

Helsinki, 3 May 2022

Addressees

Registrants of JS_97925-95-6 as listed in Appendix 3 of this decision

Date of submission of the dossier subject to this decision

26/02/2021

Registered substance subject to this decision ("the Substance")

Substance name: Ethanol, 2,2'-iminobis-, N-(C13-15-branched and linear alkyl) derivs.

EC number: 308-208-6

Decision number: Please refer to the REACH-IT message which delivered this communication (in format TPE-D-XXXXXXXXXX-XX-XX/F)**DECISION ON TESTING PROPOSAL(S)**

Based on Article 40 of Regulation (EC) No 1907/2006 (REACH), you must submit the information listed below by **8 February 2024**.

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

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

1. Simulation testing on ultimate degradation in surface water, same information as required under Annex IX (triggered by Annex VIII, Section 9.2.), section 3 below.
2. Identification of degradation products, same information as required under Annex IX (triggered by Annex VIII, Section 9.2.), section 4 below.

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

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. Non-extractable residues (NER) must be quantified and a scientific justification of the selected extraction procedures and solvents must be provided.
4. Identification of degradation products (Annex IX, 9.2.3.; test method: EU C.25./OECD TG 309)

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

In the list of requests above, the same information requirement is mentioned under different Annexes. This is because the information is required under different conditions,

dependent on the tonnage of the registration. While the reasons for the information requirement may thus differ, only one study is requested and 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. In addition, the studies relating to biodegradation and bioaccumulation are necessary for the PBT assessment. However, to determine the testing needed to reach the conclusion on the persistency and bioaccumulation of the Substance you should consider the sequence in which these tests are performed and other conditions described in this Appendix.

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.

Authorised¹ 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 for the decision(s) related to the information under Annex VIII of REACH**1. Simulation testing on ultimate degradation in surface water**

- 1 Further degradation testing must be considered if the chemical safety assessment (CSA) according to Annex I indicates the need to investigate further the degradation of the substance (Annex VIII, Section 9.2., Column 2).
- 2 This information requirement is triggered in case the chemical safety assessment (CSA) indicates the need for further degradation investigation (Annex I, Section 4; Annex XIII, Section 2.1), such as if the substance is a potential PBT/vPvB substance (Guidance on IRs and CSA, Section R.11.4.). This is the case if the Substance itself or any of its constituent or impurity present in concentration $\geq 0.1\%$ (w/w) or relevant transformation/degradation product meets the following criteria:
 - it is potentially persistent or very persistent (P/vP) as it is not readily biodegradable (*i.e.* $<60/70\%$ degradation in an OECD 301B)
 - it is potentially bioaccumulative or very bioaccumulative (B/vB) as:
 - it has a high potential to partition to lipid storage (*e.g.* $\log K_{ow} > 4.5$);
 - for some groups of substances (*e.g.* organometals, ionisable substances, surfactants) other partitioning mechanisms may drive bioaccumulation (*e.g.* binding to protein/cell membranes) and high potential for bioaccumulation cannot be excluded solely based on its potential to partition to lipid;
 - it meets the T criteria set in Annex XIII: $EC_{50} < 0.01$ mg/L or NOEC or $EC_{10} < 0.01$ mg/L or classification as carc. 1A or 1B, muta. 1A or 1B, repro. 1A, 1B or 2, or STOT RE 1 or 2.
- 3 Your registration dossier provides the following information on the Substance:
 - The Substance is not readily biodegradable (37% degradation after 28 days in OECD TG 301B);
 - The Substance has a high potential to partition to lipid storage (Log K_{ow} of 4.88 based on QSAR estimations);
 - The Substance is surface active (surface tension of 29 mN/m at saturation based on OECD TG 115) and therefore high potential for bioaccumulation cannot be excluded based on available information; and
 - The Substance meets the T criteria: NOEC (72h) of 0.0044 mg/L for algae and is classified as Repro 1B.
- 4 Based on the above, the available information on the Substance indicates that it is a potential PBT/vPvB substance.
- 5 Therefore, the chemical safety assessment (CSA) indicates the need for further degradation investigation.
- 6 The examination of the information provided, your considerations of alternative methods, as well as the selection of the requested test and the test design are addressed under Appendix 1, Section 3.

2. Identification of degradation products

- 7 Further degradation testing must be considered if the chemical safety assessment (CSA) according to Annex I indicates the need to investigate further the degradation of the substance (Annex VIII, Section 9.2., Column 2).
- 8 Under Article 40(3)(c) of REACH, ECHA may require a registrant to carry out one or more additional tests in case of non-compliance of the testing proposal with Annexes IX, X or XI of the REACH Regulation. The information requirement on Degradation (Section 9.2.) at Annex IX requires to provide information on Biotic degradation (Section 9.2.1.) and on the identity of degradation products (Section 9.2.3.) for the Substance. You have submitted a testing proposal for simulation testing on ultimate degradation in surface water. In case of data gap for the identification of degradation products, it is necessary to request this information as an additional test to ensure compliance with the endpoint.
- 9 As already explained under Appendix 1, Section 1, the Substance is a potential PBT/vPvB substance. Therefore, the chemical safety assessment (CSA) indicates the need for further degradation investigation.
- 10 The reasons for considering a data gap, as well as for the selection of the requested test and the test design are addressed under Appendix 1, Section 4.
- 11 Under Article 40(3)(c), you are requested to conduct the additional test with the Substance, as specified in Appendix 1, Section 4.

Reasons for the decision(s) related to the information under Annex IX of REACH**3. Simulation testing on ultimate degradation in surface water**

12 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 to fulfil the information requirement

13 You have submitted a testing proposal for an Aerobic mineralisation in Surface Water – Simulation biodegradation test (test method: OECD TG 309).

14 Your registration dossier also includes:

- i. the following justification to omit the study: *“the study does not need to be conducted because direct and indirect exposure of sediment is unlikely”*; and
- ii. an adaptation under Annex XI, Section 3 with the following justification: *“no hazard in the environment is expected based on the outcome of the exposure assessment (all Risk Characterisation Ratios (RCR) < 1), further simulation tests are not needed”*. ECHA understands that you justify your adaptation by the provisions of Annex XI, Section 3.2(a).

15 We have assessed this information and identified the following issues:

3.1.1. Your justification under point i. above has no clear legal basis

16 A registrant may only adapt this information requirement based on the specific rules set out in the second column of Section 9.2.1.2. of Annex IX or the general rules set out in Annex XI. It is noted that Column 2 of Annex IX, Section 9.2.1.2 does not allow omitting the need to submit information on the absence of direct and indirect exposure to the sediment.

3.1.2. Annex XI, Section 3.2(a) is not a valid adaptation for potential PBT/vPvB substances

17 Under Annex XI, Section 3(a), this information may be omitted based on the exposure scenario(s) developed in the Chemical Safety Report. The justification must be based on a rigorous exposure assessment in accordance with Annex I, Section 5 and must meet any one of the following criteria:

- i. the absence or no significant exposure in all scenarios of the manufacture and all identified uses referred to in Annex VI, Section 3.5.,
- ii. a predicted no effect concentration (PNEC) can be derived from available data, which:
 - o must be relevant and appropriate both to the information requirement to be omitted and for risk assessment purposes and therefore must be based on reliable information on the hazardous properties of the substance on at least three trophic levels;
 - o must take into account the increased uncertainty resulting from the omission of the information requirement, in this case by selecting an appropriate assessment factor (AF) as described in ECHA Guidance R.10.3, and
- iii. the ratio between the results of the exposure assessment (PECs) and the PNEC are always well below 1.

- 18 For substances satisfying the PBT and vPvB criteria of Annex XIII, long-term effects and the estimation of the long-term exposure cannot be carried out with sufficient reliability (Annex I, Section 4.0.1). As a result, for such substances PNEC and PECs cannot be derived with sufficient reliability to demonstrate that the ratio between PECs and the PNEC are always well below 1 (conditions (ii) and (iii) above). Consequently, such information cannot be used to demonstrate that no significant exposure occurs in all scenarios of the manufacture and all identified uses referred to in Annex VI, Section 3.5 (condition (i) above).
- 19 As already explained under Appendix 1, Section 1, the information from your dossier currently does not allow excluding that the Substance may be PBT/vPvB.
- 20 Therefore, you have not demonstrated that the ratio between the reported PECs and the currently available PNEC provide a reliable means to demonstrate the absence of significant exposure of the environment. As a result, the conditions set out under Annex XI, Section 3.2(a) are not met.
- 21 On this basis the information requirement is not fulfilled and ECHA agrees that an appropriate simulation study on ultimate degradation in surface water is needed.

3.2. Test selection and study specifications

- 22 The proposed Aerobic mineralisation in Surface Water – Simulation biodegradation test (test method: OECD TG 309 / EU C 25) is appropriate to cover the information requirement for degradation/biodegradation (Guidance on IRs and CSA, Section R.7.9.4.1).
- 23 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.
- 24 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.).
- 25 The required test temperature is 12°C, which corresponds to the average environmental temperature for the EU (Guidance on IRs and CSA, Section R.16, Table R.16-8) and is in line with the applicable test conditions of the OECD TG 309.
- 26 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 substance concentration and the formation of non-extractable residues (NERs) may be significant in surface water tests. Therefore, non-extractable residues (NER) must be quantified. The reporting of results must include a scientific justification of the used extraction procedures and solvents. By default, total NER is regarded as non-degraded Substance. However, if reasonably justified and analytically demonstrated a certain part of NER may be differentiated and quantified as irreversibly bound or as degraded to biogenic NER, 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.
- 27 Relevant transformation/degradation products are at least those detected at $\geq 10\%$ 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.).

3.3. Outcome

28 Your testing proposal is accepted under Article 40(3)(a) and you are requested to conduct the test with the Substance, as specified above.

4. Identification of degradation products

29 Identification of degradation products is an information requirement under Annex IX to REACH (Section 9.2.3.).

30 Under Article 40(3)(c) of REACH, ECHA may require a registrant to carry out one or more additional tests in case of non-compliance of the testing proposal with Annexes IX, X or XI of the REACH Regulation. The information requirement on Degradation (Section 9.2.) at Annex IX requires to provide information on Biotic degradation (Section 9.2.1.) and on the identity of degradation products (Section 9.2.3.) for the Substance. You have submitted a testing proposal for simulation testing on ultimate degradation in surface water only. In case of data gap for the identification of degradation products, it is necessary to request this information as an additional test to ensure compliance with the endpoint.

4.1. Information provided to fulfil the information requirement

31 You have provided no information on the identity of transformation/degradation products for the Substance.

32 Therefore, the information requirement is not fulfilled and an identification of degradation products is needed.

4.2. Test selection and study specifications

33 Regarding the selection of appropriate and suitable test method(s), the method(s) will have to be substance specific. Identity, stability, behaviour, and molar quantity of the degradation/transformation products relative to the Substance must be evaluated and reported, when analytically possible. In addition, degradation half-life, log K_{ow} and potential toxicity of the transformation/degradation may need to be investigated. You may obtain this information from the degradation study requested in Appendix 1, Section 3. or by some other measure. If any other method is used for the identification of the transformation/degradation products, you must provide a scientifically valid justification for the chosen method.

34 To determine the degradation rate of the Substance, the requested study according to OECD TG 309 (Appendix 1, Section 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).

4.3. Outcome

35 Based on the above, according to Article 40(3)(c) of the REACH Regulation, you are requested to carry out the additional test with the Substance, as specified above.

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

ECHA started the testing proposal evaluation in accordance with Article 40(1) on 20 May 2021.

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

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

ECHA did not receive any comments within the commenting period.

ECHA notified the draft decision to the competent authorities of the Member States for proposals for amendment.

As no amendments were proposed, ECHA took the decision according to Article 51(3) of the REACH Regulation.

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;
- 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]

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 summaries².

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 and other parameters relevant for the property to be tested.

This information is needed to assess 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 dossiers³.

² <https://echa.europa.eu/practical-guides>

³ <https://echa.europa.eu/manuals>

2. General recommendations for conducting and reporting new tests

2.1. Strategy for the PBT/vPvB assessment

Under Annex XIII, the information must be based on data obtained under conditions relevant for the PBT/vPvB assessment. You must assess the PBT properties of each relevant constituent of the Substance present in concentrations at or above 0.1% (w/w) and of all relevant transformation/degradation products. Alternatively, you would have to justify why you consider these not relevant for the PBT/vPvB assessment.

You are advised to consult Guidance on IRs & CSA, Sections R.7.9, R.7.10 and R.11 on PBT assessment to determine the sequence of the tests needed to reach the conclusion on PBT/vPvB. The guidance provides advice on 1) integrated testing strategies (ITS) for the P, B and T assessments and 2) the interpretation of results in concluding whether the Substance fulfils the PBT/vPvB criteria of Annex XIII.

In particular, you are advised to first conclude whether the Substance fulfils the Annex XIII criteria for P and vP, and then continue with the assessment for bioaccumulation. When determining the sequence of simulation degradation testing you are advised to consider the intrinsic properties of the Substance, its identified uses and release patterns as these could significantly influence the environmental fate of the Substance. You must revise your PBT assessment when the new information is available.

2.2. 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.