

Helsinki, 19 January 2023

**Addressees**

Registrants of JS\_mCresol as listed in Appendix 3 of this decision

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

12/01/2022

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

Substance name: m-cresol

EC number: 203-577-9

**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)**

Under Article 40 of Regulation (EC) No 1907/2006 (REACH), you must submit the information listed below by **28 April 2025**.

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

**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: EU C.47./OECD TG 210) with analogue substance p-cresol, EC number 203-398-6

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.

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**

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**Reasons for the decision(s) related to the information under Annex IX of REACH****1. Long-term toxicity testing on fish**

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

*1.1. Information provided to fulfil the information requirement*

2 You have submitted a testing proposal for a Fish, Early-Life Stage Toxicity Test (test method: OECD TG 210) with the analogue substance p-cresol, EC number 203-398-6.

3 You have further provided:

- i. a publication on a study similar to a fish early-life stage toxicity test (1984) with the analogue substance p-cresol, EC number 203-398-6
- ii. a publication on a study similar to a fish short-term toxicity test on embryo and sac-fry stages (1985) with the Substance

4 You have assigned a Klimisch score of 3 to publication (ii).

5 Further, in the read-across justification document attached in section 13.2 of the registration dossier, you provide an explanation as to why a Klimisch score of 4 has to be assigned to publication (i).

6 ECHA agrees that the reporting of publications (i) and (ii) is not sufficient to conduct an independent assessment of their reliability.

7 ECHA requested your considerations for alternative methods to fulfil the information requirement for long-term toxicity on fish. You provided your considerations, and you apply read-across to fulfil the respective information requirement, and you conclude that no other alternative methods are available. ECHA has taken these considerations into account.

8 ECHA agrees that an appropriate study on long-term toxicity on fish is needed.

*1.2. Grouping of substances and read-across approach*

9 You propose using Annex XI, Section 1.5. (Grouping of substances and read-across approach) based on experimental data from the following substances:

- |                    |  |
|--------------------|--|
| Category member 01 | p-Cresol, EC No. 203-398-6;                      |
| Category member 02 | m-Cresol, EC No. 203-577-9 (i.e. the Substance); |
| Category member 03 | o-Cresol, EC No. 202-423-8.                      |

10 You propose to predict the properties of the Substance from information on long-term toxicity to fish that will be obtained from the following source substance:

- |                    |                             |
|--------------------|-----------------------------|
| Category member 01 | p-Cresol, EC No. 203-398-6; |
|--------------------|-----------------------------|

11 You provide the following reasoning for the prediction of this information requirement:

- i. the members of the category are regioisomers and have similar structures;
- ii. their physico-chemical parameters (including vapour pressure, water solubility, octanol-water partition coefficient, organic carbon partition

coefficient, and dissociation constant) are in the same range;

- iii. they are all readily biodegradable;
- iv. their effect concentration values regarding short-term toxicity to fish and toxicity to algae are in the same range.

12 ECHA understands that you predict the properties of the Substance using a read-across hypothesis which assumes that different compounds have the same type of effects. The properties of your Substance are predicted based on a worst-case approach.

13 You have provided a Read-across justification document in Section 13.2 of your IUCLID dossier.

14 ECHA considers that the read-across hypothesis is supported by the information available in your read-across justification document. On this basis, your grouping and read-across approach is accepted.

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

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

#### *1.4. Outcome*

16 Your testing proposal is accepted under Article 40(3)(a) and you are requested to conduct the test with the analogue substance p-cresol, EC number 203-398-6, as specified above.

17 When updating your dossier with the new information, please also update the reliability scoring of publications (i) and (ii) in section 6.1.2 of the registration dossier to align them with the content of the read-across justification document in section 13.2 of the registration dossier.

## 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 (2012).

**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**

ECHA started the testing proposal evaluation in accordance with Article 40(1) on 10 March 2022.

ECHA held a third party consultation for the testing proposal(s) from 10 May 2022 until 27 June 2022. ECHA did not receive information from third parties.

ECHA followed the procedure detailed in Articles 50 and 51 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.

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 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 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]
[REDACTED]	[REDACTED]	[REDACTED]
[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.



## 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>.

#### 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

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

prepare registration and PPORD dossiers<sup>3</sup>.

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

References to Guidance on REACH and other supporting documents can be found in Appendix 1.

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