~~Confidential~~

Helsinki, 07 September 2022

Addressees
Registrants of JS_OMC_EC_226-775-7 as listed in Appendix 3 of this decision

Date of submission of the dossier subject to this decision
13/07/2021

Registered substance subject to this decision ("the Substance")
Substance name: 2-Ethylhexyl trans-4-methoxycinnamate
EC number: 629-661-9

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)

Based on Article 40 of Regulation (EC) No 1907/2006 (REACH), you must submit the information listed below by ***13 March 2024***.

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

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

1. Long-term toxicity testing on sediment organisms (Annex X, Section 9.5.1.; test method: EU C.35/OECD TG 225)

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[1] 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

Contents

Reasons for the decision(s) related to the information under Annex X of REACH

1. Long-term toxicity to sediment organisms (Annex X, Section 9.5.1.)

1 Long-term toxicity to sediment organisms is an information requirement under Annex X to REACH (Section 9.5.1.).

1.1. Information provided to fulfil the information requirement

2 You have submitted a testing proposal for a Sediment-Water Lumbriculus Toxicity Test Using Spiked Sediment (test method: EU C.35/OECD TG 225).

3 Your registration dossier includes the following information on long-term toxicity on sediment organisms:

i. A test according to OECD TG 225, with the Substance

ii. A test according to OECD TG 218, with the Substance

4 You provide a reference to a scientific paper titled Ecotoxicological effect characterisation of widely used organic UV filters (published in 2012) that is the source of the data presented in studies i) and ii).

5 The paper describes tests conducted with three substances used as UV filters, one of which is the Substance. A battery of in vivo tests were conducted with following test organisms: snails: Potamopyrgus antipodarum, Melanoides tuberculate; worms: Lumbriculus variegatus; midges: Chironomus riparius; fish: Danio rerio; bacteria: Arthrobacter globiformis. The two snail species were found to be the most sensitive organisms tested. The paper concludes that the Substance "caused a toxic reproductive effect in both snails with no observed effect concentrations (NOEC) of 0.08 mg/kg and 2 mg/kg, respectively. […] All effects occurred at concentrations which are by far higher than those reported for field sediments. This indicates a low toxicity of the test compounds which is probably due to their low bioavailability for sediment-dwelling organisms."

6 In Section 6.2 of your registration dossier, you provide the following considerations on the validity and reliability of the experimental data presented in studies i) and ii):

7 Deviation from the technical specifications described in the relevant test guidelines that impacts the sensitivity/reliability of the test:

1. Composition of artificial sediment used differed from the composition described by OECD TG 225 and OECD TG 218

8 Insufficient reporting detail of methodology and results with respect to the following:

2. Information on purity and impurities of the test material

3. Reason for the use of solvent

4. Preparation of the test substrate for the different treatments

5. Number of test animals used per treatment

6. Test conditions, including water quality parameters (pH and dissolved oxygen concentration of the overlying water)

7. Method used for analytical monitoring
8. If the treatment homogeneity in sediment was ensured
9. Acclimatisation of test animals

9 In Section 6.2 of your registration dossier, you assign a Klimisch score of 3 to studies i) and ii) and you indicate that they should be disregarded due to major methodological deficiencies. Further, you claim that the available information is not considered reliable and adequate for the purpose of risk assessment in the sediment compartment.

10 ECHA agrees with your conclusion that the provided data from studies i) and ii) are not adequate for the purpose of risk assessment. Therefore, there is a data gap and an appropriate study on long-term toxicity to sediment organisms is needed.

1.2. Test selection and study specifications

11 The proposed Sediment-Water Lumbriculus Toxicity Test Using Spiked Sediment (test method: EU C.35/OECD TG 225) is appropriate to cover the information requirement for long-term toxicity to sediment organisms (Guidance on IRs and CSA, Section R.7.8.9.1.).

1.3. Outcome

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

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

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

The Substance is listed in the Community rolling action plan (CoRAP) where substance evaluation started in 2016.

ECHA started the testing proposal evaluation in accordance with Article 40(1) on 22 September 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.

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

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 6 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 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 summaries[2].

(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

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.

[2] https://echa.europa.eu/practical-guides

Technical instructions on how to report the above is available in the manual on How to prepare registration and PPORD dossiers[3].

2. General recommendations for conducting and reporting new tests

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

[3] https://echa.europa.eu/manuals