~~Confidential~~

Helsinki, 15 October 2020

Addressees
Registrant of 6-amino-5-chloro-2-cyclopropylpyrimidine-4-carboxylic acid listed in the last Appendix of this decision

Date of submission for the dossier subject of a decision
06/02/2020

Registered substance subject to this decision, hereafter 'the Substance'
Substance name: 6-amino-5-chloro-2-cyclopropylpyrimidine-4-carboxylic acid
EC number: 617-769-9
CAS number: 858956-08-8

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 ***22 July 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 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 Substance.

Conditions to comply with the requests

You are bound by the requests for information corresponding to the REACH Annexes applicable to your own registered tonnage of the Substance at the time of evaluation.

Therefore you have to comply with the requirements of:

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

Registrants are only required to share the costs of information they are required to submit to fulfil the information requirements for their registration.

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[1] under the authority of Christel Schilliger-Musset, Director of Hazard Assessment

[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 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).

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 to be very persistent because it is not readily biodegradable, and thus a long-term test on terrestrial invertebrates should be considered.

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.

The long-term test on earthworms would meet the information requirements under REACH (Annex IX, Section 9.4.1, column 2).

Therefore, under Article 40(3)(a) of REACH, you are requested to carry out the proposed test with the Substance.

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).

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 current registration dossier does not contain a long-term test on terrestrial plants.

As explained under point 1 above, the Substance is considered to be very persistent and thus a long-term test on terrestrial plants should be considered.

Consequently there is an information gap and it is necessary to provide information for this endpoint.

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).

Therefore, under Article 40(3)(a) of REACH, you are requested to carry out the test with the Substance.

Appendix B: Procedural history

ECHA received your registration containing the testing proposals for examination on 13 February 2020.

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.

The decision making followed the procedure of Articles 50 and 51 of REACH, as described below:

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

ECHA did not receive any comments within the notification 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 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'[2].

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. 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"[3].

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

5. List of references of the ECHA Guidance and other guidance/ reference documents[4]

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)[5]

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.

[4] https://echa.europa.eu/guidance-documents/guidance-on-information-requirements-and-chemical-safety-assessment
[5] https://echa.europa.eu/support/registration/how-to-avoid-unnecessary-testing-on-animals/grouping-of-substances-and-read-across

Appendix D: Addressees of this decision and the corresponding information requirements applicable to them

Registrant Name	Registration number	(Highest) Data requirements to be fulfilled
[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.