

*4.3. Study design and test specifications*

27 The Substance is difficult to test due to its potential for adsorption (as it is ionised under environmentally relevant pH) and low solubility. OECD TG 202 specifies that, for difficult to test substances, you must consider the approach described in OECD GD 23 or other approaches, if more appropriate for your substance. In all cases, the approach selected must be justified and documented. Due to the properties of Substance, it may be difficult to achieve and maintain the desired exposure concentrations. Therefore, you must monitor the test concentration(s) of the Substance throughout the exposure duration and report the results. If it is not possible to demonstrate the stability of exposure concentrations (i.e. measured concentration(s) not within 80-120% of the nominal concentration(s)), you must express the effect concentration based on measured values as described in OECD TG 202. In case a dose-response relationship cannot be established (no observed effects), you must demonstrate that the approach used to prepare test solutions was adequate to maximise the concentration of the Substance in the test solution.

## 5. Growth inhibition study aquatic plants

28 Growth inhibition study on aquatic plants is an information requirement under Annex VII to REACH (Section 9.1.2.).

*5.1. Information provided*

29 You have provided the following statement: "*Investigation of algal growth rate inhibition is ongoing and relevant publicly available data are not available. PNECs required for risk assessment are therefore based on current company prediction (EC50 0.023 mg/L)*".

*5.2. Assessment of the information provided*

*5.2.1. Your justification to omit the study has no legal basis*

30 A registrant may only adapt this information requirement based on the specific rules of Annex VII, Section 9.1.2., column 2 or the general rules set out in Annex XI.

31 Your statement that the study is currently ongoing does not refer to any legal ground for adaptation under Annex VII, Section 9.1.2., column 2 or Annex XI to REACH. It is also noted that, while you refer to "*current company prediction*", you have provided no further information or documentation on what this prediction refers to.

32 Therefore, you have not demonstrated that this information can be omitted.

33 On this basis, the information requirement is not fulfilled.

*5.3. Study design and test specifications*

34 OECD TG 201 specifies that, for difficult to test substances, OECD GD 23 must be followed. As already explained above, the Substance is difficult to test. Therefore, you must fulfil the requirements described in 'Study design and test specifications' under Request 4.

## 6. Ready biodegradability

35 Ready biodegradability is an information requirement in Annex VII to REACH (Section 9.2.1.1.).

*6.1. Information provided*

36 You have provided a study according to OECD TG 306 on the Substance (2007).

*6.2. Assessment of the information provided*

*6.2.1. Test material not representative of the Substance*

37 To comply with this information requirement, the test material in a study must be representative for the Substance; Article 10 and Recital 19 of REACH; Guidance on IRs and CSA, Section R.4.1.

38 The provided study was conducted with Amines, N-coco alkyltrimethylenedi-, acetates, EC No. 263-196-9. On the test material, you specify that "*No details of the test material were supplied by the sponsor and no characterisation was performed by the testing house*".

39 In the absence of composition information on the test material, the identity of the test material and its impurities cannot be assessed, and you have not demonstrated that the test material is representative for the Substance.

*6.2.2. Ready biodegradation tests are normally intended for pure substances*

40 The revised introduction to the OECD Guidelines For Testing Of Chemicals, Section 3 Part I states that ready biodegradability tests are intended for pure substances but may also be relevant, on a case-by-case basis, to mixtures of structurally similar chemicals (i.e. which are composed of constituents expected to show similar degradation kinetics). However, such tests are not generally applicable for complex mixtures or substances (i.e. UVCB or multi-constituent substances) containing different types of constituents. For complex substances, a single ready biodegradability test does not allow to conclude on the ready

biodegradability of all constituents and therefore, does not fulfil the information requirement.

41 You have provided a study conducted on a test material claimed to be representative of the Substance as a whole. In Section 1.1. of your dossier you describe the Substance as UVCB. In Section 1.2, you describe the substance as a mixture of 1-(Alkyl amino)-3-aminopropane diacetate with an alkyl chain length ranging from C8 to C18. You also specify that the substance contains undefined cyclic by-products and undefined amide by-products with a typical concentration of [redacted]% and [redacted]w/w), respectively. Finally the Substance also contains [redacted]% (w/w) of Coconut diamine (CAS RN 61791-63-7).

42 The Substance is a complex substance and contains constituents with significant structural differences described above. Therefore, the provided study does not provide unequivocal conclusion that all constituents can safely be regarded as readily biodegradable.

*6.2.3. The provided study does not meet the specifications of the applicable test guideline*

43 As specified in the Guidance on IRs and CSA, Section R.7.9.4.1., the OECD TG 306 explicitly indicates that results of those tests (shake flask and closed bottle) "*are not to be taken as indications of ready biodegradability*". However, it is acknowledged that biodegradation in seawater is generally slower.and therefore, the results of an study conducted according to OECD TG 306 can be regarded as a piece of evidence that the substance is likely to fulfil the criteria for ready biodegradability. However, to fulfil the information requirement, a biodegradability in sea water study must comply with the OECD TG 306 (Article 13(3) of REACH). Therefore, for a closed bottle test (similar to OECD TG 301D) according to OECD TG 306, the following requirements must be met:

44 Validity criteria

a) the blank respiration must not exceed 30 per cent of the oxygen in the test bottle. If it is not possible to meet this criterion using freshly collected seawater, the seawater must be aged for about a week before use;
b) the possibility that nitrogen-containing compounds may affect the results must be considered. In practice, this means that correction for nitrification as described in the OECD TG 301D is applied on the theoretical oxygen demand (*i.e.* $ThOD_{NO3}$) unless it can be demonstrated that nitrification did not occur (*e.g.* by monitoring changes in concentrations in nitrite and nitrate).

45 Reporting of the methodology and results

c) the calculation of the ThOD is described and justified.

46 Your registration dossier provides an OECD TG 306 study (using the closed bottle method) showing the following:

47 Validity criteria

a) the blank respiration reached 41% of the oxygen present in the test bottle. The sea water sample was collected on 29 January 2007 and the test was started on 02 February. Therefore, the seawater was not aged for about a week prior to conducting the test;
b) the Substance is a nitrogen containing substance. However, no correction for nitrification of the theoretical oxygen demand was applied and you have provided no justification that nitrification did not occur during the test;

48 Reporting of the methodology and results

c) the calculation of the ThOD is not described.

49 Based on the above,

- the validity criteria of OECD 306 are not met;
- the reporting of the study is not sufficient to conduct an independent assessment of its reliability as you have not documented that the ThOD value used for estimating the measured % biodegradation is representatitive of the Substance as a whole and takes into account oxygen consumption originating from nitrification.

50 On this basis, the information requirement is not fulfilled.

*6.3. Study design and test specification*

51 For the reasons provided above, testing on the Substance as a whole does not fulfil the information requirement. For the generation of information on ready biodegradability, you must consider the level of information required for the purposes of classification and labelling and, if applicable to your registration, the PBT/vPvB assessment and the exposure assessment/risk characterisation. In order to conclude on which of constituents of the Substance are and which are not readily biodegradable, you may have to consider conducting more than one study using selected individual constituents and/or fractions. If you choose to test one (or more) fraction(s) of the Substance, you must provide a justification that their constituents within chosen fraction(s) are similar enough so that similar degradation kinetics can be assumed. If you decide to conduct a single study in order to prove that all constituents of the Substance are readily biodegradable, you must provide a justification that the selected constituent/fraction can be considered a reasonable worst-case for the Substance as a whole in terms of degradation kinetics.

52 Justification for selection of relevant constituent and/or fractions for the testing, must consider degradation kinetics of constituents of the Substance based, as minimum, on the similarity/differences of the chemical structures and the physico-chemical properties of constituents of the Substance. For that purpose, tools and approaches mentioned in Guidance on IRs and CSA, Sections R.7b and R.11 should be considered.

**References**

The following documents may have been cited in the decision.

***Guidance on information requirements and chemical safety assessment (Guidance on IRs & CSA)***

Chapter R.4 Evaluation of available information; ECHA (2011).
Chapter R.6 QSARs, read-across and grouping; ECHA (2008).
Appendix to Chapter R.6 for nanoforms; ECHA (2019).
Chapter R.7a Endpoint specific guidance, Sections R.7.1 – R.7.7; ECHA (2017).
Appendix to Chapter R.7a for nanomaterials; ECHA (2017).
Chapter R.7b Endpoint specific guidance, Sections R.7.8 – R.7.9; ECHA (2017).
Appendix to Chapter R.7b for nanomaterials; ECHA (2017).
Chapter R.7c Endpoint specific guidance, Sections R.7.10 – R.7.13; (ECHA 2017).
Appendix to Chapter R.7a for nanomaterials; ECHA (2017).
Appendix R.7.13-2 Environmental risk assessment for metals and metal compounds; ECHA (2008).
Chapter R.11 PBT/vPvB assessment; ECHA (2017).
Chapter R.16 Environmental exposure assessment; ECHA (2016).

***Guidance on data-sharing***; ECHA (2017).

All Guidance on REACH is available online: https://echa.europa.eu/guidance-documents/guidance-on-reach

***Read-across assessment framework (RAAF)***

RAAF, 2017 Read-across assessment framework (RAAF), ECHA (2017)
RAAF UVCB, 2017 Read-across assessment framework (RAAF) – considerations on multi- constituent substances and UVCBs), ECHA (2017).

The RAAF and related documents are available online:
https://echa.europa.eu/support/registration/how-to-avoid-unnecessary-testing-on-animals/grouping-of-substances-and-read-across

***OECD Guidance documents* (OECD GDs)**

OECD GD 23 Guidance document on aquatic toxicity testing of difficult substances and mixtures; No. 23 in the OECD series on testing and assessment, OECD (2019).
OECD GD 29 Guidance document on transformation/dissolution of metals and metal compounds in aqueous media; No. 29 in the OECD series on testing and assessment, OECD (2002).
OECD GD 150 Revised guidance document 150 on standardised test guidelines for evaluating chemicals for endocrine disruption; No. 150 in the OECD series on testing and assessment, OECD (2018).
OECD GD 151 Guidance document supporting OECD test guideline 443 on the extended one-generation reproductive toxicity test; No. 151 in the OECD series on testing and assessment, OECD (2013).

**Appendix 2: Procedure**

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

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

The compliance check was initiated on 07 December 2021.

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

In your comments, you indicate that you will [redacted] your registration tonnage band to [redacted]. Upon ECHA's request, you have provided the documentary evidence supporting the tonnage band [redacted].

You also request an extension of the deadline to 24 months from the date of adoption of the decision. You did not provide documentary evidence for the lab availability (including the scheduling timelines for the studies in question of the lab facility to justify why an extension to the stated deadline is required).

ECHA took into account your comments and amended 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.

The deadline of the decision is set based on standard practice for carrying out OECD TG tests. It has been exceptionally extended by 12 months from the standard deadline granted by ECHA to take into account currently longer lead times

**Appendix 3: Addressees of this decision and their corresponding information requirements**

In accordance with Articles 10(a) and 12(1) of REACH, the information requirements for individual registrations are defined as follows:

- the information specified in Annex VII to REACH, for registration at 1-10 tonnes per year (tpa), or as a transported isolated intermediate in quantity above 1000 tpa;
- the information specified in Annexes VII and VIII to REACH, for registration at 10-100 tpa;

| 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.

## Appendix 4: Conducting and reporting new tests for REACH purposes

### 1. Requirements when conducting and reporting new tests for REACH purposes

### 1.1. Test methods, GLP requirements and reporting

(1) Under Article 13(3) of REACH, all new data generated as a result of this decision must be conducted according to the test methods laid down in a European Commission Regulation or to international test methods recognised by the Commission or ECHA as being appropriate.

(2) Under Article 13(4) of REACH, ecotoxicological and toxicological tests and analyses must be carried out according to the GLP principles (Directive 2004/10/EC) or other international standards recognised by the Commission or ECHA.

(3) Under Article 10(a)(vi) and (vii) of REACH, all new data generated as a result of this decision must be reported as study summaries, or as robust study summaries, if required under Annex I of REACH. See ECHA Practical Guide on How to report robust study summaries[2].

(4) Under the introductory part of Annexes VII/VIII/IX/X to REACH, where a test method offers flexibility in the study design, for example in relation to the choice of dose levels or concentrations, the chosen study design must ensure that the data generated are adequate for hazard identification and risk assessment.

### 1.2. Test material

1. *Selection of the Test material(s)*

   The Test Material used to generate the new data must be selected taking into account the following:

   a) the impact of each constituent/ impurity on the test results for the endpoint to be assessed. For example, if a constituent/ impurity of the Substance is known to have an impact on (eco)toxicity, the selected Test Material must contain that constituent/ impurity.

2. *Information on the Test Material needed in the updated dossier*

   a) You must report the composition of the Test Material selected for each study, under the "Test material information" section, for each respective endpoint study record in IUCLID.

   b) The reported composition must include the careful identification and description of the characteristics of the Tests Materials in accordance with OECD GLP (ENV/MC/CHEM(98)16) and EU Test Methods Regulation (EU) 440/2008 (Note, Annex), namely all the constituents must be identified as far as possible as well as their concentration. Also any constituents that have harmonised classification and labelling according to the CLP Regulation must be identified and quantified using the appropriate analytical methods,

With that detailed information, ECHA can confirm whether the Test Material is relevant for the Substance .

Technical instructions on how to report the above is available in the manual on How to prepare registration and PPORD dossiers[3].

[2] https://echa.europa.eu/practical-guides
[3] https://echa.europa.eu/manuals

## 2. General recommendations for conducting and reporting new tests

### 2.1. Environmental testing for substances containing multiple constituents

Your Substance contains multiple constituents and, as indicated in Guidance on IRs & CSA, Section R.11.4.2.2, you are advised to consider the following approaches for persistency, bioaccumulation and aquatic toxicity testing:

- the "known constituents approach" (by assessing specific constituents), or
- the "fraction/block approach, (performed on the basis of fractions/blocks of constituents), or
- the "whole substance approach", or
- various combinations of the approaches described above

Selection of the appropriate approach must take into account the possibility to characterise the Substance (i.e. knowledge of its constituents and/or fractions and any differences in their properties) and the possibility to isolate or synthesize its relevant constituents and/or fractions.

References to Guidance on REACH and other supporting documents can be found in Appendix 1.