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Helsinki, 22 May 2024

Addressee(s)
Registrant(s) of 99422018_REG2010_11_19 as listed in Appendix 3 of this decision

Date of submission of the dossier subject to this decision
29 November 2022

Registered substance subject to this decision ("the Substance")
Substance name: Reaction mass of Octadecanamide, 12-hydroxy-N-[2-[(1-oxodecyl)amino]ethyl]- and N,N'-ethane-1,2-diylbis(12-hydroxyoctadecan-1-amide) and Decanamide, N,N'-1,2-ethanediylbis-
EC/List number: 907-495-0

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 ***27 February 2026***.

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

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

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

The reasons for the request(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. The addressees of the decision and their corresponding information requirements based on registered tonnage band are listed in Appendix 3.

You are only required to share the costs of information that you must submit to fulfil your information requirements.

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.

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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 request(s)
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 request(s)

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Reasons related to the information under Annex VII of REACH

1. Growth inhibition study aquatic plants

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

1.1. Information provided

2 You have provided a Growth inhibition study on aquatic plants/algae (2010) with the Substance.

1.2. Assessment of the information provided

1.2.1. The provided study does not meet the specifications of the test guideline(s)

3 To fulfil the information requirement, a study must comply with OECD TG 201 and the specifications of OECD GD 23 if the substance is difficult to test (Article 13(3) of REACH). Therefore, the following specifications must be met:

Technical specifications impacting the sensitivity/reliability of the test

a) the test concentrations are below the limit of solubility of the test material in the dilution water;

Additional requirements applicable to difficult to test substances

b) if water-accommodated fractions (WAFs) are used, a preliminary study must be conducted to determine that saturation has been achieved;

c) the efficacy of the separation method is assessed (*e.g.* by checking for the Tyndall effect or by any other appropriate means);

Reporting of the methodology and results

d) adequate information on the analytical method (including performance parameters of the method) and on the results of the analytical determination of exposure concentrations is provided;

4 In the provided study:

Technical specifications impacting the sensitivity/reliability of the test

a) the solubility of the Substance in water as reported in your dossier is 0.021 mg/L while the test was conducted at nominal concentrations ranging from 4.27 mg/L to 100 mg/L. While you have not provided an estimate of the solubility of the test material in the specific test medium (see point b) below), it is likely that the nominal concentrations were well above the limit of solubility of the test material in the dilution water.

Additional requirements applicable to difficult to test substances

b) you have used water-accommodated fractions (WAFs) to conduct the study. However, you have not provided a preliminary study to demonstrate that saturation has been achieved;

c) you report that test solutions were "*left to stand for approximately 24 h. After standing, aliquots (1 L) were then removed mid vessel to provide the aqueous*

media (WAF's) used in the test". However, you have provided no information on the efficacy of this separation method;

Reporting of the methodology and results

d) the test design is reported (*e.g.*, whether or not the test media prepared specifically for analysis of exposure concentrations during the test is treated identically to those used for testing (i.e. inoculated with algae and incubated under identical conditions));

e) you state that you have used non-specific analysis of total organic carbon (TOC) for analytical monitoring. You have provided no information on the performance parameter of the selected analytical method. You state that chromatographic methods are not a suitable analysis method for the test material but you provided no experimental proof to support this statement. ECHA also notes that you have provided no reporting of the result of the analytical determination of exposure concentration obtained from the selected analytical method (i.e., TOC).

5 Based on the above, the Substance is difficult to test due to poor water solubility (water solubility of 0.021 mg/L), and adsorptive properties (Log Kow of 6.5-10.6) and there are critical methodological deficiencies resulting in the rejection of the study results. More specifically,

- you have used test solutions prepared using loading rates that are order of magnitude above the expected water solubility of the Substance. However, you have provided no supporting information to demonstrate that the separation method you used is adequate to remove the undissolved fraction. Therefore, you have not demonstrated that measured concentrations reflect the dissolved fraction of the substance.
- in the absence of a preliminary study to determine the saturation concentration of the test material in the test medium, of an unambiguous description of the test design (i.e., whether the test media prepared specifically for analysis of exposure concentrations during the test were inoculated with algae) and of the results of the analytical determination of exposure concentrations, it is not possible to assess the reliability of measured exposure concentrations;
- the OECD GD 23 specifies that for UVCBs, it must normally be demonstrated that concentrations were consistently maintained within 80-120% of the initial or mean measured values over the exposure duration based on a comparison of the mass spectral full-scan GC or HPLC chromatogram peak area. You claim that chromatographic methods are not a suitable analysis method for the test material. However, ECHA notes that such method was successfully used in a long-term toxicity study on aquatic invertebrates available in your dossier. Taking also into account the other deficiencies already explained above, you have not demonstrated that exposure concentrations were maintained within 20% of the nominal loading rates throughout the tests and that effect concentrations can be expressed based on nominal loading rates.

6 On this basis, the specifications of OECD TG 201 are not met.

7 Therefore, the information requirement is not fulfilled.

8 In your comments on the draft decision you agree to perform the requested study.

1.3. Study design

9 The Substance is difficult to test due to the low water solubility (0.021 mg/L) and/or adsorptive properties (Log K_{ow} 6.5-10.6). OECD TG 201 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 201. 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.

10 For multi-constituents/UVCBs, the analytical method must be adequate to monitor qualitative and quantitative changes in exposure to the dissolved fraction of the test material during the test (e.g. by comparing mass spectral full-scan GC or HPLC chromatogram peak areas or by using targeted measures of key constituents or groups of constituents).

11 If you decide to use the Water Accommodated Fraction (WAF) approach, in addition to the above, you must:

- provide a full description of the method used to prepare the WAF (including, among others, loading rates, details on the mixing procedure, method to separate any remaining non-dissolved test material including a justification for the separation technique);
- prepare WAFs separately for each dose level (*i.e.* loading rate) and in a consistent manner.

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).
Guidance for monomers and polymers; ECHA (2023).
***Guidance on intermediates*;** ECHA (2010).
All guidance documents are 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 22 February 2023.

The deadline of the decision is set based on standard practice for carrying out OECD TG tests. It has been exceptionally extended by 6 months from the standard deadline granted by ECHA to take into account currently longer lead times in contract research organisations.

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

You have provided comments during the decision-making phase which were found to address some of the incompliance(s) identified in the draft decision and you included this information in an update of your registration dossier (submission date: 30 October 2023). Therefore, the original requests for information on skin sensitisation (Annex VII, Section 8.3.) and for an *in vitro* mammalian cell micronucleus (Annex VIII, Section 8.4.2.) were removed.

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 3: Addressee(s) 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;
- the information specified in Annexes VII, VIII and IX to REACH, for registration at 100-1000 tpa;
- the information specified in Annexes VII to X to REACH, for registration at more than 1000 tpa.

Registrant Name	Registration number	Highest REACH Annex applicable to you
[redacted]	[redacted]	[redacted]
[redacted]	[redacted]	[redacted]
[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.

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 (https://echa.europa.eu/practical-guides).
(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

Before generating new data, you must agree within the joint submission on the chemical composition of the material to be tested (Test Material) which must be relevant for all the registrants of the Substance.

(1) Selection of the Test material(s)

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

- the variation in compositions reported by all members of the joint submission,
- the boundary composition(s) of the Substance,
- 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

- 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.
- The reported composition must include all constituents of each Test Material and their concentration values.

With that detailed information, ECHA can confirm whether the Test Material is relevant for the Substance and whether it is suitable for use by all members of the joint submission.

Technical instructions on how to report the above is available in the manual on How to prepare registration and PPORD dossiers (https://echa.europa.eu/manuals).