

Helsinki, 7 March 2017

Addressee: [REDACTED]

Decision number: TPE-D-2114355664-43-01/F

Substance name: N-TERT-BUTYLBENZOTHIAZOLE-2-SULPHENAMIDE

EC number: 202-409-1

CAS number: 95-31-8

Registration number: [REDACTED]

Submission number: [REDACTED]

Submission date: 07.06.2016

Registered tonnage band: 1000+T

### **DECISION ON A TESTING PROPOSAL**

Based on Article 40 of Regulation (EC) No 1907/2006 (the 'REACH Regulation'), ECHA has taken the following decision.

**Your testing proposals are accepted and you are requested to carry out:**

- 1. 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.**
- 2. Long-term toxicity on terrestrial invertebrates (Annex X, Section 9.4.4.; test method: Earthworm reproduction test, OECD TG 222) using the registered substance.**
- 3. Long-term toxicity testing on plants (Annex X, Section 9.4.6.; test method: Terrestrial plants, 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.**

You may adapt the testing requested above according to the specific rules outlined in Annexes VI to X and/or according to the general rules contained in Annex XI of the REACH Regulation. In order to ensure compliance with the respective information requirement, any such adaptation will need to have a scientific justification, referring and conforming to the appropriate rules in the respective Annex, and an adequate and reliable documentation.

You are required to submit the requested information in an updated registration dossier by **14 March 2018**. You shall also update the chemical safety report, where relevant.

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

### **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, shall 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<sup>1</sup> by Kevin Pollard, Head of Unit, Evaluation E1

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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 1: Reasons**

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

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

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. You, as 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.), long-term toxicity testing on plants (Annex X, section 9.4.6.) and effects on soil microorganisms (Annex IX, section 9.4.2.).

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 a toxicity test with soil microorganisms (Soil microorganisms: nitrogen transformation test, OECD TG 216). ECHA agrees 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 2.0, November 2014), ECHA considers the nitrogen transformation test (EU C.21/OECD TG 216) suitable for non-agrochemicals.

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: Soil microorganisms: nitrogen transformation test, EU C.21/OECD TG 216.

### **2. Long-term toxicity to terrestrial invertebrates (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. You, as 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.), long-term toxicity testing on plants (Annex X, section 9.4.6.) and effects on soil microorganisms (Annex IX, section 9.4.2.).

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.

You have submitted a testing proposal for a long-term toxicity test to soil invertebrates (Earthworm Reproduction Test (*Eisenia fetida*/*Eisenia andrei*), OECD TG 222).

According to Section R.7.11.5.3., Chapter R.7c of the ECHA *Guidance on information requirements and chemical safety assessment* (version 2.0, November 2014), substances that are ionisable or have a  $\log K_{ow}/K_{oc} > 5$  are considered highly adsorptive, whereas substances with a half-life  $> 180$  days are considered very persistent in soil. ECHA notes that based on the evidence presented within the registration dossier, you consider substance being as not readily biodegradable. Thus, the substance is considered very persistent which is default setting for not readily biodegradable substances, when value of the half-life in soil is not available. Therefore ECHA agrees that a long-term testing is indicated and the proposed test is appropriate to fulfil the information requirement of Annex X, Section 9.4.4.

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 (*Eisenia fetida*/*Eisenia andrei*) OECD 222).

### **3. Long-term toxicity to terrestrial plants (Annex X, Section 9.4.6.)**

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.), long-term toxicity testing on plants (Annex X, section 9.4.6.) and effects on soil microorganisms (Annex IX, section 9.4.2.).

The information on "long-term toxicity to plants" 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 a long-term toxicity to terrestrial plants (Terrestrial Plants Test: Seedling Emergence and Seedling Growth Test), OECD TG 208). This test is suitable to address the information requirement of Annex X, section 9.4.6. and at the same time that of Annex IX, section 9.4.3. As noted in the section 2 above, ECHA agrees that a long-term testing is indicated.

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 shall be conducted with species from different families, as a minimum with 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, 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: Terrestrial plants, growth test (OECD 208), with at least six species tested (with as a minimum two monocotyledonous species and four dicotyledonous species).

**Deadline to submit the requested Information**

In the draft decision communicated to you the time indicated to provide the requested information was 9 months from the date of adoption of the decision. In your comments on the draft decision, you requested an extension of the timeline. You sought to justify this request by the need to isolate test material and the current work load of the analytical service provider. Your request is substantiated by the attached letter from the service provider which indicates that you might need additional 3 months to qualify your test material. Therefore, ECHA has granted the request and set the deadline to 12 months.

## **Appendix 2: Procedural history**

ECHA received your registration containing the testing proposals for examination pursuant to Article 40(1) on 29 February 2016.

This decision does not take into account any updates after **26 October 2016**, 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.

ECHA took into account your comments and amended the deadline.

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 request(s) in this decision, or to fulfil otherwise the information requirement(s) 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 test(s) 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 test(s) 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 test(s) must be suitable to assess these grades. Finally there must be adequate information on substance identity for the sample tested and the grade(s) registered to enable the relevance of the test(s) to be assessed.