EUROPEAN CHEMICALS AGENCY

Helsinki, 26 November 2018

Addressee: [redacted]

Decision number: TPE-D-2114450359-44-01/F
Substance name: sodium 1H-benzotriazolide
EC number: 239-269-6
CAS number: 15217-42-2
Registration number: [redacted]
Submission number: [redacted]
Submission date: 11/04/2016
Registered tonnage band: 100-1000

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. **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 analogue substance 1H-Benzotriazole (EC no. 202-394-1).**
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 including the identification of the degradation products (Annex IX, Section 9.2.3.) using the analogue substance 1H-Benzotriazole (EC no. 202-394-1).**
3. **Long-term toxicity on terrestrial invertebrates (Annex IX, Section 9.4.1. column 2; test method: Earthworm reproduction test, OECD TG 222) using the analogue substance 1H-Benzotriazole (EC no. 202-394-1).**
4. **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 analogue substance 1H-Benzotriazole (EC no. 202-394-1).**

Your testing proposal is modified and you are requested to carry out the study under point 3 or:

5. **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 analogue substance 1H-Benzotriazole (EC no. 202-394-1).**

You may adapt the testing requested above according to the specific rules outlined in Annexes VI to IX and/or according to the general rules contained in Annex XI to the REACH Regulation.

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 have to submit the requested information in an updated registration dossier by ***2 June 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.

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 Ofelia Bercaru, Head of Unit, Evaluation E3

[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.

TOXICOLOGICAL AND ECOTOXICOLOGICAL INFORMATION

In accordance with Articles 10(a) and 12(1) of the REACH Regulation, a technical dossier registered at 100 to 1000 tonnes per year must contain, as a minimum, the information specified in Annexes VII to IX to the REACH Regulation. The information to be generated for the dossier must fulfil the criteria in Article 13(4) of the same regulation.

Grouping and read-across approach for toxicological and ecotoxicological information

Your registration dossier contains for multiple endpoints adaptation arguments in form of a grouping and read-across approach according to Annex XI, 1.5 of the REACH Regulation. ECHA has assessed first the scientific and regulatory validity of your Grouping and read-across approach for toxicological and ecotoxicological endpoints in general before the individual endpoints (sections 1 - 5).

You have sought to adapt information requirements by applying a read-across approach in accordance with Annex XI, Section 1.5. of the REACH Regulation, for the endpoints:

- Pre-natal developmental toxicity study (Annex IX, Section 8.7.2.);
- Biodegradation in water and sediment: simulation tests (Annex IX, 9.2.1.2);
- Toxicity to terrestrial arthropods (Annex X; 9.4.4);
- Toxicity to terrestrial plants (Annex X, 9.4.6);
- Toxicity to soil microorganisms (Annex IX, 9.4.2).

According to Annex XI, Section 1.5., two conditions shall be necessarily fulfilled. Firstly, there needs to be structural similarity between substances which results in a likelihood that the substances have similar physicochemical, toxicological and ecotoxicological properties so that the substances may be considered as a group or category. Secondly, it is required that the relevant properties of a substance within the group may be predicted from data for reference substance(s) within the group (read-across approach). ECHA considers that the generation of information by such alternative means should offer equivalence to prescribed tests or test methods.

Based on the above, a read-across hypothesis needs to be provided. This hypothesis establishes why a prediction for a toxicological or ecotoxicological property is reliable and should be based on recognition of the structural aspects the chemical structures have in common and the differences between the structures of the source and registered substances[2]. This hypothesis explains why the differences in the chemical structures should not influence the toxicological/ ecotoxicological properties or should do so in a regular pattern. The read-across approach must be justified scientifically and documented thoroughly, also taking into account the differences in the chemical structures. There may be several lines of supporting evidence used to justify the read-across hypothesis, with the aim of strengthening the case.

Due to the different nature of each endpoint and consequent difference in scientific considerations (e.g. key parameters, biological targets), a read-across must be specific to

[2] Please see for further information ECHA *Guidance on information requirements and chemical safety assessment* (version 1, May 2008), Chapter R.6: QSARs and grouping of chemicals.

the endpoint or property under consideration. Key physicochemical properties may determine the fate of a compound, its partitioning into a specific phase or compartment and largely influence the availability of compounds to organisms, e.g. in bioaccumulation and toxicity tests. Similarly, biotic and abiotic degradation may alter the fate and bioavailability of compounds as well as be themselves hazardous, bioaccumulative and/or persistent. Thus, physicochemical and degradation properties influence the human health and environmental properties of a substance and should be considered in read-across assessments. However, the information on physicochemical properties is only a part of the read-across hypothesis, and it is necessary to provide additional justification which is specific to the endpoint or property under consideration.

The ECHA Read-across assessment framework foresees that there are two options which may form the basis of the read-across hypothesis[3]- (1) (Bio)transformation to common compound(s) and (2) Different compounds have the same type of effect(s).
Finally, Annex XI, Section 1.5. lists several additional requirements, which deal with the quality of the studies which are to be read-across.

A. Description of the grouping and read-across approach proposed by the Registrant

You have provided a read-across documentation as a separate attachment.
In your read-across documentation you propose read-across between the substances:

- 1H-Benzotriazole, EC No 202-394-1 (CAS No 95-14-7, here after 'benzotriazole'),
- 4(or 5)-methyl-1h-benzotriazole, EC 249-596-6 (CAS No 29385-43-1, here after 'methyl benzotriazole'),
- Sodium 1H-benzotriazolide (EC no. 239-269-6), here after 'sodium benzotriazolide') and
- Sodium 4(or 5)-methyl-1H-benzotriazolide (EC no. 265-004-9) (here after 'sodium methyl benzotriazolide').

You claim that either of these substances can be the source substance.

In your registration dossier you have provided testing proposals to achieve compliance with the REACH information requirements for the registered substance sodium 1H-benzotriazolide (EC no. 239-269-6), (here after 'sodium benzotriazolide') using data of structurally similar substance 1H-Benzotriazole, EC No 202-394-1 (CAS No 95-14-7, hereafter the 'source substance').

You use the following arguments to support the prediction of properties of the registered substance from data for source substance and you claim that on the basis of the following it is possible to predict the human health and ecotoxicological properties of the registered substance:

- structural similarity (same fused rings, similar reactivity, deprotonation of Nitrogen atom leading to the conjugated base as sodium salt, in physiological environment (pH 6-8) protonation of the salt occurs and the source substance is present)
- similarity in physico-chemical properties (molecular weight, physical form, vapour pressure, Log Pow, water solubility)
- similar ecotoxicological properties (resulting in similar PNEC and N/LOAEL)
- toxicological similarity (based on the results from toxicological endpoints and QSAR modelling), including similarity in toxicokinetics (based on similar physicochemical properties and based on absorption, distribution, metabolism and excretion)

[3] Please see ECHA's Read-Across Assessment Framework (https://echa.europa.eu/support/registration/how-to-avoid-unnecessary-testing-on-animals/grouping-of-substances-and-read-across).

ECHA considers that this information is your read-across hypothesis, which provides the basis whereby you predict the properties of the registered substance from the source substance.

B. ECHA's analysis of the grouping and read-across approach

Your proposed adaptation argument is that the similarity in chemical structure and similarity in some of the physico-chemical, ecotoxicological and toxicological properties between the source and registered substance is a sufficient basis for predicting the properties of the registered substance for other endpoints. Structural similarity is a prerequisite for applying the grouping and read-across approach. However similarity in chemical structure and similarity of some of the physico-chemical, ecotoxicological and toxicological properties does not necessarily lead to predictable or similar human health and environmental properties in other endpoints. Your justification based on structural similarity, similar physico-chemical, ecotoxicological and toxicological properties has not established why the prediction is reliable for the human health and environmental endpoints for which the read across is claimed.

However, ECHA notes that despite the deficiencies of your read-across hypothesis, in this specific case you propose that the properties of a sodium salt of a base may be predicted from data from the corresponding base. In this case, it is also likely that both substances will dissociate in water to form the same species.

Therefore the read across from the 1H-Benzotriazole, EC No 202-394-1 (source substance) to its sodium salt: Sodium 1H-benzotriazolide (EC no. 239-269-6) is considered plausible.

ECHA considers that your read-across approach may provide a reliable basis whereby the human health, environmental effects and environmental fate of the registered substance may be predicted from data for source substance. Hence, this approach is considered plausible in order to fulfill the general rules of adaptation as set out in Annex XI, Section 1.5. of the REACH Regulation.

C. Conclusion on the grouping and read-across approach

For the reasons as set out above, ECHA considers that this grouping and read-across approach may provide a reliable basis whereby the human health effects, environmental effects and environmental fate of the registered substance may be predicted from data for reference substance.

Hence, this approach is considered plausible for the purpose of the testing proposal evaluation. ECHA emphasises that any final determination on the validity of the read-across, including the grouping approach proposed by you, would be premature at thispoint in time. The eventual validity of the read-across hypothesis and grouping approach will be reassessed once the requested information is submitted.

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 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 with the analogue substance 1H-Benzotriazole (EC No. 202-394-1).

ECHA requested your considerations for alternative methods to fulfil the information requirement for Reproductive toxicity (pre-natal developmental toxicity). ECHA notes that you provided your considerations and you applied read-across to fulfil the respective information requirement, and no other alternative methods were available. ECHA has taken these considerations into account.

ECHA has evaluated your proposal to perform the test with the analogue substance 1H-Benzotriazole (EC No. 202-394-1), as set out in section "Grouping and read-across approach for toxicological and ecotoxicological information" above. ECHA concludes that the read across from the 1H-Benzotriazole, EC No 202-394-1 (source substance) to its sodium salt: Sodium 1H-benzotriazolide (EC no. 239-269-6) is considered plausible for this endpoint.

ECHA considers that the proposed study performed with the analogue substance 1H-Benzotriazole (EC No. 202-394-1) is appropriate to fulfil the information requirement of Annex IX, Section 8.7.2. of the REACH Regulation.

You did not specify the species to be used for testing. 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 did not specify the route for testing. 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) Chapter R.7a, Section 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.

Outcome

Therefore, pursuant to Article 40(3)(a) of the REACH Regulation, you are requested to carry out the proposed study with the analogue substance [1H-Benzotriazole (EC No. 202-394-1)]: 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 analogue substance 1H-Benzotriazole (CAS: 95-14-7, EC: 202-394-1) with the following justification: *"In accordance with EC 1907/2006, Annex XI 1.5 sodium benzotriazole is registered in a group approach covering 1H-Benzotriazole and Tolyltriazole as well as the conjugated sodium salts of these two substances. A simulation study according to OECD guideline 309 with 1H-Benzotriazole (CAS# 95-14-7) has been proposed by the REACH lead registrant ([redacted]) for the substance (CAS# 95 -14 -7). The results from this study will be included in this registration dossier for sodium 1H-benzotriazolide once the study on 1H-Benzotriazole has been completed by the lead registrant for CAS# 95-14-7. As sodium benzotriazole is registered in a group approach covering 1H-Benzotriazole and Tolyltriazole as well as the conjugated sodium salts further testing with other group members is considered to be not necessary."*

ECHA has evaluated your proposal to perform the test with the analogue substance 1H-Benzotriazole (EC No. 202-394-1), as set out in section "Grouping and read-across approach for toxicological and ecotoxicological information" above. ECHA concludes that the read across from the 1H-Benzotriazole, EC No 202-394-1 (source substance) to its sodium salt: Sodium 1H-benzotriazolide (EC no. 239-269-6) is considered plausible for this endpoint.

ECHA considers that the proposed study performed with the analogue substance 1H-Benzotriazole (EC No. 202-394-1) is appropriate to fulfil the information requirement of Annex IX,Section 9.2.1.2. of the REACH Regulation.

The information currently available in the technical dossier and the Chemical Safety Assessment (CSA) is not sufficient to conclude on the biodegradation potential and consequently the persistence of the registered substance or its degradation products in water and thus, it is necessary to generate additional information for this endpoint.

ECHA notes that the information from the simulation study may also be needed for the purposes of the PBT, vPvB assessment.

In the OECD TG 309 Guideline two test options, the "pelagic test" and the "suspended sediment test", are described. ECHA considers that the pelagic test option should be followed as that is the recommended option for P assessment. The amount of suspended solids in the pelagic test 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. 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.

According to Section 9.2.3 in Annex IX of the REACH Regulation identification of degradation products is a standard information 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 also noted that the OECD TG 309 Test Guideline features the formation and identification of the degradation products.

Therefore, pursuant to Article 40(3)(a) of the REACH Regulation, you are requested to carry out the proposed study using the analogue substance 1H-Benzotriazole (EC No. 202-394-1: Aerobic mineralisation in surface water - simulation biodegradation test (test method: EU C.25/OECD TG 309) at a temperature of 12°C, including the identification of the degradation products (Annex IX, Section 9.2.3.). The biodegradation of each relevant constituent present in concentration at or above 0.1% (w/w) or, if not technically feasible, in concentrations as low as technically detectable shall be assessed. This can be done simultaneously during the same study.

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.11.1.3. 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. 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 analogue substance 1H-Benzotriazole (CAS: 95-14-7, EC: 202-394-1) *"In accordance with EC 1907/2006 Annex XI 1.5 sodium benzotriazole is registered in a group approach covering 1H-Benzotriazole and Tolyltriazole as well as the conjugated sodium salts of these two substances. A long-term study on toxicity to reproduction with earthworms (OECD 222) for 1H-Benoztriazole (CAS# 95-14-7) has been proposed by the REACH lead registrant ([redacted]) for the substance (CAS# 95 -14 -7). The results from this study will be included in this registration dossier for sodium 1H-benzotriazolide once the study on 1H-Benzotriazole has been completed by the lead registrant for CAS# 95-14-7. As sodium benzotriazole is registered in a group approach covering 1H-Benzotriazole and Tolyltriazole as well as the conjugated sodium salts further testing with other group members is considered to be not necessary."*

ECHA has evaluated your proposal to perform the test with the analogue substance 1H-Benzotriazole (EC No. 202-394-1 as set out in section "Grouping and read-across approach for toxicological and ecotoxicological information" above. ECHA concludes that the read across from the 1H-Benzotriazole, EC No 202-394-1 (source substance) to its sodium salt: Sodium 1H-benzotriazolide (EC no. 239-269-6) is considered plausible for this endpoint.

ECHA considers that the proposed study performed with the analogue substance 1H-Benzotriazole (EC No. 202-394-1) is appropriate to fulfil the information requirement of Annex IX,Section 9.4.1. of the REACH Regulation.

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 analogue 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 analogue substance using adapted sludge also showed 0% biodegradation.

The analogue substance and therefore also 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, July 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 not based on the integrated testing strategy. Therefore, ECHA would like to note that as only one confirmatory long-term soil toxicity test is necessary you may choose to perform one of the tests requested under points 3 or 5. Consequently you may adapt the other testing requested under the points 3 or 5 - according to the specific rules outlined in Annexes VI to IX and/or according to the general rules contained in Annex XI to 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 analogue substance 1H-Benzotriazole (EC No. 202-394-1): Earthworm reproduction test (OECD TG 222)

4. 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 analogue substance 1H-Benzotriazole (EC No. 202-394-1) on soil microorganisms in accordance with OECD Guideline 216 (Soil Microorganisms: Nitrogen Transformation Test) with the following justification: *"In accordance with EC 1907/2006 Annex XI 1.5 sodium benzotriazole is registered in a group approach covering 1H-Benzotriazole and Tolyltriazole as well as the conjugated sodium salts of these two substances. A Nitrogen transformation (OECD 216) study with 1H-Benzotriazole (CAS# 95-14-7) has been proposed by the REACH lead registrant ([redacted]) for the substance (CAS# 95-14-7). The results from this study will be included in this registration dossier for sodium 1H-benzotriazolide once the study on 1H-Benzotriazole has been completed by the lead registrant for CAS# 95-14-7. As sodium benzotriazole is registered in a group approach covering 1H-Benzotriazole and Tolyltriazole as well as the conjugated sodium salts further testing with other group members is considered to be not necessary."*

ECHA has evaluated your proposal to perform the test with the analogue substance 1H-Benzotriazole (EC No. 202-394-1), as set out in section "Grouping and read-across approach for toxicological and ecotoxicological information" above. ECHA concludes that the read across from the 1H-Benzotriazole, EC No 202-394-1 (source substance) to its sodium salt: Sodium 1H-benzotriazolide (EC no. 239-269-6) is considered plausible for ths endpoint.

ECHA considers that the proposed study performed with the analogue substance 1H-Benzotriazole (EC No. 202-394-1) 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 analogue substance 1H-Benzotriazole (EC No. 202-394-1): Soil microorganisms: nitrogen transformation test, EU C.21/OECD TG 216.

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

Pursuant to Article 40(3)(a) and (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 analogue substance 1H-Benzotriazole (EC No. 202-394-1). You do not indicate the number or type of plant species to be tested.

You provided the following justification: *"In accordance with EC 1907/2006 Annex XI 1.5 sodium benzotriazole is registered in a group approach covering 1H-Benzotriazole and Tolyltriazole as well as the conjugated sodium salts of these two substances. A long-term study with plants (OECD 208) for 1H-Benzotriazole (CAS# 95-14-7) has been proposed by the REACH lead registrant (*[redacted]*) for the substance (CAS# 95-14-7). The results from this study will be included in this registration dossier for sodium 1H-benzotriazolide once the study on 1H-Benzotriazole has been completed by the lead registrant for CAS# 95-14-7. As sodium benzotriazole is registered in a group approach covering 1H-Benzotriazole and Tolyltriazole as well as the conjugated sodium salts further testing with other group members is considered to be not necessary."*
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, July 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 analogue 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 analogue substance using adapted sludge also showed 0% biodegradation.

The analogue and therefore also 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.

ECHA has evaluated your proposal to perform the test with the analogue substance 1H-Benzotriazole (EC No. 202-394-1), as set out in section "Grouping and read-across approach for toxicological and ecotoxicological information" above. ECHA concludes that the read across from the 1H-Benzotriazole, EC No 202-394-1 (source substance) to its sodium salt: Sodium 1H-benzotriazolide (EC no. 239-269-6) is considered plausible for this endpoint.

ECHA considers that the proposed study performed with the analogue substance 1H-Benzotriazole (EC No. 202-394-1) is appropriate to fulfil the information requirement of Annex IX,Section 9.4.3. of the REACH Regulation.

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, July 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 not based on the integrated testing strategy. Therefore, ECHA would like to note that as only one confirmatory long-term soil toxicity test is necessary you may choose to perform one of the tests requested under points 3 or 5. Consequently you may adapt the other testing requested under the points 3 or 5 - according to the specific rules outlined in Annexes VI to IX and/or according to the general rules contained in Annex XI to the REACH Regulation.

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)(a) and (b) of the REACH Regulation, you are requested to carry out the proposed test under modified conditions using the analogue substance 1H-Benzotriazole (EC No. 202-394-1): 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 in accordance with Article 40(1) on 11 April 2016.

ECHA held a third party consultation for the testing proposals from 16 December 2016 until 30 January 2017. ECHA did not receive information from third parties.

This decision does not take into account any updates after **3 January 2018**, 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 did not receive any comments by the end of the commenting period.

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.

4. If the required tests are conducted with an analogue substance in the context of a read-across approach, the identity of the test material used to perform the test should be specified in line with the ECHA's Practical Guide on "How to use alternatives to animal testing to fulfil your information requirements" (chapter 4.4). This is required to show that the test material is representative of the analogue substance identified in the read-across approach and used to predict the properties of the registered substance.