EUROPEAN CHEMICALS AGENCY

Helsinki, 26 November 2018

Addressee: [redacted]

Decision number: TPE-D-2114450358-46-01/F
Substance name: benzotriazole
EC number: 202-394-1
CAS number: 95-14-7
Registration number: [redacted]
Submission number: [redacted]
Submission date: 07.05.2018
Registered tonnage band: 100-1000T

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 proposals are accepted and you are requested to carry out:

1. **Pre-natal developmental toxicity study (Annex IX, Section 8.7.2.; test method: OECD TG 414) in a first species (rat or rabbit), oral route using the registered substance.**
2. **Simulation testing on ultimate degradation in surface water (Annex IX, Section 9.2.1.2.; test method: Aerobic mineralisation in surface water – simulation biodegradation test, EU C.25./OECD TG 309) at a temperature of 12°C using the registered substance.**

In addition, you are requested to perform:

3. **Identification of the degradation products (Annex IX, Section 9.2.3.) by means of the above test method (request 2)**

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

4. **Long-term toxicity on terrestrial invertebrates (Annex IX, Section 9.4.1. column 2; test method: Earthworm reproduction test, OECD TG 222) using the registered substance.**
5. **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.**

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

6. **Long-term toxicity testing on plants (Annex IX, Section 9.4.3. column 2; 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 ***2 June 2020***. 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[1] by Claudio Carlon, Head of Unit, Evaluation E2

[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 proposal(s) submitted by you and scientific information submitted by third parties.

1. Pre-natal developmental toxicity study (Annex IX, Section 8.7.2.) in a first species

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

a) Examination of the testing proposal

A pre-natal developmental toxicity study for a first species is a standard information requirement as laid down in Annex IX, Section 8.7.2. of the REACH Regulation. The information on this endpoint 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 pre-natal developmental toxicity study according to OECD TG 414. You have indicated the test material to be the registered substance.

The following statement is included in the endpoint study record for the proposed pre-natal developmental toxicity testing: *" There is no Information currently available to fulfil the information requirements according to (EC) No. 1907/2006, Annex IX, 8.7.2. For this endpoint, no reliable alternative Methods (QSAR, in-vitro-testing) are available. Information on alternative substances, suitable for Read Across, is not available either. Therefore, proposing an in vivo test is identified as the last resort to meet the information requirements for this endpoint."*

ECHA considers that the proposed study performed with the registered substance is appropriate to fulfil the information requirement of Annex IX, Section 8.7.2. of the REACH Regulation.

According to the test method OECD TG 414, the rat is the preferred rodent species and the rabbit the preferred non-rodent species. On the basis of this default consideration, ECHA considers testing should be performed with the rat or rabbit as a first species.

You specified the route for testing to be oral route. ECHA considers that the oral route is the most appropriate route of administration for substances except gases to focus on the detection of hazardous properties on reproduction as indicated in ECHA *Guidance on information requirements and chemical safety assessment* (version 6.0, July 2017) R.7a, chapter R.7.6.2.3.2. Since the substance to be tested is a solid, ECHA concludes that testing should be performed by the oral route.

b) Consideration of the information received during third party consultation

ECHA received third party information concerning the testing proposal during the third party consultation. For the reasons explained further below the information provided by third parties is not sufficient to fulfil this information requirement.
A third party has provided information on an OECD 422 screening study performed with the registered substance subject to the present decision.

However, ECHA notes that an OECD 422 screening study is not a test method that corresponds to the standard information requirement of Annex IX, Section 8.7.2 for a pre-natal developmental toxicity study because it does not provide equivalent information. The screening study does not cover the key parameters of a pre-natal developmental toxicity study which are, for example, examinations of the foetuses for skeletal and visceral malformations. Therefore, the criteria listed in Annex XI, Section 1.1.2. are not met.

Another third party provided information that the sponsors of the benzotriazole category for the US Environmental Protection Agency (EPA) proposed to do an OECD TG 414 test in 2002, but the status of this proposed test is unknown. They also note a 2011 US test rule, which includes some benzotriazoles, and propose that testing be coordinated between the US and Europe.

ECHA notes no information on an existing OECD TG 414 test is available and that the proposed test rule does not appear to include PNDT testing for benzotriazole, but a repro screening test (OECD 421/422) which would not satisfy the information requirement of pre-natal developmental study.

Consequently, the information provided by third parties is not sufficient to adapt this information requirement.

c) Outcome

Therefore, pursuant to Article 40(3)(a) of the REACH Regulation, you are requested to carry out the proposed study with the registered substance subject to the present decision: Pre-natal developmental toxicity study in a first species (rats or rabbits), oral route (test method: OECD TG 414).

Notes for your consideration

For the selection of the appropriate species you are advised to consult ECHA *Guidance on information requirements and chemical safety assessment* (version 6.0, July 2017), Chapter R.7a, section R.7.6.2.3.2.

2. Simulation testing on ultimate degradation in surface water (Annex IX, Section 9.2.1.2.)

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

"Simulation testing on ultimate degradation in surface water" is a standard information requirement as laid down in Annex IX, Section 9.2.1.2. of the REACH Regulation. The information on this endpoint 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 Simulation biodegradation study in surface water (OECD TG 309 / EU C.25) with the following justification: "*Based on all available information the substance is considered to be neither readily biodegradable nor highly insoluble in water. In addition, monitoring studies observed relevant concentrations of the test substance in European surface waters.*" You have indicated the test material to be the registered substance.

ECHA considers that the proposed study performed with the registered substance is appropriate to fulfil the information requirement of Annex IX, Section 9.2.1.2. of the REACH Regulation.

In the OECD TG 309 Guideline two test options, the "pelagic test" and the "suspended sediment test", are described. The pelagic test is normally the preferred option when assessing persistency. In an attachment submitted in your dossier under the ready biodegradation endpoint you have identified several potential transformation pathways leading to potentially different degradation/transformation Therefore, in this case, you may also consider the "suspended sediment test" described in OECD TG 309 to enhance the concentration of the inocula in the test system and thus increase the probability of more diverse microbial population to simulate the diverse transformation pathways. In addition as described below in section 3 of this appendix you may consider higher test concentrations when identifying the degradation products.

If the pelagic test is followed, the amount of suspended solids should be representative of the level of suspended solids in EU surface water. The concentration of suspended solids in the surface water sample used should therefore be approximately 15 mg dw/L. Testing natural surface water containing between 10 and 20 mg SPM dw/L is considered acceptable. In case the "suspended sediment test" is followed then the concentration of suspended solids should be between 0.01 and 1 g/L.

Furthermore, when reporting the non-extractable residues (NER) in your test results you should explain and scientifically justify the extraction procedure and solvent used obtaining a quantitative measure of NER.

In the testing proposal you have not specified the temperature at which the test shall be performed. One of the purposes of the simulation test is to provide the information that must be considered for assessing the P/vP properties of the registered substance in accordance with Annex XIII of REACH regulation to decide whether it is persistent in the environment. Annex XIII also indicates that "*the information used for the purposes of assessment of the PBT/vPvB properties shall be based on data obtained under relevant conditions*". The Guidance on information requirements and chemical safety assessment R.7b (version 4.0, June 2017) specifies that simulation tests "attempt to simulate degradation in a specific environment by use of indigenous biomass, media, relevant solids [...], and a typical temperature that represents the particular environment". The Guidance on information requirements and chemical safety assessment Chapter R.16 on Environmental Exposure Estimation, Table R.16-8 (version 3.0 February 2016) indicates 12°C (285K) as the average environmental temperature for the EU to be used in the chemical safety assessment. Performing the test at the temperature of 12°C is within the applicable test conditions of the Test Guideline OECD TG 309. Therefore, the test should be performed at the temperature of 12°C.

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: Aerobic mineralisation in surface water – simulation biodegradation test (test method: EU C.25/OECD TG 309) at a temperature of 12°C.

Notes for your consideration

In accordance with Annex I, Section 4, of the REACH Regulation you should revise the PBT assessment when results of the test detailed above is available. The Registrant is also

advised to consult the ECHA Guidance on information requirements and chemical safety assessment (version 3.0, June 2017), Chapter R.11.2.2. and Figure R. 11-1 on PBT assessment for the integrated testing strategy for persistency assessment in particular taking into account the degradation products of the registered substance.

3. Identification of the degradation products (Annex IX, Section 9.2.3)

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.

According to Section 9.2.3 in Annex IX of the REACH Regulation identification of degradation products is a standard information requirement. You have not justified an adaptation of this requirement. Consequently there is an information gap and it is necessary to provide information for this information requirement. The identification of degradation products should therefore be included in the requested degradation simulation test.

It is noted that the OECD TG 309 Test Guideline features the formation and identification of the degradation products. The OECD 309 Test Guideline suggests that higher concentrations of the test substance (e.g. >100 µg/l) can be used for identification and quantification of major transformation products due to analytical limitations. You may consider this option in your study design for identification of the degradation/transformation products.

Notes for your consideration

In accordance with Annex I, Section 4, of the REACH Regulation you should revise the PBT assessment when results of the test detailed above is available. The Registrant is also advised to consult the ECHA Guidance on information requirements and chemical safety assessment (version 3.0, June 2017), Chapter R.11.2.2. and Figure R. 11-1 on PBT assessment for the integrated testing strategy for persistency assessment in particular taking into account the degradation products of the registered substance.

4. Long-term toxicity on terrestrial invertebrates (Annex IX, Section 9.4.1. column 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, 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.). Furthermore, Annex IX, Section 9.4., column 2 specifies that long-term toxicity testing shall be considered by the Registrant instead of short-term, in particular for substances that have a high potential to adsorb to soil or that are very persistent.

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 invertebrates OECD Guideline 222 (Earthworm Reproduction Test (Eisenia fetida/Eisenia andrei)) on the registered substance with the following justification: "*Based on intrinsic properties of Benzotriazole, Tolyltriazole and their conjugated sodium salts binding to organic soil compounds is assumed. However, polar interactions based on the ionic form of salts and the strong dipole moments in the uncharged molecules are supposed to be more relevant for the retention in soil. Hence, long-term exposure to soil-dwelling organisms that feed on soil particles are considered as most relevant and consequently a test on reproduction with earthworms has been proposed.*"

According to Section R.7.11.5.3., Chapter R.7c of the ECHA *Guidance on information requirements and chemical safety assessment* (version 3.0, June 2017), 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. According to the evidence presented within the Registration dossier, the registered substance is considered as not readily biodegradable since there was 0% degradation of the substance over 28 days in an OECD 301 D test on ready biodegradability using both adapted and non-adapted sludge. An OECD 301B ready biodegradability study on the registered substance using adapted sludge also showed 0% biodegradation.

The registered substance must therefore be considered as very persistent in soil in the absence of information on its half-life in soil. This is the default setting for not readily biodegradable substances, when a 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 IX, Section 9.4.1., column 2.

Furthermore, based upon the available aquatic toxicity information and the physico-chemical properties of the substance, and in relation to Section R.7.11.6., Chapter R.7c of the ECHA *Guidance on information requirements and chemical safety assessment* (version 3.0, June 2017), ECHA considers that the substance would fall into soil hazard category 3. In the context of an integrated testing strategy for soil toxicity, the Guidance advocates performing an initial screening assessment based upon the Equilibrium Partitioning Method (EPM), together with a confirmatory long-term soil toxicity test. The PNECscreen is calculated through EPM on the basis of aquatic toxicity data only.

ECHA notes that the strategy pursued by you is based on the observed concern in the terrestrial compartments and you have also proposed testing for long-term toxicity to terrestrial plants.

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)

5. 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, 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 microorganisms" 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 test using the registered substance on soil microorganisms in accordance with OECD Guideline 216 (Soil Microorganisms: Nitrogen Transformation Test) with the following justification: *"Available information on inhibition of nitrification in topsoil samples indicate a strong inhibitory potential of Benzotriazole and Tolyltriazole. In observations with 45 heterocyclic N compounds in three different soils significant inhibition of nitrification (35, 55, and 81 %) at 12 µg Benzotriazole /g soil has been found (McCarty et al.). By comparing the different molecular structures the three vicinal Nitrogen atoms in the triazole ring has been suspected as responsible fragment for the inhibitory effect. However, the existing data are considered to be not adequate for the chemical safety assessment due to inadequacies in the study design and insufficient information on the purity of the test substances."*

ECHA considers that the proposed study performed with the registered substance is appropriate to fulfil the information requirement of Annex IX, Section 9.4.2. of the REACH Regulation.

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.

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

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

"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.). Furthermore, Annex IX, Section 9.4., column 2 specifies that long-term toxicity testing shall be considered by the Registrant instead of short-term, in particular for substances that have a high potential to adsorb to soil or that are very persistent.

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 test to plants in accordance with OECD Guideline 208 (Terrestrial Plants Test: Seedling Emergence and Seedling Growth Test) on the registered substance. You do not indicate the number or type of plant species to be tested. You provided the following justification: *"Wu et al. have conducted a series of test with different plants (Pumpkins, Alfalfa, Cottonwood, Corkscrew willow, horseraddish) indicating toxic effects of Benzotriazole on the growth of plants (Wu et al., 1998). In*

addition, findings in tomato plants (Davis, 1954), cucumber seedlings and bushbean plants (EPA report 1977) has been reported. Lupher et al. have observed adverse effects on sunflowers and fescues (Lupher et al., 1999). As available information with regard to toxic effects on plants are not adequate for the chemical safety asssessment and the provisional assessment (PNECsoil calculated by EPM) indicates a risk for the soil compartment further tests have to be proposed. Hence, Benzotriazole and Tolyltriazole as well as the conjugated forms show a similar behaviour in the environment the test will be used for the other substances too."

According to Section R.7.11.5.3., Chapter R.7c of the ECHA *Guidance on information requirements and chemical safety assessment* (version 3.0, June 2017), 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. According to the evidence presented within the Registration dossier, the registered substance is considered as not readily biodegradable since there was 0% degradation of the substance over 28 days in an OECD 301 D test on ready biodegradability using both adapted and non-adapted sludge. An OECD 301B ready biodegradability study on the registered substance using adapted sludge also showed 0% biodegradation.

The registered substance must therefore be considered as very persistent in soil in the absence of information on its half-life in soil. This is the default setting for not readily biodegradable substances, when a 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 IX, Section 9.4.3., column 2.

Furthermore, based upon the available aquatic toxicity information and the physico-chemical properties of the substance, and in relation to Section R.7.11.6., Chapter R.7c of the ECHA *Guidance on information requirements and chemical safety assessment* (version 3.0, June 2017), ECHA considers that the substance would fall into soil hazard category 3. In the context of an integrated testing strategy for soil toxicity, the Guidance advocates performing an initial screening assessment based upon the Equilibrium Partitioning Method (EPM), together with a confirmatory long-term soil toxicity test. The PNECscreen is calculated through EPM on the basis of aquatic toxicity data only.

ECHA notes that the strategy pursued by you is based on the observed concern in the terrestrial compartments and you have also proposed testing for long-term toxicity to soil macro-organisms.

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. You do not indicate the number or type of plant species to be tested. ECHA therefore concludes on the following modifications regarding the species to be used when carrying out the test: testing shall be conducted with at least six 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)(b) of the REACH Regulation, you are requested to carry out the proposed test under modified conditions using the registered substance subject to the present decision: Terrestrial plants, growth test (test method: OECD TG 208), with at

least six species tested (with as a minimum two monocotyledonous species and four dicotyledonous species).

Appendix 2: Procedural history

ECHA received your registration containing the testing proposals for examination pursuant to Article 40(1) on 21 May 2013.

ECHA held a third party consultation for the testing proposals from 22 October 2013 until 5 December 2013. ECHA received information from third parties (see Appendix 1).

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 did not amend the requests.

You updated your registration on 12 August 2016. ECHA took the information in the updated registration into account, and did not amend the draft decision. The updated information is reflected in the Reasons (Appendix 1).

You were notified that the draft decision does not take into account any updates after 3 August 2016. You updated your registration with submission number [redacted] on 12 August 2016. In your updated dossier you have clarified the testing proposals and the read-across category related to three other substances. Given the exceptional circumstances, ECHA has taken into account the above update when processing this decision.

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

ECHA received proposal(s) for amendment and modified the draft decision.

ECHA invited you to comment on the proposed amendment(s).

For procedural reasons, ECHA withdrew the TPE draft decision and restarted the decision making process pursuant to Article 50(1) of the REACH Regulation.

This decision does not take into account any updates after **4 July 2018**, 30 calendar days after the end of the commenting period.

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.

You updated your registration on 7 May 2018. The updated information does not have any impact on this decision.

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.