

Helsinki, 27 January 2021

**Addressees**

Registrant of EC 605-140-1 listed in the last Appendix of this decision

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

31/10/2019

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

Substance name: 4-(2-chlorophenyl)-N-cyclohexyl-N-ethyl-5-oxo-4,5-dihydro-1H-tetrazole-1-carboxamide

EC number: 605-140-1

CAS number: 158237-07-1

**Decision number:** Please refer to the REACH-IT message which delivered this communication (in format TPE-D-XXXXXXXXXX-XX-XX/F)**DECISION ON A TESTING PROPOSAL**

Based on Article 40 of Regulation (EC) No 1907/2006 (REACH), ECHA requests that you submit the information listed below by the deadline of **3 November 2021**.

**A. Requirements applicable to all the Registrants subject to Annex IX of REACH**

1. Long-term toxicity to terrestrial invertebrates (Annex IX, Section 9.4.1., column 2); test method: Earthworm reproduction test (OECD TG 222) using the registered substance.
2. Long-term toxicity to terrestrial plants (Annex IX, Section 9.4.3., column 2; test method: Terrestrial plant test: seedling emergence and seedling growth test, OECD TG 208 with at least six species tested (with as a minimum two monocotyledonous species and four dicotyledonous species) using the registered substance.

**Conditions to comply with the requests**

Each addressee of this decision is bound by the requests for information corresponding to the REACH Annexes applicable to their own registered tonnage of the Substance at the time of evaluation of the jointly submitted dossier.

To identify your legal obligations, please refer to the following:

- you have to comply with the requirements of Annexes VII to IX of REACH, if you have registered a substance at 100-1000 tpa;

The Appendix entitled Observations and technical guidance addresses the generic approach for the selection and reporting of the test material used to perform the required studies and provides generic recommendations and references to ECHA guidance and other reference documents.

You must submit the information requested in this decision by the deadline indicated above in an updated registration dossier and also update the chemical safety report, where relevant,

including any changes to classification and labelling, based on the newly generated information.

**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 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 for the requirements applicable to all the Registrants subject to Annex IX of REACH**

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

1. **Long-term toxicity testing on terrestrial invertebrates (Annex IX, Section 9.4.1., column 2)**

Short-term toxicity testing on terrestrial invertebrates is a standard information requirement at Annex IX of REACH Section 9.4.1. However, if the Substance has a high potential to adsorb to soil or is very persistent, the registrant shall consider long-term toxicity testing instead of short-term (Annex IX, Section 9.4.1, column 2).

The current registration dossier does not contain a long-term test on terrestrial invertebrates. Consequently there is an information gap and it is necessary to provide information for this endpoint. You have submitted a testing proposal for long-term toxicity testing on earthworms according to OECD TG 222 (Earthworm Reproduction Test (*Eisenia fetida*/*Eisenia andrei*)) with the Substance.

The Substance is considered having a high potential to adsorb to soil and is very persistent and thus, a long-term test on terrestrial invertebrates should be considered. In addition, the Substance meets the requirements to be classified in "Soil Hazard Category 4" (ECHA guidance R.7.c 2017) and since equilibrium partition model is not recommended for Hazard category 4 substances, the long-term test on earthworms would meet the information requirements under REACH (Annex IX, Section 9.4.1, column 2).

In your comments on the draft decision, you submitted information demonstrating that direct and indirect exposure to soil can be excluded.

The information provided states that in accordance with Regulation (EC) No 1907/2006, Annex IX, column 2, testing of effects on terrestrial organisms is not required since direct and indirect exposure of the soil compartment for the substance Fentrazamide does not occur. Furthermore you state that the evaluation of the PEC/PNEC ratio indicates no risk for the terrestrial compartment (RCR << 1).

You have provided a description on how potential releases are eliminated or controlled during manufacturing and formulation, which are the only two uses relevant for the Substance in the EU. You explain that there is no application/ end-use of the substance in the EU. The substance is exported directly outside the EU after formulation. In the course of the testing proposal, more detailed information on potential exposure and the routes of exposure have been obtained. In conclusion, based on the new information you consider that, direct exposure as well as indirect exposure for the Substance to soil, sewer and air is unlikely. You add that the substance is handled at the relevant EU manufacturing sites in rigorous contained systems with minimized potential release.

ECHA has assessed the provided information in the comment. ECHA agrees that the submitted information is sufficient to fulfil the information requirement. However, this information is not in the version of the technical dossier submitted at the time ECHA notified you of the draft decision.

Therefore, under Article 40(3)(a) of REACH, you are requested to carry out the proposed test with the Substance, fentrazamide, i.e. 4-(2-chlorophenyl)-N-cyclohexyl-N-ethyl-5-oxo-4,5-dihydro-1H-tetrazole-1-carboxamide (CAS: 158237-07-1, EC: 605-140-1).

The proposed test does not need to be performed if you include the information provided in your comments on the draft decision in an updated version of the technical dossier by the deadline set in the decision.

2. **Long-term toxicity testing on terrestrial plants (Annex IX, Section 9.4.3., column 2)**

Short-term toxicity testing on terrestrial plants is a standard information requirement at Annex IX of REACH Section 9.4.3. However, if the Substance has a high potential to adsorb to soil or is very persistent, the registrant shall consider long-term toxicity testing instead of short-term (Annex IX, Section 9.4.3, column 2).

The current registration dossier does not contain a long-term test on terrestrial plants. Consequently there is an information gap and it is necessary to provide information for this endpoint. You have submitted a testing proposal for long-term toxicity testing on plants according to OECD TG 208 (Terrestrial Plant Test: Seedling Emergence and Seedling Growth Test with at least six species tested, with as a minimum two monocotyledonous species and four dicotyledonous species) with the Substance.

The Substance is considered having a high potential to adsorb to soil and is very persistent and thus, a long-term test on terrestrial plants should be considered. In addition, the Substance meets the requirements to be classified in "Soil Hazard Category 4" (ECHA guidance R.7.c 2017) and since equilibrium partition model is not recommended for Hazard category 4 substances and the proposed long-term test on terrestrial plants would provide adequate information on the intrinsic properties of the Substance. The proposed test OECD TG 208 with at least six test species and with a minimum of two monocotyledonous and four dicotyledonous species can be considered as a long-term test and meets the information requirements under REACH (Annex IX, Section 9.4.3, column 2).

In your comments on the draft decision, you submitted information demonstrating that direct and indirect exposure to soil can be excluded. This information has been summarised in section 1 above.

ECHA has assessed the provided information in the comment. ECHA agrees that the submitted information is sufficient to fulfil the information requirement. However, this information is not in the version of the technical dossier submitted at the time ECHA notified you of the draft decision.

Therefore, under Article 40(3)(a) of REACH, you are requested to carry out the test with the Substance, fentrazamide, i.e. 4-(2-chlorophenyl)-N-cyclohexyl-N-ethyl-5-oxo-4,5-dihydro-1H-tetrazole-1-carboxamide (CAS: 158237-07-1, EC: 605-140-1).

The proposed test does not need to be performed if you include the information provided in your comments to the draft decision in an updated version of the technical dossier by the deadline set in the decision.

## **Appendix B: Procedural history**

ECHA received your registration containing the testing proposals for examination on 21 November 2019.

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

In your comments on the draft decision you submitted information demonstrating that direct and indirect exposure to soil can be excluded.

ECHA took into account your comments and did not amend the requests. However, the proposed tests do not need to be performed if you include the information provided in your comments on the draft decision in an updated version of the technical dossier by the deadline set in the decision.

For the purpose of the decision-making, this decision does not take into account any updates of registration dossiers after the date on which you were notified the draft decision according to Article 50(1) of REACH.

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 C: Observations and technical guidance

1. This testing proposal examination decision does not prevent ECHA from initiating compliance checks at a later stage on the registrations present.
2. Failure to comply with the requests in this decision, or to otherwise fulfil the information requirements with a valid and documented adaptation, will result in a notification to the enforcement authorities of your Member State(s).
3. Test guidelines, GLP requirements and reporting

Under Article 13(3) of REACH, all new data generated as a result of this decision needs to be conducted according to the test methods laid down in a European Commission Regulation or according to international test methods recognised by the Commission or ECHA as being appropriate.

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.

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: 'How to report robust study summaries'<sup>2</sup>.

4. Test material

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

The registrants of the Substance are responsible for agreeing on the composition of the test material to be selected for carrying out the tests required by the present decision. The test material selected must be relevant for all the registrants of the Substance, i.e. it takes into account the variation in compositions reported by all members of the joint submission. The composition of the test material(s) must fall within the boundary composition(s) of the Substance.

While selecting the test material you must take into account the impact of each constituent/impurity is known to have or could have 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.

### *Technical reporting of the test material*

The composition of the selected test material must be reported in the respective endpoint study record, under the Test material section. The composition must include all constituents of the test material and their concentration values and other parameters relevant for the property to be tested. Without such detailed reporting, ECHA may not be able to confirm that the test material is relevant for the Substance and to all the registrants of the Substance.

Technical instructions are available in the manual "How to prepare registration and PPORD dossiers"<sup>3</sup>.

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

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

5. List of references of the ECHA Guidance and other guidance/ reference documents<sup>4</sup>

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 in this decision.

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

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.

OECD Guidance documents

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

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

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<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>

**Appendix D: List of the registrants to which the decision is addressed and the corresponding information requirements applicable to them**

<b>Registrant Name</b>	<b>Registration number</b>	<b>(Highest) Data requirements to be fulfilled</b>
[REDACTED]	[REDACTED]	[REDACTED]

Note: where applicable, the name of a third party representative (TPR) may be displayed in the list of recipients whereas the decision is sent to the actual registrant.