~~Confidential~~

Helsinki, 22 May 2024

Addressees
Registrants of JS_EBS_1 as listed in Appendix 3 of this decision

Date of submission of the dossier subject to this decision
10 June 2022

Registered substance subject to this decision ("the Substance")
Substance name: Amides, C16-C18 (even) , N,N'-ethylenebis
EC/List number: 931-299-4

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 August 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. *In vitro* gene mutation study in bacteria (Annex VII, Section 8.4.1.; test method: Bacterial reverse mutation test, OECD TG 471).

2. Long-term toxicity testing on aquatic invertebrates, also requested below (triggered by Annex VII, Section 9.1.1., Column 2).

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

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

4. Long-term toxicity testing on fish, also requested below (triggered by Annex VIII, Section 9.1.3., Column 2).

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

5. Long-term toxicity testing on aquatic invertebrates (Annex IX, Section 9.1.5.; test method: EU C.20./OECD TG 211).

6. Long-term toxicity testing on fish (Annex IX, Section 9.1.6.; test method: EU C.47./OECD TG 210).

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.

In the requests above, the same study has been requested under different Annexes. This is because some information requirements may be triggered at lower tonnage band(s). In such cases, only the reasons why the information requirement is triggered are provided for the lower tonnage band(s). For the highest tonnage band, the reasons why the standard information requirement is not met and the specification of the study design are provided. Only one study is to be conducted; all registrants concerned must make every effort to reach an agreement as to who is to carry out the study on behalf of the others under Article 53 of REACH.

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.

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)

Reasons related to the information under Annex VII of REACH

1. *In vitro* gene mutation study in bacteria

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

1.1. Information provided

2 You have provided an *in vitro* gene mutation study in bacteria (1978) 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

3 To fulfil the information requirement, a study must comply with OECD TG 471 (Article 13(3) of REACH). Therefore, the following specifications must be met:

a) the test is performed with 5 strains: four strains of *S. typhimurium* (TA98; TA100; TA1535; TA1537 or TA97a or TA97) and one strain which is either *S. typhimurium* TA102 or *E. coli* WP2 uvrA or *E. coli* WP2 uvrA (pKM101);

b) the maximum dose tested induces a reduction in the number of revertant colonies per plate compared to the negative control, or the precipitation of the tested substance. If no precipitate or limiting cytotoxicity is observed, the highest test dose corresponds to 5 mg/plate or 5 µl/plate;

c) the mean number of revertant colonies per plate is reported for the treated doses and the controls.

4 In the provided study:

a) the test was performed with the strains *S. typhimurium* TA 1535, TA 1537, TA 1538, TA 98, TA 100 and *Saccharomyces cerevisiae* D4 (i.e., the strain *E. coli* WP2 uvrA or *E. coli* WP2 uvrA (pKM101) is missing);

b) the maximum dose tested did not induced a reduction in the number of revertant colonies per plate compared to the negative control, or the precipitation of the tested substance and it was less than 5 mg/plate or 5 µl/plate;

c) the mean number of revertant colonies per plate for the treated doses and the controls was not reported.

5 The information provided does not cover the specification(s) required by the OECD TG 471.

6 Therefore, the information requirement is not fulfilled.

2. Long-term toxicity testing on aquatic invertebrates

7 Short-term toxicity testing on aquatic invertebrates is an information requirement under Annex VII, Column 1, Section 9.1.1. However, under Column 2, long-term toxicity testing on aquatic invertebrates may be required by the Agency if the substance is poorly water soluble, i.e. solubility below 1 mg/L.

2.1. Triggering of the information requirement

8 You have provided information which indicates that the Substance includes constituents that are poorly water soluble and the key value that you have provided for water solubility is < 1 mg/L. The information available supporting this conclusion consists of QSAR predictions and information from an OECD TG 105 (2021) study, reported as weight of evidence. The shake flask method was attempted in the OECD TG 105 study and the test item remained undissolved in water. The reported result from the study was < 1 mg/L.

9 Therefore, the Substance is poorly water soluble and information on long-term toxicity on aquatic invertebrates must be provided.

2.2. Information requirement not fulfilled

10 The information provided, its assessment and the specifications of the study design are addressed under request 4.

3. Growth inhibition study aquatic plants

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

3.1. Information provided

12 You have provided a Growth inhibition study on aquatic plants/algae (2005) with the Substance.

3.2. Assessment of the information provided

3.2.1. The provided study does not meet the specifications of the test guideline

13 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). The test material is difficult to test due to its low water solubility (i.e., < 1 mg/L). Therefore, the following specifications must be met:

Additional requirements applicable to difficult to test substances

a) if the test material is poorly water soluble, the maximum dissolved concentration that can be achieved in the specific test solution under the test conditions is determined;

b) if the test material is tested at the saturation concentration, evidence must be provided that all reasonable efforts have been taken to achieve a saturation concentration, which include:

1) an analytical method validation report demonstrating that the analytical method is appropriate, and

2) information on the saturation concentrations of the test material in water and in the test solution, and

3) the results of a preliminary experiment demonstrating that the test solution preparation method is adequate to maximize the concentration of the test material in solution.

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

14 In the provided study:

Additional requirements applicable to difficult to test substances

a) you have not described and reported the results of a preliminary solubility study to determine the maximum dissolved concentration that can be achieved in the specific test solution under the test conditions;

b) you claim that the test material was tested up to the saturation concentration. However, you have not provided adequate evidence to support that all reasonable efforts have been taken to achieve a saturation concentration. In particular:

(1) you have not provided an analytical method validation report for the analytical method to support that it is appropriate to quantify all relevant constituents of the test material;

(2) as explained under point a), you have not provided reliable information on the saturation concentrations of the test material in water and in the test solution;

(3) you have not provided the results of a preliminary experiment demonstrating that the test solution preparation method is adequate to maximize the concentration of the test material in solution.

c) you state that undissolved test material was removed by filtration through "*No. 2 filter paper*" and that "*test water was colorless after preparation*". However, as specified in the OECD GD 23, visual observations is not sufficient to demonstrate that water solubility limit is reached.

15 Based on the above, the Substance is difficult to test (water solubility < 1mg/L) and there are critical methodological deficiencies resulting in the rejection of the study results. More specifically, have not provided adequate information to support that the methodology used in this study allowed to maximize exposure to the test material. In particular, your robust study summary lacks a reliable estimate of the saturation concentration of the test material in the specific test medium. Furthermore, it remains unclear whether the selected analytical method and the methodology used to prepare the test solutions allowed to reach saturation and to provide reliable estimate of dissolved concentrations. Therefore, you have not demonstrated that the test organisms were satisfactorily exposed to the test material.

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

17 Therefore, the information requirement is not fulfilled.

3.3. Study design

18 The Substance is difficult to test due to the low water solubility (< 1 mg/L) and adsorptive properties (Log K_{OC} 7.87 – 8.91 (predicted)). 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.

19 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).

20 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.

Reasons related to the information under Annex VIII of REACH

4. Long-term toxicity testing on fish

21 Short-term toxicity testing on fish is an information requirement under Annex VIII, Column 1, Section 9.1.3. However, long-term toxicity testing on fish may be required by the Agency (Section 9.1.3., Column 2) if the substance is poorly water soluble, i.e. solubility below 1 mg/L.

4.1. Triggering of the information requirement

22 As already explained in request 2, the Substance is poorly water soluble and information on long-term toxicity on fish must be provided.

4.2. Information requirement not fulfilled

23 The information provided, its assessment and the specifications of the study design are addressed under request 5.

Reasons related to the information under Annex IX of REACH

5. Long-term toxicity testing on aquatic invertebrates

24 Long-term toxicity testing on aquatic invertebrates is an information requirement under Annex IX to REACH (Section 9.1.5.).

5.1. Information provided

25 You have provided a long-term toxicity study on Daphnia magna (2005) with the Substance.

5.2. Assessment of the information provided

5.2.1. The provided study does not meet the specifications of the test guideline

26 To fulfil the information requirement, a study must comply with the OECD TG 211 and the specifications of OECD GD 23 if the substance is difficult to test (Article 13(3) of REACH). The test material is difficult to test due to its low water solubility (i.e., < 1 mg/L). Therefore, the following specifications must be met:

Additional requirements applicable to difficult to test substances

a) if the test material is poorly water soluble, the maximum dissolved concentration that can be achieved in the specific test solution under the test conditions is determined;

b) if the test material is tested at the saturation concentration, evidence must be provided that all reasonable efforts have been taken to achieve a saturation concentration, which include:

1) an analytical method validation report demonstrating that the analytical method is appropriate, and

2) information on the saturation concentrations of the test material in water and in the test solution, and

3) the results of a preliminary experiment demonstrating that the test solution preparation method is adequate to maximize the concentration of the test material in solution.

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

27 In the provided study:

Additional requirements applicable to difficult to test substances

a) you have not described and reported the results of a preliminary solubility study to determine the maximum dissolved concentration that can be achieved in the specific test solution under the test conditions;

b) you claim that the test material was tested up to the saturation concentration. However, you have not provided adequate evidence to support that all reasonable efforts have been taken to achieve a saturation concentration. In particular:

(1) you have not provided an analytical method validation report for the analytical method to support that it is appropriate to quantify all relevant constituents of the test material;

(2) as explained under point a), you have not provided reliable information on the saturation concentrations of the test material in water and in the test solution;

(3) you have not provided the results of a preliminary experiment demonstrating that the test solution preparation method is adequate to maximize the concentration of the test material in solution.

c) you state that undissolved test material was removed by filtration through "*No. 2 filter paper*" and that "*test water was always colorless when it was freshly prepared*". However, as specified in the OECD GD 23, visual observations is not sufficient to demonstrate that water solubility limit is reached.

28 Based on the above, the Substance is difficult to test (water solubility < 1mg/L) and there are critical methodological deficiencies resulting in the rejection of the study results. More specifically, have not provided adequate information to support that the methodology used in this study allowed to maximize exposure to the test material. In particular, your robust study summary lacks a reliable estimate of the saturation concentration of the test material in the specific test medium. Furthermore, it remains unclear whether the selected analytical method and the methodology used to prepare the test solutions allowed to reach saturation and to provide reliable estimate of dissolved concentrations. Therefore, you have not demonstrated that the test organisms were satisfactorily exposed to the test material.

29 On this basis, the specifications of OECD TG 211 are not met.

30 Therefore, the information requirement is not fulfilled.

5.3. Study design

31 OECD TG 211 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" under request 2.

6. Long-term toxicity testing on fish

32 Long-term toxicity testing on fish is an information requirement under Annex IX to REACH (Section 9.1.6.).

6.1. Information provided

33 You have adapted this information requirement by using Column 2 of Annex IX, Section 9.1. To support the adaptation, you have provided the following justification: "[…] *The substance is insoluble in water and the available short-term toxicity studies for fish, daphnia and algae indicate no aquatic toxicity of the substance to aquatic organisms. The available chronic data for aquatic invertebrates (OECD 211) and algae (OECD 201) determined no chronic effects of the substance. Since there is no indication in the short-term tests that invertebrates are less sensitive than fish, it is unlikely that a long-term test with fish will generate different results than the available long-term study with aquatic invertebrates. The available study on the bioaccumulation potential of the substance in fish determined BCF values clearly < 2000 L/kg. Based on these considerations and in order to avoid unnecessary vertebrate testing for animal welfare reasons, no further long-term test with fish was proposed*. […]".

6.2. Assessment of information provided

6.2.1. Annex IX, Section 9.1., Column 2 is not a valid basis to omit the study

34 A registrant may only adapt this information requirement based on the general rules set out in Annex XI. Column 2 of Annex IX, Section 9.1., does not allow omitting the need to submit information on long-term toxicity to fish under Column 1 (Decision of the Board of Appeal in case A-011-2018).

35 Minimisation of vertebrate animal testing is not on its own a legal ground for adaptation under the general rules of Annex XI or Annex IX, Section 9.1., Column 2.

36 Your adaptation is therefore rejected.

37 Therefore, the information requirement is not fulfilled.

6.3. Study design

38 To fulfil the information requirement for the Substance, the Fish, Early-life Stage Toxicity Test (test method OECD TG 210) is the most appropriate (Guidance on IRs and CSA, Section R.7.8.2.).

39 OECD TG 210 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" under request 2.

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.

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).

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 in contract research organisations.

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

(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 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 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).

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.