EUROPEAN CHEMICALS AGENCY

Helsinki, 15 April 2019

Addressee: [redacted]

Decision number: TPE-D-2114465975-31-01/F
Substance name: 1,2,4-triazole
EC number: 206-022-9
CAS number: 288-88-0
Registration number: [redacted]
Submission number: [redacted]
Submission date: 06/02/2018
Registered tonnage band: Over 1000

DECISION ON A TESTING PROPOSAL

Based on Article 40 of Regulation ((EC) No 1907/2006) (the REACH Regulation), ECHA examined your testing proposal(s) and decided as follows.

Your testing proposal is accepted and you are requested to carry out:

1. **Long-term toxicity on terrestrial invertebrates (Annex X, Section 9.4.4.; test method: Earthworm reproduction test, OECD TG 222) using the registered substance.**
2. **Effects on soil micro-organisms (Annex IX, Section 9.4.2.; test method: Soil microorganisms: nitrogen transformation test, EU C.21./OECD TG 216) using the registered substance.**

You are additionally requested to perform:

3. **Effects on soil micro-organisms (Annex IX, Section 9.4.2.; test method: Soil microorganisms: carbon transformation test, EU C.22/OECD TG 217) using the registered substance.**

You have to submit the requested information in an updated registration dossier by **22 January 2020**. You also have to update the chemical safety report, where relevant.

The reasons for this decision are set out in Appendix 1. The procedural history is described in Appendix 2 and advice and further observations are provided in Appendix 3.

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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.

Authorised[1] by **Claudio Carlon**, Head of Unit, 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 1: Reasons

The decision of ECHA is based on the examination of the testing proposals submitted by you.

1. **Long-term toxicity to terrestrial invertebrates (Annex IX, Section 9.4.1. and Annex X, Section 9.4.4.)**

Pursuant to Article 40(3)(a) of the REACH Regulation, ECHA may require the Registrant to carry out the proposed test.

"Effects on terrestrial organisms" is a standard information requirement as laid down in Annex IX and X, Section 9.4. of the REACH Regulation. The Registrant must address the standard information requirements set out in Annex IX and X, Section 9.4., for different taxonomic groups: short-term toxicity testing on invertebrates (Annex IX, Section 9.4.1.), long-term toxicity testing on invertebrates (Annex X, section 9.4.4.), short-term toxicity testing on plants (Annex IX, section 9.4.3.) and long-term toxicity testing on plants (Annex X, section 9.4.6.).

You have submitted a testing proposal for a long-term toxicity test to invertebrates (Earthworm reproduction test, OECD TG 222) with the following justification: *"Exposure of 1,2,4 -triazole to soil cannot be excluded. Therefore, according to column 2 of annex IX of Reach regulation, "in the absence of toxicity data for soil organisms, the equilibrium partitioning method may be applied to assess the hazard to soil organisms. ECHA's guidance on information requirements and chemical safety assessment, chapter R.7c (v4.0 ; June 2017 ; pp.158 -159) explains how EPM should be used. In the absence of any soil toxicity data, a soil hazard category must be assigned to the substance. Triazole is not readily biodegradable but not H400/H410. It falls therefore within the scope of soil hazard category 3. In this category, it is demanded to conduct one confirmatory long-term soil testing. It is our understanding that invertebrate testing is preferred to plant testing in a first approach (ECHA's guidance R.7c; v4.0 ; June 2017 ; p. 149, fourth paragraph). Therefore a study according to OECD 222 guideline is proposed."*

The information on "long-term toxicity to invertebrates" is not available for the registered substance but needs to be present in the technical dossier to meet the information requirements. Consequently there is an information gap and it is necessary to provide information for this endpoint.

Therefore, pursuant to Article 40(3)(a) of the REACH Regulation, you are requested to carry out the proposed study using the registered substance subject to the present decision:

- Earthworm reproduction test (OECD TG 222)

In your comments on the draft decision you expressed your agreement with the data requirements highlighted in the draft decision (OECD 222 and 216), including the test on soil microorganisms (OECD TG 217).

You also pointed out that you recently became aware of existing GLP study reports following the OECD 216, 217, and 222 test guidelines which already provide the requested information, however these studies are not available to you yet. For this reason, you requested the option to provide robust study summaries of these existing study reports corresponding to the draft decision requirements under points 1, 2, and 3 listed above instead of performing new tests.

ECHA notes that you may fulfil the information requirements by conducting the tests as requested or by submitting the robust study summaries of the already available studies provided that they are adequate for risk assessment and classification and labelling.

2. and 3. Effects on soil micro-organisms (Annex IX, Section 9.4.2.)

Pursuant to Article 40(3)(c) of the REACH Regulation, ECHA may require the Registrant to carry out one or more additional tests in case of non-compliance of the testing proposal with Annexes IX, X or XI of the REACH Regulation.

"Effects on terrestrial organisms" is a standard information requirement as laid down in Annex IX, Section 9.4. of the REACH Regulation. The Registrant must address the standard information requirements set out in Annex IX, Section 9.4., for different taxonomic groups: short-term toxicity testing on invertebrates (Annex IX, Section 9.4.1.), effects on soil micro-organisms (Annex IX, Section 9.4.2.), and short-term toxicity testing on plants (Annex IX, Section 9.4.3.).

The information on "effects on soil micro-organisms" is not available for the registered substance but needs to be present in the technical dossier to meet the information requirements. Consequently there is an information gap and it is necessary to provide information for this endpoint.

You have submitted a testing proposal for effects on soil microorganisms (Soil microorganisms: nitrogen transformation test OECD TG 216) with the following justification: *"Exposure of 1,2,4 -triazole to soil cannot be excluded. Therefore, according to column 2 of annex IX of Reach regulation, "in the absence of toxicity data for soil organisms, the equilibrium partitioning method may be applied to assess the hazard to soil organisms". ECHA's guidance on information requirements and chemical safety assessment, chapter R.7c (v4.0 ; June 2017 ; pp.158 -159) explains how EPM should be used. In the absence of any soil toxicity data, a soil hazard category must be assigned to the substance. Triazole is not readily biodegradable but not H400/H410. It falls therefore within the scope of soil hazard category 3. In this category, it is demanded to conduct one confirmatory long-term soil testing. It is our understanding that invertebrate testing is preferred to plant testing in a first approach (ECHA's guidance R.7c; v4.0 ; June 2017 ; p. 149, fourth paragraph). Therefore a study according to OECD 222 guideline is proposed. In addition, for substance which are not in the soil hazard category 1, it is considered that soil microorganisms are not covered by EPM. Therefore, a study according to OECD 216 guideline is proposed".*

ECHA agrees that the proposed test that ECHA accepted under point (1) above is not sufficient to address this standard information requirement. ECHA concludes that the effects on soil microorganisms need to be ascertained by performing a relevant test.

To address this endpoint, either a nitrogen transformation test (test method: EU C.21/OECD TG 216) or a carbon transformation test (test method: EU C.22/OECD TG 217) could be performed. According to Section R.7.11.3.1, Chapter R.7c of the ECHA *Guidance on information requirements and chemical safety assessment* (version 3.0, June 2017), ECHA considers the nitrogen transformation test (EU C.21/OECD TG 216) suitable for non-agrochemicals. For agrochemicals the carbon transformation test (EU: C.22/OECD TG 217) is also required.

ECHA responded to your comments on this endpoint under point 1.

Therefore, pursuant to Article 40(3)(a) of the REACH Regulation, you are requested to carry out the following test using the registered substance subject to the present decision: Soil microorganisms: nitrogen transformation test, EU C.21/OECD TG 216
and pursuant to Article 40(3)(c) of the REACH Regulation the following additional test using the carbon transformation test, EU C.22/OECD TG 217.

Notes for your consideration

ECHA reminds you to update the CSR and include an assessment of use as a fertilizer.

As the Guidance advocates performing an initial screening assessment based upon the EPM, together with a confirmatory long-term soil toxicity test (the long-term toxicity to terrestrial invertebrates test, specified above), which the Registrant is requested to carry out by the present decision, ECHA considers that at this stage it is not possible to determine whether another test will be required to fulfil the standard information requirements of Annex IX, Section 9.4.3. and Annex X, Section 9.4.6. of the REACH Regulation.

Therefore, once results of the requested toxicity test on terrestrial invertebrates are available, the Registrant should consider whether there is a need to investigate further the effects on terrestrial organisms in order to fulfil the information requirements of section 9.4 of Annex IX, and if necessary, submit testing proposals for additional terrestrial toxicity tests. If the Registrant concludes that no further investigation of effects on terrestrial organisms is required, he should update his technical dossier by clearly stating the reasons for adapting the information requirements of Annex IX, Section 9.4.3. and Annex X, Section 9.4.6. of the REACH Regulation.

ECHA emphasises that the intrinsic properties of soil microbial communities are not addressed through the EPM extrapolation method and therefore the potential adaptation possibility outlined for the information requirement of Annex IX, Section 9.4.3. does not apply for the present endpoint.

Appendix 2: Procedural history

ECHA started the testing proposal evaluation in accordance with Article 40(1) on 6 February 2018.

This decision does not take into account any updates after **14 January 2019**, 30 calendar days after the end of the commenting period.

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

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 requests.

ECHA notified the draft decision to the competent authorities of the Member States for proposals for amendment.

As no amendments were proposed, ECHA took the decision according to Article 51(3) of the REACH Regulation.

Appendix 3: Further information, observations and technical guidance

1. This decision does not imply that the information provided in your registration dossier is in compliance with the REACH requirements. The decision does not prevent ECHA from initiating a compliance check on the registration at a later stage.

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 the Member States.

3. In relation to the information required by the present decision, the sample of the substance used for the new tests must be suitable for use by all the joint registrants. Hence, the sample should have a composition that is suitable to fulfil the information requirement for the range of substance compositions manufactured or imported by the joint registrants.

   It is the responsibility of all joint registrants who manufacture or import the same substance to agree on the appropriate composition of the test material and to document the necessary information on their substance composition. In addition, it is important to ensure that the particular sample of the substance tested in the new tests is appropriate to assess the properties of the registered substance, taking into account any variation in the composition of the technical grade of the substance as actually manufactured or imported by each registrant.

   If the registration of the substance by any registrant covers different grades, the sample used for the new tests must be suitable to assess these grades. Finally there must be adequate information on substance identity for the sample tested and the grades registered to enable the relevance of the tests to be assessed.