

Helsinki, 11 November 2021

**Addressees**

Registrant(s) of JS\_64401-02-1 as listed in the last Appendix of this decision

**Date of submission of the dossier subject to this decision**

18/01/2021

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

Substance name: Esterification products of acrylic acid and 4,4'-isopropylidenediphenol ethoxylated

EC number: 701-362-9

CAS number: NS

**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 the deadline of **16 August 2023**.

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

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

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

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

1. Long-term toxicity testing on fish (Annex IX, Section 9.1.6.; test method: OECD TG 210)
2. Identification of degradation products (Annex IX, 9.2.3.; test method: using an appropriate test method)

Reasons for the request(s) are explained in the appendices entitled "Reasons to request information required", under Annexes VIII and IX of REACH, respectively.

**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 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.

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

For certain endpoints, ECHA lists in the above the same study under the requirements at different tonnages. In such cases, only the reasoning why the information is required at lower tonnages is provided in the corresponding Appendices. The full reasoning for the request including study design is given in the Appendix which relates to the tonnage band where the study is a standard information requirement. Only one study is to be conducted; the registrants concerned must make every effort to reach an agreement as to who is to carry out the study on behalf of the other registrants under Article 53 of REACH.

### **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". In addition, you should follow the general recommendations provided under the Appendix entitled "General recommendations 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, 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<sup>1</sup> under the authority of Christel Schilliger-Musset, 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 VIII of REACH****1. Long-term toxicity testing on fish**

Short-term toxicity testing on fish is an information requirement under Annex VIII to REACH (Section 9.1.3.). Long-term toxicity testing on fish must be considered (Section 9.1.3., Column 2) if the substance is poorly water soluble.

You have provided an OECD TG 203 study (████████ 2013) but no information on long-term toxicity on fish for the Substance.

We have assessed this information and identified the following issue:

Poorly water soluble substances require longer time to reach steady-state conditions. As a result, the short-term tests does not give a true measure of toxicity for this type of substances and the long-term test is required. A substance is regarded as poorly water soluble if, for instance, it has a water solubility below 1 mg/L or below the detection limit of the analytical method of the test material (ECHA Guidance R.7.8.5).

In the provided OECD TG 105 study (████████ 2013), the saturation concentration of the Substance in water was determined to be 0.425 mg/L.

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

The examination of the information provided, as well as the selection of the requested test and the test design are addressed under section B 1.

## Appendix B: Reasons to request information required under Annex IX of REACH

### 1. 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.).

You have provided the following information: a justification 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:

*"In accordance with column 2 of REACH Annex IX, the study shall be proposed if the chemical safety assessment according to Annex I indicates the need to investigate further the effects on aquatic organisms. As the exposure assessment does not indicate the need to investigate further the effects on aquatic organisms (as all the RCR's to all the compartments are below 1 and all the supported uses are therefore assessed to be safe) no further long-term testing is proposed for aquatic compartments."*

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.

In the comments to the draft decision, you agree to perform the requested study.

#### *Study design*

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

The Substance is difficult to test due to the low water solubility (0.425 mg/L). OECD TG 210 specifies that for difficult to test substances OECD GD 23 must be followed 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 202. 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.

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).

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

- use loading rates that are sufficiently low to be in the solubility range of most constituents (or that are consistent with the PEC value). This condition is mandatory to provide relevant information for the hazard and risk assessment (ECHA Guidance, Appendix R.7.8.1-1, Table R.7.8-3);
- 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.

## 2. Identification of degradation products

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

You have provided an adaptation under Annex IX, Section 9.2.1, Column 2 with the following justification:

*"In a CO<sub>2</sub> evolution test conducted according to OECD 301B testing guideline, a biodegradation (ThCO<sub>2</sub>) of 21% after 28 days was found for the test item. An extended test was carried out according to OECD 301D testing guideline. The biodegradation reached 20% at Day 28 and continued up to 61% at Day 60. Based on these results, the chemical safety assessment did not indicate the need to investigate further the biodegradation potential. According to column 2 of annexes IX and X of REACH regulation EC 1907/2006, further biotic degradation testing shall be proposed by the registrant if the chemical safety assessment according to annex I indicates the need to investigate further the degradation of the substance and its degradation products. Firstly, according to the PBT/vPvB assessment, the substance is not considered PBT/vPvB since it is demonstrated that none of the components of the substance are B/vB. Furthermore, degradation levels at day 60 in an extended ready biodegradation test indicate that the substance is not P/vP. Lastly, according to the chemical risk assessment, the risks for aquatic, sediment and soil compartments are considered all acceptable (all RCR are below 1 in all exposure scenarios). Therefore, the CSA does not indicate the need to investigate further hazards and risks for those compartments, nor that further degradation testing is necessary in those compartments."*

We have assessed this information and identified the following issue:

Under Section 9.2., Column 2 of Annex IX to REACH, this information may be omitted if the chemical safety assessment (CSA) does not indicate the need for further biotic degradation testing. In the context of the PBT/vPvB assessment (Annex I, Section 4) and the risk assessment (Annex I, Section 6) of the Substance, the CSA must address relevant transformation/degradation products (Annex XIII, 5<sup>th</sup> paragraph; ECHA Guidance R.11.4.1.).

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

Your PBT assessment provided in the registration dossier is solely based on the properties of the parent substance and does not address the identity and PBT/vPvB properties of its relevant transformation/degradation products.

Without this information, your CSA does not demonstrate that there is no need for further biotic degradation testing.

Therefore, your adaptation is rejected.

In the comments to the draft decision, you agree to perform the requested study.

*Study design*

Regarding the selection of appropriate and suitable test method(s), you are recommended to use the OECD TG 309 test with water amended with suspended solids/sediment of 0.01 to 1 g/L dry weight ("suspended sediment test"). To determine the degradation rates a study according to OECD TG 309 must be conducted at 12°C and at a test concentration < 100 µg/L. However, if only information on the identification and quantification of major transformation/degradation products needs to be generated, the test may be conducted 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) to overcome potential analytical limitations.

You may also use other appropriate and suitable test method(s) to provide information on the identity of the transformation/degradation products, for example an enhanced screening level degradation test or modelling tools. You will need to provide a scientifically valid justification for the chosen method. The provided information should include, identification, stability, behaviour, molar quantity of transformation/degradation products relative to the parent compound. In addition, degradation half-life, log  $K_{ow}$  and potential toxicity of the transformation/degradation may need to be investigated.

## **Appendix C: 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 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 be identified and quantified using the appropriate analytical methods.

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 D: General recommendations when conducting and reporting new tests for REACH purposes**

### **A. 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 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 ECHA Guidance R.7b (Section R.7.9.), R.7c (Section R.7.10) and R.11 on PBT assessment for advice on the interpretation of results in concluding whether the Substance, including the relevant transformation and degradation products, fulfils the PBT/vPvB criteria of Annex XIII.

You must revise your PBT assessment when the new information is available.



## **Appendix E: 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 12 February 2021.

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

In your comments you agreed to the draft decision. ECHA took your comments into account and did not amend the request(s).

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 F: 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 multiconstituent 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 G: Addressees of this decision and their corresponding information requirements**

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]
[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.