~~Confidential~~

Helsinki, 19 January 2024

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

Date of submission of the dossier subject to this decision
14 December 2017

Registered substance subject to this decision ("the Substance")
Substance name: nitroethane
EC/List number: 201-188-9

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 **27 July 2026**.

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

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

1. Short-term toxicity testing on fish (Annex VIII, Section 9.1.3.; test method: OECD TG 203)

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

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

3. Simulation testing on ultimate degradation in surface water (Annex IX, Section 9.2.1.2.; test method: EU C.25./OECD TG 309) at a temperature of 12°C.

4. Identification of degradation products (Annex IX, 9.2.3.; test method: EU C.25/OECD TG 309)

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.

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 VIII of REACH

1. Short-term toxicity testing on fish

1 Short-term toxicity testing on fish is an information requirement under Annex VIII to REACH (Section 9.1.3.).

1.1. Information provided

2 You have provided:

(i) a short-term toxicity study on fish (1990) with the Substance;

(ii) in your dossier under Section 6.1.1. of IUCLID under "Rational and reliability (including deficiencies)" you also refer to a source study that was performed on an analogue substance, i.e. 1-Nitropropane, without providing any study record.

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 203 Article 13(3) of REACH). Therefore, the following specifications must be met:

4 *Technical specifications impacting the sensitivity/reliability of the test*

a) the test duration is 96 hours or longer;

b) at least five concentrations are tested

5 *Characterisation of exposure*

c) in static tests, if the concentrations of the test material are not expected to remain within ± 20 % of the nominal, then the test substance concentration is determined (in one replicate) in all concentrations at the beginning, at 48 hours and at the end of the test

6 *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 are provided.

7 In study (i):

Technical specifications impacting the sensitivity/reliability of the test

a) the test duration was 48 hours;

b) only three concentrations were tested

Characterisation of exposure

c) the test was conducted under static conditions and in your dossier you state that the Substance is volatile (vP = 2.79 kPa), hence the Substance is not expected to remain within ± 20 % of the nominal. However, the test substance concentration was not determined in all concentrations at the beginning, at 48 hours and at the end of the test (i.e. 96 hours). Therefore, it is not possible to confirm whether the Substance remains stable throughout the test.

Reporting of the methodology and results

d) on the analytical method, adequate information, e.g. performance parameters of the method is not reported. Regarding the results of the analytically determined exposure concentrations, you have reported three concentrations i.e. 800, 1100 and 1300 mg/L and you specify that "*the report does not indicate whether this was nominal or measured concentrations but the table format suggests analytical"*. On this basis you indicate them as measured. However, as you have not provided the results of the analytically determined exposure concentrations, there is no evidence that would confirm that the reported concentrations are measured and not nominal.

8 Based on the above,

- there are critical methodological deficiencies resulting in the rejection of the study results. More specifically, the duration of the study (i.e. the duration of exposure that was used to determine the LC_{50} value) was only 48 hours and only three test concentrations were used. Therefore, it cannot be determined if potential mortality effects (i.e lower LC_{50} values) would be observed during the required duration of exposure of 96 hours to five test concentrations.
- the substance is volatile and there is a lack of analytical information to confirm whether the Substance was stable until the end of the test, and whether (or not) the test organisms were exposed to the Substance. As a consequence, it is not possible to assess the reliability of the reported LC_{50} value. Furthermore, the reporting of the study is not sufficient to conduct an independent assessment of its reliability.

9 On this basis, the specifications of OECD TG 203 are not met.

1.2.2. Absence of read-across documentation

10 Annex XI, Section 1.5. requires that whenever read-across is used adequate and reliable documentation of the applied method must be provided. Such documentation must include an explanation why the properties of the Substance may be predicted from information on the source substance(s).

11 You have not provided documentation to explain why this information is relevant for the Substance and why the properties of the Substance may be predicted from information on the source substance(s).

12 In the absence of such documentation, we are not in a position to assess the reliability of the provided information.

1.2.3. Missing robust study summary summaries

13 Annex XI, Section 1.5. requires that whenever read-across is used adequate and reliable documentation of the applied method must be provided. Such documentation must include robust study summary for each source study used in the adaptation.

14 In your dossier you refer to a study that was performed on the analogue substance i.e. 1-Nitropropane. However, you have not provided detailed information on the methods, results and conclusions, allowing for an independent assessment of the study.

1.2.4. Study not conducted according to GLP

15 (Eco)toxicological studies must comply with GLP or another recognised international standard; Art. 13(4) of REACH.

16 You have indicated that the study (i) is "not GLP-compliant", without further explanation.

17 The test does not comply with GLP or another recognised international standard and is therefore rejected.

18 Therefore, the information requirement is not fulfilled.

Reasons related to the information under Annex IX of REACH

2. Long-term toxicity testing on fish

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

2.1. Information provided

20 In your dossier you have provided the following information: "The risk characterisation shows that the PEC/PNEC ratio for surface water is clearly <1, indicating no need for further information and testing"

2.2. Assessment of the information provided

2.2.1. Your justification to omit the study has no legal basis

21 A registrant may only adapt this information requirement based on the general rules set out in Annex XI. It is noted that 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).

22 Your justification to omit this information does not refer to any legal ground for adaptation under Annex XI to REACH.

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

24 As a consequence, the information requirement is not fulfilled.

2.1. Study design

25 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.).

3. Simulation testing on ultimate degradation in surface water

26 Simulation testing on ultimate degradation in surface water is an information requirement under Annex IX to REACH (Section 9.2.1.2.).

3.1. Information provided

27 You have adapted this information requirement by using Column 2 of Annex IX, Section 9.2. To support the adaptation, you have provided following information: "In accordance with REACH guidance, degradation simulation testing in water and/or sediment does not need to be conducted as from the chemical safety assessment it can be concluded that there is no risk for the aquatic compartment. A further refinement of the PECs using additional information on the degradation of the substance and its degradation products in water and sediment is therefore not required"

3.1. Assessment of information provided

3.1.1. Annex IX, Section 9.2., Column 2 is not a valid basis to omit the study

28 Annex IX, Section 9.2., Column 2 provides that "further" biodegradation testing must be proposed if the chemical safety assessment according to Annex I indicates the need to investigate further the degradation of the substance and its degradation products. That

provision allows a registrant to propose, or ECHA to require, biotic degradation testing not covered by the information on degradation listed under Annex IX, section 9.2., Column 1. Therefore, this provision cannot be used as a justification for omitting the submission of information on simulation testing on ultimate degradation in surface water required under Annex IX, Section 9.2.1.2, Column 1.

29 Therefore, your adaption is rejected.

30 Therefore, the information requirement is not fulfilled.

3.1. Study design

31 Simulation degradation studies must include two types of investigations (Guidance on IRs and CSA, Section R.7.9.4.1.):

1) a degradation pathway study where transformation/degradation products are quantified and, if relevant, are identified, and

2) a kinetic study where the degradation rate constants (and degradation half-lives) of the parent substance and of relevant transformation/degradation products are experimentally determined.

32 You must perform the test, by following the pelagic test option with natural surface water containing approximately 15 mg dw/L of suspended solids (acceptable concentration between 10 and 20 mg dw/L) (Guidance on IRs and CSA, Section R.11.4.1.1.3.).

33 The required test temperature is 12°C, which corresponds to the average environmental temperature for the EU (Guidance on IRs and CSA, Table R.16-8) and is in line with the applicable test conditions of the OECD TG 309.

34 As specified in Guidance on IRs and CSA, Section R.7.9.4.1., the organic carbon (OC) concentration in surface water simulation tests is typically 2 to 3 orders of magnitude higher than the test material concentration and the formation of non-extractable residues (NERs) may be significant in surface water tests. Paragraph 52 of the OECD TG 309 provides that the "*total recovery (mass balance) at the end of the experiment should be between 90% and 110% for radiolabelled substances, whereas the initial recovery at the beginning of the experiment should be between 70% and 110% for non-labelled substances*". NERs contribute towards the total recovery. Therefore, the quantity of the (total) NERs must be accounted for the total recovery (mass balance), when relevant, to achieve the objectives of the OECD TG 309 to derive degradation rate and half-life. The reporting of results must include a scientific justification of the used extraction procedures and solvents.

35 For the persistence assessment by default, total NERs is regarded as non-degraded Substance. However, if reasonably justified and analytically demonstrated a certain part of NERs may be differentiated and quantified as irreversibly bound or as degraded to biogenic NERs, such fractions could be regarded as removed when calculating the degradation half-life(s) (Guidance on IRs and CSA, Section R.11.4.1.1.3.). Further recommendations may be found in the background note on options to address non-extractable residues in regulatory persistence assessment available on the ECHA website (NER - summary 2019 (europa.eu)).

36 Relevant transformation/degradation products are at least those detected at ≥ 10% of the applied dose at any sampling time or those that are continuously increasing during the study even if their concentrations do not exceed 10% of the applied dose, as this may indicate persistence (OECD TG 309; Guidance on IRs and CSA, Section R.11.4.1.).

4. Identification of degradation products

37 Identification of abiotic and biotic degradation products is an information requirement under Annex IX to REACH (Section 9.2.3.).

4.1. Information provided

38 You have adapted this information requirement by using Column 2 of Annex IX, Section 9.2. To support the adaptation, you have provided following information:

39 "In accordance with REACH guidance, degradation simulation testing in water and/or sediment does not need to be conducted as from the chemical safety assessment it can be concluded that there is no risk for the aquatic compartment. A further refinement of the PECs using additional information on the degradation of the substance and its degradation products in water and sediment is therefore not required"

4.1. Assessment of information provided

40 Annex IX, Section 9.2., Column 2 provides that "further" biodegradation testing must be proposed if the chemical safety assessment according to Annex I indicates the need to investigate further the degradation of the substance and its degradation products. That provision allows a registrant to propose, or ECHA to require, biotic degradation testing not covered by the information on degradation listed under Annex IX, section 9.2., Column 1. Therefore, this provision cannot be used as a justification for omitting the submission of information on Identification of degradation products required under Annex IX, Section 9.2.3, Column 1.

41 Therefore, your adaption is rejected.

42 Therefore, the information requirement is not fulfilled.

4.2. Study design

43 Simulation degradation studies must include two types of investigations (Guidance on IRs and CSA, Section R.7.9.4.1.):

(1) a degradation pathway study where transformation/degradation products are quantified and, if relevant, are identified, and
(2) a kinetic study where the degradation rate constants (and degradation half-lives) of the parent substance and of relevant transformation/degradation products are experimentally determined.

44 Identity, stability, behaviour, and molar quantity of the degradation/transformation products relative to the Substance must be evaluated and reported. In addition, identified transformation/degradation products must be considered in the CSA including PBT assessment.

45 You must obtain this information from the degradation study requested in request 3.

46 To determine the degradation rate of the Substance, the requested study according to OECD TG 309 (request [3]) must be conducted at 12°C and at a test concentration < 100 µg/L. However, to overcome potential analytical limitations with the identification and quantification of major transformation/degradation products, you may consider running a parallel test at higher temperature (but within the frame provided by the test guideline, e.g. 20°C) and at higher application rate (i.e. > 100 µg/L).

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 23 January 2023.

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

ECHA took into account your comments and did not amend the deadline.

In your comments on the draft decision, you requested an extension of the deadline to provide information without indicating any precise timelines. You state that due to multiple successive steps that need to be considered to provide the information requested in the decision i.e. delays due to laboratory capacity, technical difficulties due to the properties of the substance, time to update the dossier and CSA etc, 30 months deadline is too short. However, you have not provided any documentation to support your arguments.

Furthermore, as indicated above, the deadline set in this decision has already been extended by 12 months.

On this basis ECHA has not modified the deadline to provide the information.

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;

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) Selection of the Test material(s)
The Test Material used to generate the new data must be selected taking into account the following:

- 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

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).