EUROPEAN CHEMICALS AGENCY

Helsinki, 15 May 2020

**Addressees**
Registrants of [redacted] listed in the last Appendix of this decision

**Date of submission for the jointly submitted dossier subject of a decision**
22 March 2019

**Registered substance subject to this decision, hereafter 'the Substance'**
Substance name: N-cyclohexylbenzothiazole-2-sulfenamide
EC number: 202-411-2
CAS number: 95-33-0

**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 ***24 May 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) *or* Enchytraeid reproduction test (OECD TG 220)) with the 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 21) with the Substance;

3. 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)) with the 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;
- you have to comply with the requirements of Annexes VII to X of REACH, if you have registered a substance at above 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.

Appendix A states the reasons for the requests for information to fulfil the requirements set out in the respective Annexes of REACH.

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 to terrestrial invertebrates (Annex IX, Section 9.4.1., column 2)**

"Effects on terrestrial organisms" is a standard information requirement as laid down in Annex IX, Section 9.4. of the REACH Regulation. Adequate information on effects on short-term toxicity to invertebrates (Annex IX, Section 9.4.1.), effects on soil micro-organisms (Annex IX, Section 9.4.2.), and short-term toxicity to plants (Annex IX, Section 9.4.3.) must be present in the technical dossier for the registered substance to meet the information requirements. Column 2 of Annex IX, Section 9.4 specifies that, for substances that have a high potential to adsorb to soil or that are very persistent, long-term toxicity testing must be considered.

In your technical dossier you provide a log Kow estimate of 5 for the Substance and hence the Substance is expected to show high adsorption to soil. Furthermore based on currently available aquatic toxicity data the Substance meets the criteria for classification as Aquatic Acute 1 (H400). Therefore there is indication that the Substance is very toxic to aquatic organisms. According to the integrated testing strategy (ITS) described in ECHA Guidance R.7c, Section R.7.11.6. the Substance falls into the soil hazard category 4 and long-term testing must be conducted.

You have not provided information on "long-term toxicity to invertebrates" for the Substance.

You have submitted a testing proposal for a long-term toxicity test to invertebrates (Earthworm reproduction test, OECD TG 222).

ECHA agrees that a long-term testing on terrestrial invertebrates is indicated and that the proposed test is appropriate to fulfil the information requirement of Annex IX, Section 9.4.1., column 2.

The earthworm reproduction test (OECD TG 222), Enchytraeid reproduction test (OECD TG 220), and Collembolan reproduction test (OECD TG 232) are each considered capable of generating information appropriate for the fulfilment of the information requirements for long-term toxicity testing to terrestrial invertebrates. ECHA is not in a position to determine the most appropriate test protocol, since this decision is dependent upon species sensitivity and substance properties. You should apply the most appropriate and suitable test guideline among those listed above. ECHA notes that when log Kow >5 and log Koc >4, as in this case, OECD TG 232 is not appropriate as the dominant route of exposure for Collembolans is via pore water.

Therefore under Article 40(3)(a) of the REACH Regulation, you are requested to carry the following proposed test with the Substance: Earthworm reproduction test (*Eisenia fetida/Eisenia andrei*) (OECD TG 222) or an Enchytraeid reproduction test (OECD TG 220).

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

"Effects on terrestrial organisms" is a standard information requirement as laid down in Annex IX, Section 9.4. of the REACH Regulation. Adequate information on effects on short-term toxicity to invertebrates (Annex IX, Section 9.4.1.), effects on soil micro-organisms (Annex IX, Section 9.4.2.), and short-term toxicity to plants (Annex IX, Section 9.4.3.) needs to be

present in the technical dossier for the registered substance to meet the information requirements.

You have provided a toxicity study to soil microorganisms by Williams (1984) with the Substance. You have assigned a reliability score of 4 to this study with the following justification: "*documentation insufficient for assessment*".

We have assessed the available data from you dossier and note the following:

Annex XI, Section 1.1.2 imposes a number of cumulative conditions for an adaptation to be valid, in particular:

1. Adequate and reliable coverage of the key parameters foreseen to be investigated in the corresponding test methods referred to in Article 13(3), in this case the measurement of nitrate formation (for the OECD TG 216) or glucose-induced respiration rates (for the OECD TG 217);
2. Exposure duration comparable to or longer than the corresponding test methods referred to in Article 13(3);
3. Adequate and reliable documentation of the study is provided.

In the study by Williams (1984), you report that the parameter measured was growth inhibition and that the exposure duration was 14 days. You describe the test material as cyclohexyl benzothiazole (CBS). You have not reported an EC number for this test material and you state that "*no data on purity*" is available.

Therefore the key parameters of OECD TG 216 or OECD TG 217 are not covered in the provided study, because neither nitrate formation nor the glucose-induced respiration rate were measured. Furthermore the exposure duration was less than the required exposure duration of ≥ 28 days. Finally, you have not provided adequate documentation for the study and the identity of the test material and its impurity profile cannot be assessed.

Therefore we agree that the study by Williams (1984) has limited relevance to cover this information requirement.

You have also submitted a testing proposal for a nitrogen transformation test (EU C.21/OECD TG 216).

ECHA agrees that the effects on soil microorganisms need to be ascertained by performing a relevant test and that the proposed test is appropriate to fulfil the information requirement of Annex IX, Section 9.4.2.

To address this endpoint, either a nitrogen transformation test (EU C.21/OECD TG 216) or a carbon transformation test (EU C.22/OECD TG 217) must be performed. According to ECHA Guidance R.7c, Section R.7.11.3.1 the nitrogen transformation test (EU C.21/OECD TG 216) is suitable for most non-agrochemicals. For agrochemicals the carbon transformation test (EU C.22/OECD TG 217) must also be conducted.

Therefore under Article 40(3)(a) of the REACH Regulation, you are requested to carry the following proposed test with the Substance: Soil microorganisms: nitrogen transformation test (EU C.21/OECD TG 216).

### 3. Long-term toxicity to terrestrial plants (Annex IX, Section 9.4.3., column 2)

"Effects on terrestrial organisms" is a standard information requirement as laid down in Annex IX, Section 9.4. of the REACH Regulation. Adequate information on effects on short-term

toxicity to invertebrates (Annex IX, Section 9.4.1.), effects on soil micro-organisms (Annex IX, Section 9.4.2.), and short-term toxicity to plants (Annex IX, Section 9.4.3.) must be present in the technical dossier for the registered substance to meet the information requirements. Column 2 of Annex IX, Section 9.4 specifies that, for substances that have a high potential to adsorb to soil or that are very persistent, long-term toxicity testing must be considered.

In your technical dossier you provide a log Kow estimate of 5 for the Substance and hence the Substance is expected to show high adsorption to soil. Furthermore based on currently available aquatic toxicity data the Substance meets the criteria for classification as Aquatic Acute 1 (H400). Therefore there is indication that the Substance is very toxic to aquatic organisms. According to the integrated testing strategy (ITS) described in ECHA Guidance R.7c, Section R.7.11.6. the Substance falls into the soil hazard category 4 and long-term testing must be conducted.

In your technical dossier you refer to a toxicity study to terrestrial plants on 1,3-benzothiazole-2-thiol (MBT, EC no. 205-736-8) cited in the EU RAR on N-Cyclohexylbenothiazole-2-sulphenamide (ECB, 2008).

We have assessed the available data from you dossier and note the following:

Annex XI, Section 1.5 requires that whenever read-across is used adequate and reliable documentation of the applied method must be provided. Such documentation must provide a justification for the read-across including a hypothesis, explanation of the rationale for the prediction of properties and robust study summary(ies) of the source study(ies)[2].

You have provided a read-across justification document for a category of four benzothiazole sulphonamide compounds. Among the arguments to justify the proposed read-across approach you state that "*the structurally similar hydrolysis product MBT was identified for all four category members*". However, your read-across justification document does not cover the read-across from 1,3-benzothiazole-2-thiol (MBT) to the Substance. Furthermore, for the selected source study (ECB, 2008) you have not provided a robust study summary.

In the absence of such documentation, ECHA cannot verify that the properties of your Substance can be predicted from the data on the selected source substance.

Therefore the submitted information has limited relevance to cover this information requirement.

You have also submitted a testing proposal for a long-term toxicity test to terrestrial plants (Terrestrial plants: growth test, OECD TG 208).

ECHA agrees that a long-term testing on terrestrial plants is indicated and that the proposed test is appropriate to fulfil the information requirement of Annex IX, Section 9.4.3., column 2.

OECD guideline 208 (Terrestrial plants, growth test) considers the need to select the number of test species according to relevant regulatory requirements, and the need for a reasonably broad selection of species to account for interspecies sensitivity distribution. For long-term toxicity testing, ECHA considers six species as the minimum to achieve a reasonably broad selection. Testing must be conducted with species from different families, as a minimum with

[2] Guidance on information requirements and chemical safety assessment Chapter R.6: QSARs and grouping of Chemicals, Section R.6.2.6.1.

two monocotyledonous species and four dicotyledonous species, selected according to the criteria indicated in the OECD TG 208 guideline. You should consider if testing on additional species is required to cover the information requirement.

Therefore under Article 40(3)(a) of the REACH Regulation, you are requested to carry the following proposed test with the Substance: Terrestrial plants, growth test (OECD 208), with at least six species tested (with as a minimum two monocotyledonous species and four dicotyledonous species).

## Appendix B: Procedural history

ECHA started the testing proposal evaluation in accordance with Article 40(1) on 25 March 2019.

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 you of the draft decision and invited you to provide comments within 30 days of the notification.

ECHA did not receive any comments within the 30-day 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'[3].

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"[4].

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

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

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)[6]

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.

[5] https://echa.europa.eu/guidance-documents/guidance-on-information-requirements-and-chemical-safety-assessment
[6] 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**

| 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.