

Helsinki, 17 February 2022

**Addressees**

Registrants of JS\_484-470-6\_2-PO listed in the last Appendix of this decision

**Date of submission of the dossier subject of a decision**

06/11/2020

**Registered substance subject to this decision, hereafter 'the Substance'**

Substance name: 2-Pentanone oxime

EC number: 484-470-6

CAS number: 623-40-5

**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 **25 May 2023**.

The requested information must be generated using the Substance unless otherwise specified.

**A. Information required from the Registrants subject to Annex IX of REACH**

1. Viscosity (Annex IX, Section 7.17.; test method OECD TG 114);
2. Pre-natal developmental toxicity study (Annex IX, Section 8.7.2.; test method: EU B.31./OECD TG 414) by oral route, in one species (rat or rabbit)
3. Long-term toxicity testing on aquatic invertebrates (Annex IX, Section 9.1.5.; test method: EU C.20./OECD TG 211)
4. Long-term toxicity testing on fish (Annex IX, Section 9.1.6.; test method: EU C.47./OECD TG 210)
5. Long-term toxicity testing on terrestrial invertebrates (triggered by Annex IX, Section 9.4.1., column 2; test method: OECD TG 222)

Reasons for the request(s) are explained in the following appendix entitled "Reasons to request information required under Annex IX of REACH".

**Information required depends on your tonnage band**

You must provide the information listed above for all REACH Annexes applicable to you, and in accordance with Articles 10(a) and 12(1) of REACH the information specified in Annexes VII, VIII and IX to REACH, for registration at 100-1000 tpa.

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 testing and reporting requirements provided under the Appendix entitled "Requirements to fulfil when conducting and reporting new tests for REACH purposes". For references used in this decision, please consult the Appendix entitled "List of references".

**Appeal**

This decision can be appealed to the Board of Appeal of ECHA within three months of its notification. An appeal, together with the grounds thereof, has to be submitted to ECHA in writing. An appeal has suspensive effect and is subject to a fee. Further details are described under: <http://echa.europa.eu/regulations/appeals>.

Approved<sup>1</sup> under the authority of Mike Rasenberg, Director of Hazard Assessment

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<sup>1</sup> 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 A: Reasons to request information required under Annex IX of REACH**

This decision is based on the examination of the testing proposals you submitted.

**1. Viscosity**

Viscosity is an information requirement under Annex IX to REACH (Section 7.17).

*1.1. Information provided to fulfil the information requirement*

You have submitted a testing proposal for a Viscosity of liquids test (test method: OECD TG 114) on the Substance.

Your registration dossier does not include any information on viscosity.

*1.2. Test selection and study specifications*

The proposed Viscosity of liquids test (test method: OECD TG 114) is appropriate to cover the information requirement for Viscosity (ECHA Guidance R.7.1.18.3.).

*1.3. Outcome*

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

**2. Pre-natal developmental toxicity study**

A pre-natal developmental toxicity (PNDT) study (OECD 414) in one species is an information requirement under Annex IX to REACH (Section 8.7.2.).

*2.1. Information provided to fulfil the information requirement*

You have submitted a testing proposal for a PNDT study according to OECD TG 414 by the oral route with the Substance.

ECHA requested your considerations for alternative methods to fulfil the information requirement for Developmental toxicity. You provided your considerations concluding that there were no alternative methods which could be used to adapt the information requirement(s) for which testing is proposed. ECHA has taken these considerations into account.

ECHA agrees that a PNDT study in a first species is necessary.

*2.2. Specification of the study design*

You proposed testing in the rat as a first species. You may select between the rat or the rabbit because both are preferred species under the OECD TG 414 (ECHA Guidance R.7a, Section R.7.6.2.3.2.).

You proposed testing by the oral route. ECHA agrees with your proposal because this route of administration is the most appropriate to investigate reproductive toxicity (ECHA Guidance R.7a, Section R.7.6.2.3.2.).

*2.3. Outcome*

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

### **3. Long-term toxicity testing on aquatic invertebrates**

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

#### *3.1. Information provided to fulfil the information requirement*

You have submitted a testing proposal for a *Daphnia magna* reproduction test (test method: EU C.20/OECD TG 211).

Your registration dossier does not include any information on long-term toxicity on aquatic invertebrates.

ECHA agrees that an appropriate study on long-term toxicity on aquatic invertebrates is needed.

#### *3.2. Test selection and study specifications*

The proposed *Daphnia magna* reproduction test (test method: EU C.20/OECD TG 211) is appropriate to cover the information requirement for long-term toxicity on aquatic invertebrates (ECHA Guidance R.7.8.4.1.).

#### *3.3. Outcome*

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. Long-term toxicity testing on fish**

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

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 Aquatic toxicity at Annex IX covers both long-term toxicity on invertebrates (Section 9.1.5.) and on fish (Section 9.1.6.). However, you have provided a testing proposal for long-term testing on aquatic invertebrates only. In case of data gap for long-term toxicity testing on fish, 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*

You have provided the following information to omit the study which you consider to be based on Annex IX, Section 9.1., Column 2. In support of your adaptation, you provided the following justification: "Studies on the long-term toxicity to fish are not available. According to Regulation (EC) 1907/2006, Annex IX, column 2 *long-term toxicity testing shall be proposed by the registrant if the chemical safety assessment according to Annex I indicates the need to investigate further the effects on aquatic organisms. The available data on the acute toxicity of the substance to aquatic organisms demonstrate that fish are not the most sensitive organism group. Furthermore, the chemical safety assessment does not indicate a need to further investigate the potential effects on aquatic organisms (RCR < 1). On this basis and for animal welfare reasons further long term testing on fish is not considered justified*".

We have assessed this information and identified the following issue:

Annex IX, Section 9.1., Column 2 does not allow omitting the need to submit information on long-term toxicity to fish under Column 1. It must be understood as a trigger for providing further information on long-term toxicity to fish if the chemical safety assessment according to Annex I indicates the need (Decision of the Board of Appeal in case A-011-2018).

Your adaptation is therefore rejected.

On this basis, the information requirement is not fulfilled.

#### 4.2. Test selection and study specifications

The Fish, Early-Life Stage Toxicity Test (test method: OECD TG 210) is appropriate to cover the information requirement for long-term toxicity on fish (ECHA Guidance R.7.8.4.1.).

#### 4.3. Outcome

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

### 5. Long-term toxicity testing on terrestrial invertebrates

Short-term toxicity to invertebrates is an information requirement under Annex IX to REACH (Section 9.4.1). Long-term toxicity testing must be considered (Section 9.4., column 2) if the substance has a high potential to adsorb to soil or is very persistent.

Under Annex IX, Section 9.4., column 2, for substances that have a high potential to adsorb to soil or that are very persistent, long-term toxicity testing must be considered instead of short-term. ECHA Guidance R.7.11.5.3. clarifies that a substance is considered to be very persistent in soil if it has a half-life >180 days. In the absence of specific soil data, high persistence is assumed unless the substance is readily biodegradable.

Under Section 5.2.1. of your technical dossier you report an OECD TG 301B study conducted with the Substance. The Substance showed 9% biodegradation after 28 days, and therefore the Substance is concluded not to be readily biodegradable. Your technical dossier does not include any experimental soil specific data on biodegradation but as supporting evidence results derived from a (Q)SAR model – Vega Persistence in soil model. On this basis, you conclude that the Substance is not persistent in soil.

However, results obtained from biodegradation (Q)SAR models are only regarded as screening information for P/vP properties (Annex XIII, Section 3.1.). As further explained in ECHA Guidance R.11.4.1.1.4., such information is not considered sufficient on its own to conclude on non-persistence and must be supported by additional information (e.g. test data information, read-across). Irrespective to the above deficiency, the provided QSAR has the following deficiencies:

1. Under ECHA Guidance R.6.1.5.3., a substance must fall within the applicability domain specified by the model developer. However, as specified by you "*the substance is evaluated as being outside the applicability domain of the model*".
2. ECHA Guidance R.6.1.6.3 states that the information specified in or equivalent to the (Q)SAR Prediction Reporting Format document (QPRF) must be provided to have adequate and reliable documentation of the applied method. However, you have not provided such information.

Finally, in Section 2.3. of your technical dossier ('PBT assessment'), you state that "Since no

additional biodegradation data are available, it should be concluded that the substance/relevant degradation product is persistent". ECHA agrees with this statement.

On this basis, the Substance is concluded to be potentially highly persistent in soil and information on long-term toxicity on terrestrial organisms must be provided.

*5.1. Information provided to fulfil the information requirement*

You have submitted a testing proposal for an Earthworm Reproduction Test (test method: OECD TG 222) with the following justification "*The substance is not readily biodegradable, has a low potential for adsorption and is not very toxic to aquatic organisms. According to the Guidance on Information Requirements and Chemical Safety Assessment Chapter R.7c: Endpoint specific guidance (ECHA, 2017), the substance is assigned to soil hazard category 3. Thus a confirmatory long-term soil toxicity testing is proposed.*"

ECHA agrees that an appropriate study on long-term toxicity terrestrial to invertebrate is needed.

*5.2. Test selection and study specifications*

The proposed Earthworm Reproduction Test (test method: OECD TG 222) is appropriate to cover the information requirement for long-term toxicity on terrestrial invertebrates (ECHA Guidance R.7.11.3.1).

*5.3. Outcome*

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

## **Appendix B: Requirements to fulfil when conducting and reporting new tests for REACH purposes**

### **A. 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<sup>2</sup>.

### **B. 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 dossiers<sup>3</sup>.

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

<sup>3</sup> <https://echa.europa.eu/manuals>

### **Appendix C: Procedure**

ECHA started the testing proposal evaluation in accordance with Article 40(1) on 19 January 2021.

ECHA held a third party consultation for the testing proposal(s) from 18 March 2021 until 3 May 2021. ECHA did not receive information from third parties.

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 adopted the decision under Article 51(3) of REACH.



**Appendix D: List of references - ECHA Guidance<sup>4</sup> and other supporting documents**Evaluation of available information

Guidance on information requirements and chemical safety assessment, Chapter R.4 (version 1.1., December 2011), referred to as ECHA Guidance R.4 where relevant.

QSARs, read-across and grouping

Guidance on information requirements and chemical safety assessment, Chapter R.6 (version 1.0, May 2008), referred to as ECHA Guidance R.6 where relevant.

Read-across assessment framework (RAAF, March 2017)<sup>5</sup>

RAAF - considerations on multi-constituent substances and UVCBs (RAAF UVCB, March 2017)<sup>6</sup>

Physical-chemical properties

Guidance on information requirements and chemical safety assessment, Chapter R.7a (version 6.0, July 2017), referred to as ECHA Guidance R.7a in this decision.

Toxicology

Guidance on information requirements and chemical safety assessment, Chapter R.7a (version 6.0, July 2017), referred to as ECHA Guidance R.7a in this decision.

Guidance on information requirements and chemical safety assessment, Chapter R.7c (version 3.0, June 2017), referred to as ECHA Guidance R.7c in this decision.

Environmental toxicology and fate

Guidance on information requirements and chemical safety assessment, Chapter R.7a (version 6.0, July 2017), referred to as ECHA Guidance R.7a in this decision.

Guidance on information requirements and chemical safety assessment, Chapter R.7b (version 4.0, June 2017), referred to as ECHA Guidance R.7b in this decision.

Guidance on information requirements and chemical safety assessment, Chapter R.7c (version 3.0, June 2017), referred to as ECHA Guidance R.7c in this decision.

PBT assessment

Guidance on information requirements and chemical safety assessment, Chapter R.11 (version 3.0, June 2017), referred to as ECHA Guidance R.11 in this decision.

Guidance on information requirements and chemical safety assessment, Chapter R.16 (version 3.0, February 2016), referred to as ECHA Guidance R.16 in this decision.

Data sharing

Guidance on data-sharing (version 3.1, January 2017), referred to as ECHA Guidance on data sharing in this decision.

OECD Guidance documents<sup>7</sup>

<sup>4</sup> <https://echa.europa.eu/guidance-documents/guidance-on-information-requirements-and-chemical-safety-assessment>

<sup>5</sup> <https://echa.europa.eu/support/registration/how-to-avoid-unnecessary-testing-on-animals/grouping-of-substances-and-read-across>

<sup>6</sup> [https://echa.europa.eu/documents/10162/13630/raaf\\_uvcb\\_report\\_en.pdf/3f79684d-07a5-e439-16c3-d2c8da96a316](https://echa.europa.eu/documents/10162/13630/raaf_uvcb_report_en.pdf/3f79684d-07a5-e439-16c3-d2c8da96a316)

<sup>7</sup> <http://www.oecd.org/chemicalsafety/testing/series-testing-assessment-publications-number.htm>

Guidance Document on aqueous-phase aquatic toxicity testing of difficult test chemicals – No 23, referred to as OECD GD 23.

Guidance document on transformation/dissolution of metals and metal compounds in aqueous media – No 29, referred to as OECD GD 29.

Guidance Document on Standardised Test Guidelines for Evaluating Chemicals for Endocrine Disruption – No 150, referred to as OECD GD 150.

Guidance Document supporting OECD test guideline 443 on the extended one-generation reproductive toxicity test – No 151, referred to as OECD GD 151.

**Appendix E: Addressees of this decision and the corresponding information requirements applicable to them**

You must provide the information requested in this decision for all REACH Annexes applicable to you.

<b>Registrant Name</b>	<b>Registration number</b>	<b>Highest REACH Annex applicable to you</b>
[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.