

Helsinki, 30 August 2022

**Addressees**

Registrant(s) of PM\_130\_JS\_DINCD as listed in Appendix 3 of this decision

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

18/03/2022

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

Substance name: 1,4-Cyclohexanedicarboxylic acid, 1,4-diisononyl ester

EC number: [REDACTED]

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

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

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

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 requests above, the same study has been requested under different Annexes. This is because some information requirements may be triggered at lower tonnage band(s). In such cases, only the reasons why the information requirement is triggered are provided for the lower tonnage band(s). For the highest tonnage band, the reasons why the standard information requirement is not met and the specification of the study design are provided. Only one study is to be conducted.

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<sup>1</sup> 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

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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 1: Reasons for the decision**

### **Contents**

|   |          |
|---|----------|
| <b>Reasons related to the information under Annex VIII of REACH .....</b> | <b>4</b> |
| 1. Long-term toxicity testing on fish .....                               | 4        |
| <b>Reasons related to the information under Annex IX of REACH .....</b>   | <b>5</b> |
| 2. Long-term toxicity testing on fish .....                               | 5        |
| <b>References .....</b>   | <b>7</b> |

**Reasons related to the information under Annex VIII of REACH****1. Long-term toxicity testing on fish**

- 1 Short-term toxicity testing on fish is an information requirement under Column 1 of Annex VIII to REACH (Section 9.1.3.). However, long-term toxicity testing on fish must be considered (Section 9.1.3., Column 2) if the substance is poorly water soluble.

*1.1. Triggering of the information requirement*

- 2 You have provided information which indicates that the Substance includes constituents that are poorly water soluble (water solubility < 25 µg/L at 25°C).
- 3 Therefore, the Substance is poorly water soluble and information on long-term toxicity on fish must be provided.

*1.2. Information provided*

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

*1.3. Assessment of the information provided*

- 5 The examination of the information provided, as well as the selection of the requested test and the test design are addressed under section 2.

**Reasons related to the information under Annex IX of REACH****2. Long-term toxicity testing on fish**

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

*2.1. Information provided*

7 You have adapted this information requirement without providing an explicit legal basis. To  
support the adaptation, you have provided following information:

8 "A study on long-term toxicity in fish is not considered to be indicated, because no harmful  
effects has been observed in the available acute and chronic aquatic studies. The acute  
toxicity study in fish showed no toxic effects or mortalities in a saturated solution of the  
test substance. Additionally, the long-term study on reproduction with *Daphnia magna*  
showed no chronic toxic effects of the test substance at the highest attainable test  
substance concentration. There is no indication that fish would be more sensitive towards  
the test substance than invertebrates (*daphnia*) or algae. The chemical safety assessment  
is based on the available aquatic data. Hence, the need of further investigation in fish is  
not indicated and additional long-term toxicity testing in fish is not proposed, also due to  
animal welfare reasons".

9 ECHA understands that you refer to Column 2 of Annex IX, Section 9.1.

*2.2. Assessment of the information provided*

10 We have assessed this information and identified the following issue:

11 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).

12 On this basis, your adaptation is rejected and the information requirement is not fulfilled.

*2.3. Study design and test specifications*

13 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.).

14 The Substance is difficult to test due to its low water solubility (water solubility < 25 µg/L  
at 25°C) and adsorptive properties (log K<sub>oc</sub> > 6.5). OECD TG 210 specifies that, for difficult  
to test substances, you must consider the approach described in OECD GD 23 or other  
approaches, if more appropriate for your substance. In all cases, the approach selected  
must be justified and documented. Due to the properties of Substance, it may be difficult  
to achieve and maintain the desired exposure concentrations. Therefore, you must monitor  
the test concentration(s) of the Substance throughout the exposure duration and report the  
results. If it is not possible to demonstrate the stability of exposure concentrations (i.e.  
measured concentration(s) not within 80-120% of the nominal concentration(s)), you must  
express the effect concentration based on measured values as described in OECD TG 210.  
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.

- 15 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).
- 16 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 (Guidance on IRs and CSA, 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.

## 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**

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 17 November 2021.

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.

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.



**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.

| <b>Registrant Name</b> | <b>Registration number</b> | <b>Highest REACH Annex applicable to you</b> |
|------------------------|----------------------------|--|
|                        |                            |  |

Where applicable, the name of a third party representative (TPR) may be displayed in the list of recipients whereas ECHA will send the decision to the actual registrant.

## Appendix 4: Conducting and reporting new tests for REACH purposes

### 1. Requirements when conducting and reporting new tests for REACH purposes

#### 1.1. Test methods, GLP requirements and reporting

- (1) Under Article 13(3) of REACH, all new data generated as a result of this decision must be conducted according to the test methods laid down in a European Commission Regulation or to international test methods recognised by the Commission or ECHA as being appropriate.
- (2) Under Article 13(4) of REACH, ecotoxicological and toxicological tests and analyses must be carried out according to the GLP principles (Directive 2004/10/EC) or other international standards recognised by the Commission or ECHA.
- (3) Under Article 10(a)(vi) and (vii) of REACH, all new data generated as a result of this decision must be reported as study summaries, or as robust study summaries, if required under Annex I of REACH. See ECHA Practical Guide on How to report robust study summaries<sup>2</sup>.
- (4) Under the introductory part of Annexes VII/VIII/IX/X to REACH, where a test method offers flexibility in the study design, for example in relation to the choice of dose levels or concentrations, the chosen study design must ensure that the data generated are adequate for hazard identification and risk assessment.

#### 1.2. Test material

##### *Selection of the Test material(s)*

The Test Material used to generate the new data must be selected taking into account the following:

- a) the boundary composition(s) of the Substance,
- b) 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.

##### *Information on the Test Material needed in the updated dossier*

- a) 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.
- b) 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.

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>).

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

## **2. General recommendations for conducting and reporting new tests**

### **2.1. Environmental testing for substances containing multiple constituents**

Your Substance contains multiple constituents and, as indicated in Guidance on IRs & CSA, Section R.11.4.2.2, you are advised to consider the following approaches for 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.