ECHA
EUROPEAN CHEMICALS AGENCY

Decision number: CCH-D-2114296618-32-01/F Helsinki, 23 June 2015

DECISION ON A COMPLIANCE CHECK OF A REGISTRATION PURSUANT TO ARTICLE 41(3) OF REGULATION (EC) NO 1907/2006

For di(benzothiazol-2-yl) disulphide, CAS No 120-78-5 (EC No 204-424-9), registration number: [redacted]

Addressee: [redacted]

The European Chemicals Agency (ECHA) has taken the following decision in accordance with the procedure set out in Articles 50 and 51 of Regulation (EC) No 1907/2006 concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH Regulation).

I. Procedure

Pursuant to Article 41(1) of the REACH Regulation ECHA has performed a compliance check of the registration for di(benzothiazol-2-yl) disulphide, CAS No 120-78-5 (EC No 204-424-9), submitted by [redacted] (Registrant).

The scope of this compliance check decision is limited to the standard information requirements of Annex IX, Sections 9.1. and 9.4., Annex X, Sections 9.4 and 9.5.1. and Annex I, Section 3.3 and the related environmental hazard assessment of the REACH Regulation. ECHA stresses that it has not checked the information provided by the Registrant and other joint registrants for compliance with requirements regarding the identification of the substance (Section 2 of Annex VI).

This decision is based on the registration as submitted with submission number [redacted], for the tonnage band of [redacted]. This decision does not take into account any updates submitted after 15 January 2015, the date upon which ECHA notified its draft decision to the Competent Authorities of the Member States pursuant to Article 51(1) of the REACH Regulation.

This compliance check decision does not prevent ECHA from initiating further compliance checks on the present registration at a later stage.

The compliance check was initiated on 7 May 2014.

On 27 October 2014 ECHA sent the draft decision to the Registrant and invited him to provide comments within 30 days of the receipt of the draft decision.

On 28 November 2014 and on 1 December 2014 ECHA received comments from the Registrant on the draft decision.

The ECHA Secretariat considered the Registrant's comments.
The information is reflected in the Statement of Reasons (Section III) whereas no amendments to the Information Required (Section II) were made.

On 15 January 2015 ECHA notified the Competent Authorities of the Member States of its draft decision and invited them pursuant to Article 51(1) of the REACH Regulation to submit proposals for amendment of the draft decision within 30 days of the receipt of the notification.

As no proposal for amendment was submitted, ECHA took the decision pursuant to Article 51(3) of the REACH Regulation.

II. Information required

A. Information in the technical dossier derived from the application of Annexes IX and X

Pursuant to Articles 41(1), 41(3), 10(a)(vii), 12(1)(e), 13 and Annexes IX and X of the REACH Regulation the Registrant shall submit the following information using the indicated test methods and the registered substance subject to the present decision:

1. Long-term toxicity testing on aquatic invertebrates (Annex IX, Section 9.1.5.; test method: Daphnia magna reproduction test, EU C.20./OECD 211);

2. Long-term toxicity testing on fish (Annex IX, Section 9.1.6.1.; test method: Fish, early-life stage (FELS) toxicity test, OECD 210);

3. Long-term toxicity testing on terrestrial invertebrates (Annex X, 9.4.4.; test method: Earthworm reproduction test (*Eisenia fetida/Eisenia andrei*), OECD 222, or Enchytraeid reproduction test, OECD 220, or Collembolan reproduction test in soil, OECD 232);

4. Long-term toxicity testing on plants (Annex X, 9.4.6.; test method: Terrestrial Plant Test: Seedling Emergence and Seedling Growth, OECD 208, with at least six species tested (with as a minimum two monocotyledonous species and four dicotyledonous species), or Soil Quality – Biological Methods – Chronic toxicity in higher plants, ISO 22030);

5. Effects on soil micro-organisms (Annex IX, 9.4.2.; test method: Soil microorganisms: nitrogen transformation test, EU C.21./OECD 216); and

6. Long-term toxicity to sediment organisms (Annex X, 9.5.1.); using one or more of the following test methods: Sediment-water Chironomid toxicity using spiked sediment (OECD 218) or Sediment-water Lumbriculus toxicity test using spiked sediment (OECD 225) or Sediment-Water Chironomid Life-Cycle Toxicity Test Using Spiked Water or Spiked Sediment (OECD 233).

Note for consideration by the Registrant:

The Registrant 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 sound scientific justification, referring to and conforming with the appropriate rules in the respective Annex, and an adequate and reliable documentation.

Failure to comply with the requests in this decision, or to fulfil otherwise the information requirements with a valid and documented adaptation, will result in a notification to the Authorities of the Member States for possible enforcement.

B. Information related to chemical safety assessment and chemical safety report

Pursuant to Articles 41(1)(c), 41(3), 10(b) and 14 as well as Annex I of the REACH Regulation the Registrant shall submit the following information:

7. Revised PNECs for the environmental compartments on the basis of data from A. above as it becomes available and as further specified in Section III.

C. Deadline for submitting the required information

Pursuant to Articles 41(4) and 22(2) of the REACH Regulation the Registrant shall submit to ECHA by **2 January 2018** an update of the registration dossier containing the information required by this decision, including an update of the Chemical Safety Report. The timeline has been set to allow for sequential testing as appropriate.

III. Statement of reasons

Pursuant to Article 41(3) of the REACH Regulation, ECHA may require the Registrant to submit any information needed to bring the registration into compliance with the relevant information requirements.

A. Information in the technical dossier derived from the application of Annexes IX and X

Pursuant to Articles 10(a)(vii), 12(1)(e) of the REACH Regulation, a technical dossier for a substance manufactured or imported by the Registrant in quantities of 1000 tonnes or more per year shall contain as a minimum the information specified in Annexes VII, VIII, IX, and X of the REACH Regulation.

1. and 2. Long-term aquatic toxicity testing on invertebrates and fish

According to column 1 of Sections 9.1.5. and 9.1.6. of Annex IX of the REACH Regulation, long-term toxicity testing on invertebrates and on fish is required to fulfil the standard information requirements.

ECHA notes that the Registrant has sought to adapt the long-term toxicity testing on aquatic invertebrates and fish using the following justification: "According to column 2 of REACH Annex IX, long-term toxicity tests should be proposed by the registrant if the chemical safety assessment indicates the need to further investigate effects on aquatic organisms as indicated by a PEC/PNEC ratio > 1. Having a PEC/PNEC ratio < 1 for all exposure scenarios, there is no need to perform a long-term assay as the risk towards aquatic organisms is sufficiently controlled based on the already available information."

ECHA notes that in order for an adaptation of Annex IX, 9.1.5. and Annex IX, 9.1.6. Column 2 provisions to be justified, the Registrant would have to demonstrate by means of the CSR that the conditions of an adaptation possibility (Annex XI) are fulfilled.

ECHA notes that as later discussed under Section III.7. the PNEC derivation by the Registrant is not considered valid by ECHA as the Registrant has used an unjustified

assessment factor (AF). Consequently the derived aquatic PNECs and the subsequent risk characterisation ratios are not acceptable. ECHA notes further that if the standard AF of 1000 had been used by the Registrant some RCRs would be above 1 and risks would be indicated.

Furthermore, the ECHA Guidance on information requirements and chemical safety assessment (Version 1.2, November 2012), Chapter R7b, page 32, indicates that further testing according to column 2 of Annex IX, section 9.1., may be necessary for example when due to low water solubility of a substance, short term toxicity tests do not reveal any toxicity. The absence of toxicity observed in the short-term tests with the registered substance having a low water solubility can, therefore, not be used as an argument for adaptation of long-term toxicity tests.

Therefore, ECHA notes that as no effects were observed in any of the short-term aquatic toxicity studies submitted as part of the technical dossier and the substance has a low water solubility the available data does not allow to conclude on aquatic toxicity. The Registrant has not demonstrated that a weight-of-evidence approach (Annex XI, 1.2.) would be justified.

In their comments to the Draft Decision, the Registrant agreed to carry out the Long-term aquatic invertebrate study first, and also the long-term aquatic study on fish if the resulting PEC/PNEC ratio is greater than 1. However, the Registrant disagreed that in case no effect were seen in the long-term Daphnia study, also the long-term fish study would need to be conducted since "acute tests did not show any hint that fish might be a sensitive organism or more sensitive than invertebrates or algae" and "a chronic fish test would consume a high number of fish. REACH also requires considering animal welfare and avoiding unnecessary animal testing". ECHA notes that as explained above, the absence of toxicity observed in the short-term tests with the registered substance having a low water solubility cannot be used as an argument for adaptation of long-term toxicity tests. In order to avoid unnecessary testing of fish, ECHA gives Registrants the opportunity to use the aquatic ITS (please refer to the Note for consideration by the Registrant below) and the possibility to carry out first the long-term toxicity testing on Daphnia also for cases where based on acute data it is not possible to determine the order of sensitivities. In case no effects would be seen in the long-term Daphnia study, it would still not be possible for the Registrant to derive a PNECwater. In this case, the long-term fish study would also be required to conclude on the potential aquatic toxicity of the substance.

As the submitted information does not fulfil the above information requirements, there are information gaps and it is necessary to provide information for the endpoints in order to bring the registration dossier into compliance with the relevant information requirements.

Regarding the long-term toxicity testing on fish pursuant to Annex IX, section 9.1.6.1, ECHA considers that the FELS toxicity test according to OECD 210 is the most sensitive of the standard fish tests available as it covers several life stages of the fish from the newly fertilised egg, through hatch to early stages of growth and should therefore be used (see ECHA *Guidance on information requirements and chemical safety assessment* (version 1.2., November 2012), Chapter R7b, Figure R.7.8-4 page 26). The test method OECD 210 is also the only suitable test currently available for examining the potential toxic effects of bioaccumulation (ECHA Guidance R7b, version 1.2., November 2012, p. 26). For these reasons, ECHA considers the FELS toxicity test using the test method OECD 210 as appropriate and suitable.

As for the test method for the long-term toxicity testing on aquatic invertebrates, ECHA considers the standard recommended test method EU C.20./OECD 211 to be the most appropriate and suitable.

Therefore, pursuant to Article 41(1) and (3) of the REACH Regulation, the Registrant is requested to submit the following information derived with the registered substance subject to the present decision:

- Daphnia magna reproduction test (test method: EU C.20./OECD 211); and
- Fish, early-life stage (FELS) toxicity test (test method: OECD 210).

Note for consideration by the Registrant:

According to ECHA *Guidance on information requirements and chemical safety assessment* (version 1.2., November 2012), Chapter R7b (Section R.7.8.5., pages 32-57, including Figure R.7.8-4 on page 56) if based on acute aquatic toxicity data neither fish nor invertebrates are shown to be substantially more sensitive, long-term studies may be required on both. According to the integrated testing strategy, the Daphnia study is to be conducted first. If based on the results of the long-term Daphnia study and the application of a relevant assessment factor, no risks are observed (PEC/PNEC<1), no long-term fish testing may need to be conducted. However, if a risk is indicated, the long-term fish study needs to be conducted.

Due to the low solubility of the substance in water, OECD Guidance Document on Aquatic Toxicity Testing of Difficult Substances and Mixtures, ENV/JM/MONO (2000)6 and ECHA Guidance, Chapter R7b, table R. 7.8-3 summarising aquatic toxicity testing of difficult substances should be consulted by the Registrant for choosing the design of the requested long-term ecotoxicity tests and for calculation and expression of the result of this test.

3., 4. and 5. Effects on terrestrial organisms

"Effects on terrestrial organisms" is a standard information requirement as laid down in Annexes IX and X, section 9.4., of the REACH Regulation. Adequate information on effects on soil micro-organisms (Annex IX, section 9.4.2.), short-term toxicity testing on invertebrates (Annex IX, section 9.4.1.), long-term toxicity testing on invertebrates (Annex X, section 9.4.4.), short-term toxicity testing on plants (Annex IX, section 9.4.3.) and long-term toxicity testing on plants (Annex X, section 9.4.6.) needs to be present in the technical dossier for the registered substance to meet the information requirements.

a). Terrestrial Invertebrates (Annex IX, 9.4.1. and Annex X, 9.4.4.)

Toxicity to terrestrial invertebrates is a standard information requirement under Annex IX, 9.4.1. and Annex X, 9.4.4. of the REACH Regulation. The registration dossier does not contain data for these endpoints. Instead, the Registrant has proposed to adapt short- and long-term toxicity testing on effects on terrestrial invertebrates using the following justification:

"*According to column 2 of REACH Annex X, a toxicity test to terrestrial organisms shall be proposed if the outcome of the CSA indicates a need on further testing. No direct toxicity data for terrestrial compartment are available for the determination of PNECsoil for MBTS. According to the Annex IX data requirements stipulated in Regulation (EC) No 1907/2006, these tests are not required where the risk assessment based on the equilibrium partitioning*

method does not indicate a concern for the relevant compartment. Using the equilibrium partitioning method (TGD on risk assessment, part II, Chapter 3, section 3.6.2.1, p 117) a PNECsoil of 2.5 mg kg-1 (wet weight) is obtained. Having a PECsoil/PNECsoil ratio < 1 for all exposure scenarios, there is no need to perform a toxicity test for terrestrial compartment as the risk towards terrestrial organisms is sufficiently controlled based on the already available information."

In his proposed adaptation the Registrant claims that there is no need to investigate the effects on terrestrial organisms further. He justifies this conclusion by explaining that by using the equilibrium partitioning method (EPM) he has derived RCRs below 1.

The Registrant seems to consider that with the EPM alone registrants could waive all five standard information requirements for effects on terrestrial organisms. However, the provision does not state that the EPM alone is sufficient to justify the adaptation of the standard information requirements. The second subparagraph of that Column 2 provision needs to be read in its entirety. Its aim is to establish whether there is a possibility to waive some of the standard information requirements stemming from Column 1 of Annex IX, 9.4. In order for an adaptation of the Column 1 provisions to be justified, the Registrant would have to demonstrate by means of the CSR that the conditions of an adaptation possibility in Column 2 or Annex XI are fulfilled. In establishing this, in some cases, registrants may use the EPM. Upon such a basis, registrants can then depending on the case establish whether some taxonomic group(s) could be waived.

In this context registrants have to take into account the other relevant provisions in Column 2 of Annex IX. The last sub-paragraph of that provision states that when a substance has a high potential to adsorb to soil or is highly persistent, even for registrations at a tonnage level between 100 up to 1000 tonnes, long-term testing shall be considered instead of short-term testing. For registrations at a tonnage level of 1000 tonnes this is a standard information requirement.

In this specific case, ECHA notes that the Registrant has not justified an adaptation pursuant to Column 2 or Annex XI. A statement that the EPM leads to an RCR below 1 does not fulfil the conditions of any adaptation rule in REACH.

Furthermore, based on the information available in the dossier on aquatic toxicity and environmental fate 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* (November 2012), ECHA considers that there are indications that the substance is very toxic to aquatic organisms and for high persistence of the substance in soil. More specifically, ECHA notices that the substance is classified as very toxic to aquatic life. ECHA also notices that the technical dossier contains a study on ready biodegradability considered reliable by the Registrant (Klimisch score 1 or 2), in which the degradation was only 0% in 28 days. As no half-life in soil is provided and in accordance with the abovementioned section of the Guidance, the substance should thus be considered as highly persistent.

In accordance with section R.7.11.6 of ECHA Guidance Chapter R.7c, the EPM-method is not applicable for substances that are very toxic to aquatic organisms and highly persistent in soil. Consequently there is an information gap and it is necessary to provide information for short- and long-term toxicity on terrestrial invertebrates.

In their comments to the DD the Registrant agrees that based on high adsorption/persistence and substance being very toxic to aquatic organisms (harmonised classification as acute/chronic 1) the substance would fall into hazard category 4. However,

the Registrant argues that the current harmonised classification is not justified. ECHA notes that it can only base its assessment on the information currently available in the technical dossier. ECHA notes further that if based on the new information the Registrant would consider that the substance is not very toxic, then he would need to justify the selection of a different hazard category and any consequences of this selection. These would be evaluated by ECHA at the follow up stage. However, ECHA notes further that if no effects were seen in the aquatic chronic studies, it would not be possible for the Registrant to apply the soil hazard category table and to use the EPM to derive a PNEC soil screen. In such a case all three terrestrial studies may need to be conducted.

In their comments the Registrant has further reasoned that the weight-of-evidence (WoE) approach outlined in ECHA Guidance on information requirements and chemical safety assessment R.7.c (Version 1.1., November 2012, p. 124) may be applicable i.e. "where the water solubility is <1 mg/l, the absence of acute toxicity can be discounted as reliable indicator for potential effects on soil organism due to the low exposures in the test. The absence of chronic or long-term effects in aquatic organisms up to the substance solubility limit, or of acute effects within the solubility range above 10 mg/l can be used as part of a Weight of Evidence argument to modify/waive the data requirements of Annex IX and X", although the Registrant also acknowldeges that in the absence of chronic aquatic studies he is not able to justify using this WoE approach, presently. ECHA notes that, once chronic aquatic data becomes available, the Registrant may build a scientifically justified adaptation based on available information for example a WoE approach, the acceptability of which ECHA would evaluate during the follow up process. However, based on available information in the current technical dossier, the above weight-of-evidence (WoE) approach is not considered by ECHA as a scientifically justified adaptation, as the requirements of Annex XI section 1.2 are not fulfilled.
Consequently there is an information gap and it is necessary to provide information for terrestrial invertebrates.

Based on the indication for high persistence in soil, ECHA also considers that the column 2 adaptation for Annex IX, section 9.4., regarding long-term testing instead of short-term testing, is applicable to this substance.

The earthworm reproduction test (OECD 222), Enchytraeid reproduction test (OECD 220), and Collembolan reproduction test (OECD 232) are each considered capable of generating information appropriate for the fulfilment of the information requirements for long-term toxicity testing to terrestrial invertebrates. Each of these tests is suitable to also address the information requirement of Annex IX, section 9.4.1., as specified above. ECHA is not in a position to determine the most appropriate test protocol, since this decision is dependent upon species sensitivity and substance properties.

Therefore, pursuant to Article 41(1) and (3) of the REACH Regulation, the Registrant is requested to submit the following information derived with the registered substance subject to the present decision:

Earthworm reproduction test (*Eisenia fetida/Eisenia andrei*) (test method: OECD 222), or Enchytraeid reproduction test (test method: OECD 220), or Collembolan reproduction test in soil (test method: OECD 232).

b) Toxicity testing on terrestrial plants (Annex IX, 9.4.3. and Annex X, 9.4.6.)

Toxicity to terrestrial plants is a standard information requirement under Annex IX, 9.4.3. and Annex X, 9.4.6. of the REACH Regulation. The registration dossier does not contain data

for these endpoints. Instead, the Registrant has proposed to adapt short- and long-term toxicity testing on effects on terrestrial plants using the following justification:

"According to column 2 of REACH Annex X, a toxicity test to terrestrial organisms shall be proposed if the outcome of the CSA indicates a need on further testing. No direct toxicity data for terrestrial compartment are available for the determination of PNECsoil for MBTS. According to the Annex IX data requirements stipulated in Regulation (EC) No 1907/2006, these tests are not required where the risk assessment based on the equilibrium partitioning method does not indicate a concern for the relevant compartment. Using the equilibrium partitioning method (TGD on risk assessment, part II, Chapter 3, section 3.6.2.1, p 117) a PNECsoil of 2.5 mg kg-1 (wet weight) is obtained. Having a PECsoil/PNECsoil ratio < 1 for all exposure scenarios, there is no need to perform a toxicity test for terrestrial compartment as the risk towards terrestrial organisms is sufficiently controlled based on the already available information."

As it is explained above under III.1., the information available on these endpoints for the registered substance in the technical dossier does not meet the information requirements.

The Registrant in their comments to the DD for this endpoint provided the same comments as for terrestrial invertebrates. Thus, as it is explained above under III.1., the information available on this endpoint for the registered substance in the technical dossier does not meet the information requirements. Consequently there is an information gap and it is necessary to provide information for short- and long-term toxicity on terrestrial plants.

As it is also explained above under III.1., ECHA considers that the column 2 adaptation for Annex IX, section 9.4., regarding long-term testing instead of short-term testing, is applicable to this substance.

Both the Terrestrial plants, growth test (OECD 208, in the configuration as explained below) and the Soil Quality – Biological Methods – Chronic toxicity in higher plants (ISO 22030) are considered capable of generating information appropriate for the fulfilment of the information requirement for long-term toxicity testing on plants. Each of these tests is suitable to also address the information requirement of Annex IX, section 9.4.3., as specified above. ECHA is not in a position to determine the most appropriate test protocol, since this decision is dependent upon species sensitivity and substance properties.

OECD guideline 208 (Terrestrial Plant Test: Seedling Emergence and Seedling Growth) 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. The long-term toxicity 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 208 guideline. The Registrant should consider if testing on additional species is required to cover the information requirement.

Therefore, pursuant to Article 41(1) and (3) of the REACH Regulation, the Registrant is requested to submit the following information derived with the registered substance subject to the present decision:

Terrestrial Plant Test: Seedling Emergence and Seedling Growth (test method: OECD 208), with at least six species tested (with as a minimum two monocotyledonous species and four

dicotyledonous species), or Soil Quality – Biological Methods – Chronic toxicity in higher plants (test method: ISO 22030).

c) Soil micro-organisms (Annex IX, section 9.4.2.)

The hazard to soil microbial communities is a standard information requirement under Annex IX, section 9.4.2. of the REACH Regulation. The registration dossier does not contain data for this endpoint. Instead, the Registrant has proposed to adapt testing on effects on soil microorganisms using the following justification:

"According to column 2 of REACH Annex X, a toxicity test to terrestrial organisms shall be proposed if the outcome of the CSA indicates a need on further testing. No direct toxicity data for terrestrial compartment are available for the determination of PNECsoil for MBTS. According to the Annex IX data requirements stipulated in Regulation (EC) No 1907/2006, these tests are not required where the risk assessment based on the equilibrium partitioning method does not indicate a concern for the relevant compartment. Using the equilibrium partitioning method (TGD on risk assessment, part II, Chapter 3, section 3.6.2.1, p 117) a PNECsoil of 2.5 mg kg-1 (wet weight) is obtained. Having a PECsoil/PNECsoil ratio < 1 for all exposure scenarios, there is no need to perform a toxicity test for terrestrial compartment as the risk towards terrestrial organisms is sufficiently controlled based on the already available information."

As it is already explained above under III.1., the information available on this endpoint for the registered substance in the technical dossier does not meet the information requirements.

In their comments the Registrant has provided a WoE approach. As a first line of evidence he has reasoned the same WoE approach made for terrestrial invertebrates and plants as outlined in ECHA Guidance on information requirements and chemical safety assessment R.7.c (Version 1.1., November 2012, p. 124). As noted in section III a. this WoE is not acceptable in absence of chronic data for a low water solubility substance. As also noted above, the Registrant may wish to use this line of evidence once he has the chronic aquatic data available.

In their comments and the proposed WoE approach the Registrant refers also to two studies on sewage sludge microbial activity where no inhibition was observed. According to ECHA's Guidance R.7.C. (Version 1.1., November 2012, p. 125) "where inhibition of sewage sludge microbial activity has been observed in Annex VIII testing, a test on soil microbial activity will additionally be necessary for a valid PNEC to be derived." ECHA notes that the Guidance does not give the possibility to adapt the standard information requirement of Annex IX section 9.4.3. based on no inhibition of sewage sludge microbial activity. ECHA notes that absence of inhibition of sewage sludge microbial activity may be used as a line of evidence in a WoE approach. However, as discussed above, the first line of evidence cannot be accepted, hence ECHA considers that overall the WoE approach proposed does not fulfill the requirements of Annex XI section 1.2. ECHA notes that when new data become available, the Registrant may improve the WoE approach proposed, the acceptability of which ECHA would evaluate during the follow up process.
Consequently there is an information gap and it is necessary to provide information for toxicity for this endpoint.

According to ECHA *Guidance on information requirements and chemical safety assessment* (version 1.1, November 2012), Chapter R.7C, Section R.7.11.3.1., p. 115, the nitrogen transformation test is considered sufficient for most non-agrochemicals.

Therefore, pursuant to Article 41(1) and (3) of the REACH Regulation, the Registrant is requested to submit the following information derived with the registered substance subject to the present decision:

Soil microorganisms: nitrogen transformation test (test method: EU C.21./OECD 216).

Note for consideration by the Registrant

ECHA emphasises that the intrinsic properties of soil microbial communities are not addressed through the EPM extrapolation method described in section R.7.11.6., Chapter R.7c of the ECHA Guidance on information requirements and chemical safety assessment (version 1.1, November 2012)). Therefore the potential weight of evidence adaptation possibility outlined in the Guidance (based on EPM and other data that is available for the substance) does not apply for the present endpoint.

6. Long-term toxicity to sediment organisms (Annex X Section 9.5.1.)

"Long-term toxicity to sediment organisms" is a standard information requirement as laid down in Annex X, Section 9.5.1. of the REACH Regulation. Adequate information on this endpoint needs to be present in the technical dossier for the registered substance to meet this information requirement.

ECHA notes that the Registrant has sought to adapt the long-term toxicity testing on sediment organisms using the following justification: "*According to column 2 of REACH Annex X, a long term toxicity test to sediment organisms shall be proposed if the outcome of the CSA indicates a need on further testing. No direct toxicity data for sediment compartment are available for the determination of PNECsediment for MBTS. According to the Annex IX data requirements stipulated in Regulation (EC) No 1907/2006, these tests are not required where the risk assessment based on the equilibrium partitioning method does not indicate a concern for the relevant compartment. Using the equilibrium partitioning method (TGD on risk assessment, part II, Chapter 3, section 3.6.2.1, p 117) a PNECsediment of 3.1 mg kg-1 (wet weight) is obtained. Having a PECsediment/PNECsediment ratio < 1 for all exposure scenarios, there is no need to perform a long-term assay as the risk towards sediment organisms is sufficiently controlled based on the already available information.*"

ECHA points out that the justifications provided by the Registrant refer to column 2 of Section 9.4 of Annex IX to the REACH Regulation ("Effects on terrestrial organisms") and as such are not relevant for the present endpoint (long-term toxicity to sediment organisms, Section 9.5.1 of Annex X to the REACH Regulation).

In his proposed adaptation the Registrant claims that the CSR has not shown the need to for testing on sediment organisms. ECHA notes further that in order for an adaptation of Annex X, 9.5.1. Column 1 provisions to be justified, the Registrant would have to demonstrate by means of the CSR that the conditions of an adaptation possibility (Annex XI) are fulfilled. In establishing this, in some cases and as explained in ECHA *Guidance on information requirements and chemical safety assessment* (R.7.B, version 1.2. November 2012, Section R.7.8.7.), Registrants may use the EPM as part of a weight-of-evidence to adapt the standard information requirement.

However, according to ECHA *Guidance on information requirements and chemical safety assessment* (R.7.B, version 1.2. November 2012, Section R.7.8.7., p. 140) the EPM cannot

be used in a weight of evidence approach for substances that are highly insoluble and for which no effects are observed in aquatic studies. For such substances at least one sediment study has to be performed. ECHA notes that as is shown in the aquatic studies in the technical dossier no effects were observed in any of the aquatic studies performed. In addition, as the substance has a low water solubility ECHA considers that long-term sediment testing is indicated for the registered substance.

Furthermore, ECHA notes (as later discussed under Section III.7.) the aquatic PNEC derivation by the Registrant is not considered valid by ECHA as the Registrant has used an unjustified assessment factor (AF). As the Registrant has applied the equilibrium partitioning method to derive the PNECs for the sediment compartment also the PNECsediment is invalid as it is based on the aquatic PNECs derived with an unjustified AF. Consequently the derived sediment PNECs and the subsequent risk characterisation ratios are not acceptable.
ECHA notes that the Registrant has not demonstrated that available data would lead to the conclusion that the substance is or is not toxic to sediment organisms (Annex XI, 1.2.). In fact, the present substance has a high potential to adsorb to sediment. Therefore, as the standard information requirements for long-term sediment testing have not been adapted in a justified manner, testing is required.

In their comments to the DD the Registrant has reasoned that if the chronic aquatic study shows measurable toxic effects, a PNEC calculation using the EPM approach can be applied and if the resulting PEC/PNECsediment is <1, no further sediment testing would be required. ECHA notes that this is in accordance to what is outlined in the Note for consideration by Registrant under III.6. below. ECHA notes further that if however, no effects would be seen in the aquatic chronic studies, the EPM cannot be applied and a test on sediment organisms would be required.

Therefore, in this specific case, ECHA notes that the Registrant has not justified an adaptation. Consequently there is an information gap and it is necessary to provide information for toxicity for this endpoint.

Therefore, pursuant to Article 41(1) and (3) of the REACH Regulation, the Registrant is requested to submit the following information derived with the registered substance subject to the present decision:

- Sediment-water Chironomid toxicity using spiked sediment (Test method: OECD 218) OR
- Sediment-water Lumbriculus toxicity test using spiked sediment (Test method: OECD 225) OR
- Sediment-Water Chironomid Life-Cycle Toxicity Test Using Spiked Water or Spiked Sediment (OECD 233)

Notes for consideration by the Registrant

According to ECHA *Guidance on information requirements and chemical safety assessment* (R.7.B, version 1.2. November 2012) the Registrant has the possibility to use the equilibrium partitioning method (EPM) to derive a PNEC sediment screen from the PNEC aquatic (Section R.7.8.10.1, p. 130). However, as further explained in Section R.7.8.12.2., p. 140 if no effects are seen in aquatic studies, the EPM may not be used. This is because for substances that do not exhibit a toxic effect when tested in water only test systems because equilibrium was not reached during exposure phase may nevertheless exert significant toxic effects in sediment tests (Section R.7.8.10.3, page 136. ECHA therefore points out that if effects are seen in the long-term aquatic studies conducted as requested

under Section II 1 and 2, the Registrant may wish to use the EPM to derive the PNEC sediment screen. If the resulting PNEC/PEC ratio is less than one, the Registrant may construct a weight-of-evidence approach to adapt the standard information requirement of Annex X, Section 9.5.1., However, if the resulting new PEC/PNEC ratio is above one or if no effects are seen in the long-term aquatic studies, long-term sediment test(s) are required. The timeline set for the studies to be conducted allows for sequential testing.

The Sediment-water Chironomid toxicity using spiked sediment (OECD 218), Sediment-water Lumbriculus toxicity test using spiked sediment (OECD 225) and Sediment-Water Chironomid Life-Cycle Toxicity Test Using Spiked Water or Spiked Sediment (OECD 233) are in principle each considered capable of generating information appropriate for the fulfilment of the information requirements for sediment long-term toxicity testing. ECHA is not in a position to determine the most appropriate test protocol, since this decision is dependent upon species sensitivity,substance properties and uses. ECHA considers that it is the Registrants responsibility to choose the most appropriate test protocol and to give a justification for the choice. The Registrant may carry out more than one of the sediment tests defined in Section II above if he considers that further testing is required. While ECHA at this stage only requires one test, based on newly available data it may consider whether further tests are required to fulfil the standard information requirement.

Furthermore, both water and sediment exposure scenarios are described in the OECD 233 Test Guideline. The Registrant is advised to consult the OECD 233 Test Guideline and the ECHA *Guidance on information requirements and chemical safety assessment* (version 1.2., November 2012), Chapter R7b (Section R.7.8.10.1) for the selection of the appropriate method of spiking.

B. Information related to the chemical safety assessment and chemical safety report

Pursuant to Articles 10(b) and 14(1) of the REACH Regulation the registration shall contain a chemical safety report which shall document the chemical safety assessment conducted in accordance with Article 14(2) to (7) and with Annex I of the REACH Regulation.

7. Revised PNECs for the environmental compartments

Annex I, Section 3.3. of the REACH Regulation requires the Registrant to establish predicted no effect concentrations (PNEC(s)) for the registered substance, covering each environmental sphere.

ECHA notes that, the registration submitted by the Registrant contains PNECs for the aquatic compartment. ECHA notes furthermore that in the derivation of the PNECs the Registrant has applied an assessment factor (AF) of 10.

ECHA notes that the Registrant has sought to justify the use of the AF of 10 with following statement: *"Considering the low water solubility of MBTS, the high log Pow of 4.5, but low BCF (<100), no toxic effect is expected even in long-term tests up to its water solubility; and hence lower assessment factor of 10 instead of 1000 for the estimation of PNECaqua (freshwater)."*

The footnote to Annex I, Section 3.3.1. provides information on the application of assessment factors to cover the uncertainty associated with the available data, indicating that an assessment factor of 1000 is typically applied to the lowest of three short term L(E)C50 values derived from species representing different trophic levels and a factor of 10

is applied to the lowest of three long-term NOEC values derived from species representing different trophic levels. This is further explained in the ECHA *Guidance on information requirements and chemical safety assessment* (May 2008), Chapter R10 (Section R.10.3.1.2. where it is written that a factor of 10 could be applied to the lowest long-term result from only two species would also be appropriate if it has been possible to determine with high probability that the most sensitive species has been examined and the substance does not have a potential to bioaccumulate. ECHA notes that the Registrant has only an algae long-term study available in the technical dossier, hence this deviation is also not acceptable even if the Registrant has tried to deviate from the standard on basis of the experimental BCF being less than 100. Furthermore, as fully explained in Section III. "1. and 2." above, ECHA considers that for a substance with low water solubility and high Log Kow short-term aquatic studies alone are not sufficient in determining the potential effects to aquatic compartment and long-term aquatic studies are required.

ECHA concludes that the Registrant's choice of an AF is not in line with the provisions of the footnote to Annex I, Section 3.3.1. and of ECHA Guidance chapter R.10, Section R.10.3.1.2 and is not appropriate in accordance with Annex I, Section 3.3.1.

Consequently, the derived aquatic PNECs are invalid. As the Registrant has applied the equilibrium partitioning method to derive the PNECs for the sediment and terrestrial compartments also these PNECs are invalid as they are based on the aquatic PNECs derived with an inappropriate AF.

In any event, new data will become available after compliance with the requests outlined under Section II.A. The Registrant is therefore required to revise the PNECs for the environmental compartments, taking into account the incompliances observed in the current CSR in the present Section.

IV. Adequate identification of the composition of the tested material

ECHA stresses that the information submitted by the Registrant and other joint registrants for identifying the substance has not been checked for compliance with the substance identity requirements set out in Section 2 of Annex VI of the REACH Regulation. The Registrant is reminded of his responsibility and that of joint Registrants to ensure that the joint registration covers one substance only and that the substance is correctly identified in accordance with Annex VI, Section 2 of the REACH Regulation.

In addition, it is important to ensure that the particular sample of substance tested in the new studies 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 by each registrant. If the registration of the substance by any registrant covers different grades, the sample used for the new studies 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 studies to be assessed.

V. Information on right to appeal

An appeal may be brought against this decision to the Board of Appeal of ECHA under Article 51(8) of the REACH Regulation. Such an appeal shall be lodged within three months of receiving notification of this decision. Further information on the appeal procedure can be

found on ECHA's internet page at http://www.echa.europa.eu/regulations/appeals. The notice of appeal will be deemed to be filed only when the appeal fee has been paid.

[redacted]
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