EUROPEAN CHEMICALS AGENCY

Helsinki, 6 September 2016

Addressee: [redacted]

Decision number: CCH-D-2114341173-60-01/F
Substance name: 6,6'-di-tert-butyl-4,4'-butylidenedi-m-cresol
EC number: 201-618-5
CAS number: 85-60-9
Registration number: [redacted]
Submission number: [redacted]
Submission date: 04 January 2013
Registered tonnage band: 100 to 1000 tonnes per year

DECISION ON A COMPLIANCE CHECK

Based on Article 41 of Regulation (EC) No 1907/2006 (the 'REACH Regulation'), ECHA requests you to submit information on

1. **Pre-natal developmental toxicity study (Annex IX, Section 8.7.2; test method: EU B.31/OECD TG 414) in a first species (rats or rabbits), oral route with the registered substance;**

2. **Long-term toxicity to terrestrial invertebrates (Annex IX, Section 9.4.1., column 2; test method: Earthworm reproduction test (Eisenia fetida/Eisenia andrei), OECD TG 222, or Enchytraeid reproduction test, OECD TG 220, with the registered substance;**

3. **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) *or* Soil Quality – Biological Methods – Chronic toxicity in higher plants, ISO 22030) with the registered substance;**

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) with the registered substance**

5. **Bioaccumulation in aquatic species (Annex IX, Section 9.3.2.; test method: Bioaccumulation in fish: aqueous and dietary exposure, OECD TG 305, preferably aqueous exposure with the registered substance;**

6. **Long-term toxicity testing on aquatic invertebrates (Annex IX, Section 9.1.5.; test method: Daphnia magna reproduction test, EU C.20./OECD TG 211) with the registered substance;**

7. **Long-term toxicity testing on fish (Annex IX, Section 9.1.6.1.; test method: Fish, early-life stage (FELS) toxicity test, OECD TG 210) with 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 **13 March 2018**. You shall also update the chemical safety report, where relevant.

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

Appeal

This decision can be appealed to the Board of Appeal of ECHA within three months of its notification. An appeal, together with the grounds thereof, shall be submitted to ECHA in writing. An appeal has suspensive effect and is subject to a fee. Further details are described under http://echa.europa.eu/regulations/appeals.]

Authorised[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.

EUROPEAN CHEMICALS AGENCY

Appendix 1: Reasons

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

Pursuant to Articles 10(a)(vi) and/or (vii), 12(1)(d) and 13(4) of the REACH Regulation, a technical dossier registered at 100 to 1000 tonnes per year shall contain as a minimum the information specified in Annexes VII to IX of the REACH Regulation.

A "pre-natal developmental toxicity study" (test method EU B.31./OECD TG 414) for a first species is a standard information requirement as laid down in Annex IX, Section 8.7.2. 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.

In the technical dossier you have provided a study record for a "reproduction/ developmental toxicity screening test" (test method: OECD TG 421). However, this study does not provide the information required by Annex IX, Section 8.7.2., because it does not cover key parameters of a pre-natal developmental toxicity study, such as examinations of foetuses for skeletal and visceral alterations. Therefore, an adaptation of the information requirement cannot be accepted on this basis.

In the comments submitted on the draft decision you moreover proposed to cover this endpoint requirement with a study (not provided) using read-across to *4,4'-thiobis (6-t-butyl-m-cresol)*. Annex XI, Section 1.5. requires a structural similarity among the substances within a group or category such that relevant properties of a substance within the group can be predicted from the data on reference substance(s) within the group by interpolation. ECHA analysed the read-across argumentation against the criteria set out in Annex XI, 1.5. You based the read-across hypothesis on structural similarity, comparable physico-chemical and toxicological profiles.

However, from the data provided in justification it is not clear that the source and target substance would result in similar breakdown products during their metabolism. The excretion and metabolism study with the analogue substance mentioned in the comments does not explain what exactly is excreted after metabolism.

In addition, there is no information on the toxicity of the potential breakdown products. In the matrix submitted in the comments, the NOAELs for the repeated dose toxicity studies are in comparable range and in the comments it is suggested that the liver is the target organ for both substances. However, no robust study summary detailing the basis for these effects was provided for the read-across substance. It is argued that due to the low NOAEL obtained in the repeated dose study the possible reproduction effects are expected to occur only at maternal toxicity levels in the developmental toxicity test and that the repeated dose study stays critical for DNEL derivation. However, due to the fact that the substance is bio accumulating there is concern for developmental toxicity.

In addition, the regulatory value of the read-across study is questionable: *"4,4'-thiobis (6-t-butyl-m-cresol) reduced the survival of the pups in the Chernoff/kavlock assay, however due to the high maternal mortality it should be retested at a lower dose."* You did also not provide any information on the guideline/method followed in this study as well as the purity of the tested substance.

In the comments it is mentioned that 485 mg/kg bw/day of 4,4'-thiobis (6-t-butyl-m-cresol) was administered in pregnant rats for 10 days during the gestation. According to the OECD 414 guideline the test substance is administered to pregnant animals at least from implantation to one day prior to the day of scheduled kill and at least three dose levels should be used. Consequently, it is not clear how and what was tested in the above mentioned study.

Finally, you also mention a supporting study in rabbits receiving up to 20 mg/kg bw/d test substance but again no information was provided on how the study was performed and what was the purity of the tested substance. Annex XI 1.5. specifies that in all cases *"adequate and reliable documentation of the applied method shall be provided."* Therefore, due to all above uncertainties for this endpoint the adaptation cannot be accepted.

As explained above, the information provided on this endpoint for the registered substance in the technical dossier does not meet the information requirement. Consequently there is an information gap and it is necessary to provide information for this endpoint.

According to the test method EU B.31./OECD TG 414, the rat is the preferred rodent species and the rabbit the preferred non-rodent species. On the basis of this default assumption ECHA considers testing should be performed with rats or rabbits as a first species.

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 4.1, October 2015) 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.

Therefore, pursuant to Article 41(1) and (3) of the REACH Regulation, you are requested to submit the following information derived with the registered substance subject to the present decision: Pre-natal developmental toxicity study (test method: EU B.31./OECD TG 414) in a first species (rats or rabbits) by the oral route.

2. Long-term toxicity to terrestrial invertebrates (Annex IX, Section 9.4.1.)

Pursuant to Articles 10(a)(vi) and/or (vii), 12(1)(d) and 13(4) of the REACH Regulation, a technical dossier registered at 100 to 1000 tonnes per year shall contain as a minimum the information specified in Annexes VII to IX of the REACH Regulation.

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

You have sought to adapt the standard information requirements of Annex IX, section 9.4 using the following justification: *"The intended use of the substance is not likely to result in direct or indirect exposure of the substance to soil compartment. Furthermore, the substance has been assessed for toxicity to aquatic species and is not classified. Experimental assessment of this endpoint is therefore considered unnecessary"*. However, ECHA considers that exposure cannot be excluded as wide dispersive use was reported in the dossier and there is no exposure assessment provided. Furthermore, the

PNEC$_{aquatic}$ was derived based on the data from short term aquatic tests. As the substance is highly insoluble in water (< 4 µg/l) ECHA considers that the currently derived PNEC$_{aquatic}$ is not adequate. Therefore, your justification for adaptation does not meet the criteria of either the specific adaptation rules of Column 2 of Annex IX, Section 9.4, or the general adaptation rules of Annex XI. Hence, the adaptation cannot be accepted.

As explained above, the information provided 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 this endpoint.

According to section R.7.11.5.3., Chapter R.7c of the ECHA *Guidance on information requirements and chemical safety assessment* (version 2.0, November 2014), substances that are ionisable or have a log K_{ow}/K_{oc} >5 are considered highly adsorptive, whereas substances with a half-life >180 days are considered very persistent in soil. According to the evidence presented within the Registration dossier, the substance has a high potential to adsorb to soil (logK_{ow} 6.4). Therefore ECHA considers that the column II adaptation for Annex IX, section 9.4 regarding long-term testing instead of short-term testing, is applicable to this substance.

ECHA considers that accurate allocation of an appropriate soil hazard category according to table R7.11-2 of the abovementioned guidance is not possible at this time. Consequently, it is not possible to waive the standard information requirements for the terrestrial compartment through an initial screening assessment based upon the EPM, mentioned in Column 2 of Annex IX, section 9.4. Since a screening assessment for terrestrial organisms is not possible, testing for effects on all terrestrial organisms indicated in section 9.4 of Annex IX is considered necessary.

In the context of an integrated testing strategy for soil toxicity, the Guidance (Figure R.7.11-3) advocates performing soil toxicity testing according to the information requirements of Annex IX or X and that the lowest value obtained should be used to derive the PNEC soil.

The earthworm reproduction test (OECD TG 222), Enchytraeid reproduction test (OECD TG 220), and Collembolan reproduction test (OECD TG 232) are each considered capable of generating information appropriate for the fulfilment of the information requirements for long-term toxicity testing to terrestrial invertebrates. ECHA is not in a position to determine the most appropriate test protocol, since this decision is dependent upon species sensitivity and substance properties.

Therefore, pursuant to Article 41(1) and (3) of the REACH Regulation, you are 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 TG 222), or Enchytraeid reproduction test (test method: OECD TG 220)

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

"Effects on terrestrial organisms" is a standard information requirement as laid down in Annex IX, Section 9.4. of the REACH Regulation. Adequate information on effects on short-term toxicity to invertebrates (Annex IX, Section 9.4.1.), effects on soil micro-organisms (Annex IX, Section 9.4.2.), and short-term toxicity to plants (Annex IX, Section 9.4.3.) needs to be present in the technical dossier for the registered substance to meet the information requirements. Column 2 of Annex IX, Section 9.4 specifies that 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.

You have sought to adapt the standard information requirements of Annex IX, section 9.4 using the following justification: "*The intended use of the substance is not likely to result in direct or indirect exposure of the substance to soil compartment. Furthermore, the substance has been assessed for toxicity to aquatic species and is not classified. Experimental assessment of this endpoint is therefore considered unnecessary*".

However, ECHA considers that exposure cannot be excluded as wide dispersive use was reported in the dossier and there is no exposure assessment provided. Furthermore, the $PNEC_{aquatic}$ was derived based on the data from short term aquatic tests. As the substance is highly insoluble in water (< 4 µg/l) ECHA considers that the currently derived $PNEC_{aquatic}$ is not adequate. Therefore, your justification for adaptation does not meet the criteria of either the specific adaptation rules of Column 2 of Annex IX, Section 9.4, or the general adaptation rules of Annex XI. Hence, the adaptation cannot be accepted.

As established within point (2) above, the Guidance advocates performing long-term toxicity tests according to the information requirements of Annex IX and that the lowest value obtained should be used to derive the PNEC soil.

OECD TG guideline 208 (Terrestrial plants, growth test) considers the need to select the number of test species according to relevant regulatory requirements, and the need for a reasonably broad selection of species to account for interspecies sensitivity distribution. For long-term toxicity testing, ECHA considers six species as the minimum to achieve a reasonably broad selection. Testing shall be conducted with species from different families, as a minimum with two monocotyledonous species and four dicotyledonous species, selected according to the criteria indicated in the OECD TG 208 guideline. You should consider if testing on additional species is required to cover the information requirement.

Therefore, pursuant to Article 41(1) and (3) of the REACH Regulation, you are requested to submit the following information derived with 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) *or* Soil Quality – Biological Methods – Chronic toxicity in higher plants (test method: ISO 22030).

Notes for your consideration

ECHA notes that the results from the toxicity tests on fish and aquatic invertebrates requested under subsection (6 and 7) of the present Decision may allow the subsequent derivation of a PNECwater. Consequently, you may consider the ITS as recommended in section R.7.11.6., Chapter R.7c of the ECHA Guidance on information requirements and chemical safety assessment (version 2.0, November 2014), and determine the need for further testing on terrestrial organisms. If you conclude that no further investigation of effects on terrestrial organisms is required, you should update your technical dossier by clearly stating the reasons for adapting the information requirements of section 9.4. of Annex IX, of the REACH Regulation.

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

"Effects on terrestrial organisms" is a standard information requirement as laid down in Annex IX, Section 9.4. of the REACH Regulation. Adequate information on effects on short-term toxicity to invertebrates (Annex IX, Section 9.4.1.), effects on soil micro-organisms (Annex IX, Section 9.4.2.), and short-term toxicity to plants (Annex IX, Section 9.4.3.) needs to be present in the technical dossier for the registered substance to meet the information requirements. Column 2 of Annex IX, Section 9.4 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.

You have sought to adapt the standard information requirements of Annex IX, section 9.4 using the following justification: "*The intended use of the substance is not likely to result in direct or indirect exposure of the substance to soil compartment. Furthermore, the substance has been assessed for toxicity to aquatic species and is not classified. Experimental assessment of this endpoint is therefore considered unnecessary*".

However, ECHA considers that exposure cannot be excluded as wide dispersive use was reported in the dossier and there is no exposure assessment provided. Furthermore, the $PNEC_{aquatic}$ was derived based on the data from short term aquatic tests. As the substance highly insoluble in water (< 4 µg/l) ECHA considers that the currently derived $PNEC_{aquatic}$ is not adequate. Therefore, your justification for adaptation does not meet the criteria of either the specific adaptation rules of Column 2 of Annex IX, Section 9.4, or the general adaptation rules of Annex XI. Hence, the adaptation cannot be accepted.

As explained above, the information provided 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 this endpoint.

ECHA notes that the tests requested under points 2 and 3 above are not sufficient to address this standard information requirement. ECHA concludes that the effects on soil microorganisms need to be ascertained by performing a relevant test.

According to section R.7.11.3.1. of the above-mentioned guidance, the nitrogen transformation test is considered sufficient for most non-agrochemicals.

Therefore, pursuant to Article 41(1) and (3) of the REACH Regulation, you are 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 TG 216).

5. Bioaccumulation in aquatic species (Annex IX, Section 9.3.2.)

"Bioaccumulation in aquatic species, preferably fish" is a standard information requirement as laid down in Annex IX, Section 9.3.2.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.

In the technical dossier you have provided two study records: BCF model, CAESAR ([redacted]) and Bioaccumulation BCF estimation EPIWIN BCFBAF model (Arnot and Gobas, 2003). However, these study records do not provide the information required by Annex IX, Section 9.3.2., because the reliability of the predictions is questionable. ECHA notes that the predictions are out of the applicability domain of the model or are based on a very limited number of chemicals. The QSAR predictions provided are further hampered by the absence of an accurate log K_{ow} as the HPLC method used is not appropriate to determine a log K_{ow} above 6 (ECHA *Guidance on information requirements and chemical safety assessment, Chapter R.7a* (version 4.1, October 2015)). According to the ECHA *Guidance on information requirements and chemical safety assessment, Chapter R.11*, version 2.0, November 2014).) substances with log K_{ow} between 4.5 and 10 may meet the B or vB criteria.

As explained above, the information provided on this endpoint for the registered substance in the technical dossier does not meet the information requirement. Consequently there is an information gap and it is necessary to provide information for this endpoint.

According to ECHA *Guidance on information requirements and chemical safety assessment, Chapter R.7c* (version 2.0, November 2014) bioaccumulation in fish: aqueous and dietary exposure (test method EU C.13. / OECD TG 305) is the preferred test to cover the standard information requirement of Annex IX, Section 9.3.2.

Based on a discussion at the MSC 48 meeting in June 2016 on the proposal for amendment from a Member State Competent Authority requesting to conduct the test using the aqueous exposure only, it was considered that the aqueous exposure route is the preferred route since valid results from this test can be used directly for comparison with the B and vB criteria of Annex XIII of the REACH Regulation and it can be used for hazard classification and risk assessment.

ECHA notes that in the OECD 305 guideline both aqueous and dietary exposures are given as options. Due to the arguments outlined above you shall conduct the study using aqueous exposure. Only if it is justified that it is not technically possible to conduct the definitive test via the aqueous exposure, the definitive test shall then be conducted using a dietary exposure. In such a case you shall provide a scientifically valid justification for the exposure route performed in the definitive test. You are also required to estimate BCF values from data collected in the dietary exposure study.

Therefore, pursuant to Article 41(1) and (3) of the REACH Regulation, you are requested to submit the following information derived with the registered substance subject to the present decision:
Bioaccumulation in fish: aqueous and dietary exposure, OECD TG 305, preferably aqueous exposure.

Notes for your consideration

Before conducting the above test you are advised to consult the ECHA *Guidance on information requirements and chemical safety assessment*, Chapter R.11.4. and Figure R.11-4 on the PBT assessment for further information on the integrated testing strategy for the bioaccumulation assessment of the registered substance. You should revise the PBT assessment when information on bioaccumulation is available.

6. Long-term toxicity testing on aquatic invertebrates (Annex IX, Section 9.1.5.)

"Long-term toxicity testing on aquatic invertebrates" is a standard information requirement as laid down in Annex IX, Section 9.1.5. 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.

You have sought to adapt this information requirement according to Annex IX, Section 9.1.5., column 2. You provided the following justification for the adaptation "*In Annex IX of Regulation (EC) No 1907/2006, it is laid down that long-term toxicity testing on fish shall be proposed by the registrant if the chemical safety assessment indicates the need to investigate further the effects on fish.*
According to Annex I of this regulation, the chemical safety assessment triggers further action when the substance or the preparation meets the criteria for classification as dangerous according to Directive 67/548/EEC or Directive 1999/45/EC or is assessed to be a PBT or vPvB.
The hazard assessment of the substance reveals neither a need to classify the substance as dangerous to the environment, nor is it a PBT or vPvB substance, nor are there any further indications that the substance may be hazardous to the environment."

However, ECHA notes that your adaptation does not meet the specific rules for adaptation of Annex IX to the REACH Regulation.

ECHA notes that you have proposed to adapt the standard information requirements of Annex IX, 9.1.5. claiming that as the substance is not shown to be a PBT/vPvB substance and is not classified the Chemical Safety Assessment (CSA) indicates no need for long-term aquatic toxicity studies. ECHA notes that in order for an adaptation of Annex IX, 9.1.5. 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. However, as the Chemical Safety Report (CSR) submitted by you as part of the technical dossier does not contain the Exposure Assessment (EA) and the subsequent Risk Characterisation (RC) sections, ECHA considers that it is not possible to fully assess whether there may be risks to the aquatic environment.

Therefore, your adaptation of the information requirement cannot be accepted.

Furthermore, the ECHA Guidance on information requirements and chemical safety assessment (version 3.0, February 2016), Chapter R7b, page 32, indicates that the need to conduct further testing according to column 2 of Annex IX, section 9.1., may be triggered 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 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.

As explained above, the information provided on this endpoint for the registered substance in the technical dossier does not meet the information requirement. Consequently there is an information gap and it is necessary to provide information for this endpoint.

According to ECHA *Guidance on information requirements and chemical safety assessment, Chapter R.7b* (version 3.0, February 2016) *Daphnia magna* reproduction test (test method EU C.20. / OECD TG 211) is the preferred test to cover the standard information requirement of Annex IX, Section 9.1.5.

Therefore, pursuant to Article 41(1) and (3) of the REACH Regulation, you are 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 TG 211).

7. Long-term toxicity testing on fish (Annex IX, Section 9.1.6.1.)

"Long-term toxicity testing on fish" is a standard information requirement as laid down in Annex IX, Section 9.1.6. of the REACH Regulation. Adequate information on Fish, early-life stage (FELS) toxicity test (Annex IX, 9.1.6.1.), or Fish, short-term toxicity test on embryo and sac-fry stages (Annex IX, 9.1.6.2.), or Fish, juvenile growth test (Annex IX, 9.1.6.3.) needs to be present in the technical dossier for the registered substance to meet this information requirement.

You have sought to adapt this information requirement according to Annex IX, Section 9.1.6., column 2. You provided the following justification for the adaptation "*In Annex IX of Regulation (EC) No 1907/2006, it is laid down that long-term toxicity testing on fish shall be proposed by the registrant if the chemical safety assessment indicates the need to investigate further the effects on fish.*
According to Annex I of this regulation, the chemical safety assessment triggers further action when the substance or the preparation meets the criteria for classification as dangerous according to Directive 67/548/EEC or Directive 1999/45/EC or is assessed to be a PBT or vPvB.
The hazard assessment of the substance reveals neither a need to classify the substance as dangerous to the environment, nor is it a PBT or vPvB substance, nor are there any further indications that the substance may be hazardous to the environment.
Therefore, and for reasons of animal welfare, long-term toxicity testing on fish is not provided."

However, ECHA notes that your adaptation does not meet the specific rules for adaptation of Annex IX.

ECHA notes that you have proposed to adapt the standard information requirements of Annex IX, 9.1.6. claiming that as the substance is not shown to be a PBT/vPvB substance and is not classified the Chemical Safety Assessment (CSA) indicates no need for long-term aquatic toxicity studies. ECHA notes that in order for an adaptation of Annex IX, 9.1.6. 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. However, as the Chemical Safety Report (CSR) submitted by you as part of the technical dossier does not contain the Exposure Assessment (EA) and the subsequent Risk Characterisation (RC) sections, ECHA considers that it is not possible to fully assess whether there may be risks to

the aquatic environment.

Therefore, your adaptation of the information requirement cannot be accepted.

Furthermore, the ECHA Guidance on information requirements and chemical safety assessment (version 3.0, February 2016), Chapter R7b, page 32, indicates that the need to conduct further testing according to column 2 of Annex IX, section 9.1., may be triggered 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 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.

As explained above, the information provided on this endpoint for the registered substance in the technical dossier does not meet the information requirement. Consequently there is an information gap and it is necessary to provide information for this endpoint.

According to ECHA *Guidance on information requirements and chemical safety assessment, Chapter R.7b* (version 3.0, February 2016) fish early-life stage toxicity test (test method OECD TG 210), fish short-term toxicity test on embryo and sac-fry stages (test method EU C.15. / OECD TG 212) and fish juvenile growth test (test method EU C.14. / OECD TG 215) are the preferred tests to cover the standard information requirement of Annex IX, Section 9.1.6.

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 TG 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 3.0, February 2016), Chapter R7b, Figure R.7.8-4). The test method OECD TG 210 is also the only suitable test currently available for examining the potential toxic effects of bioaccumulation (ECHA Guidance Chapter R7b, version 3.0, February 2016). For these reasons, ECHA considers the FELS toxicity test using the test method OECD TG 210 as most appropriate and suitable.

Therefore, pursuant to Article 41(1) and (3) of the REACH Regulation, you are requested to submit the following information derived with the registered substance subject to the present decision: Fish, early-life stage (FELS) toxicity test (test method: OECD TG 210).

Notes for your consideration in relation to sections (6) and (7) above

Due to the low solubility of the substance in water you should consult OECD Guidance Document on Aquatic Toxicity Testing of Difficult Substances and Mixtures, ENV/JM/MONO (2000)6 and ECHA *Guidance on information requirements and chemical safety assessment* (version 3.0, February 2016), Chapter R7b, Table R.7.8-3 summarising aquatic toxicity testing of difficult substances for choosing the design of the requested ecotoxicity test(s) and for calculation and expression of the result of the test(s).

Notes for consideration in relation to sections (2), (3), (6) and (7) above

ECHA notes that the results from the toxicity tests on fish and aquatic invertebrates requested under subsection (6 and 7) of the present Decision may allow the subsequent derivation of a PNECwater. Consequently, you may consider the ITS as recommended in section R.7.11.6., Chapter R.7c of the ECHA Guidance on information requirements and chemical safety assessment (version 2.0, November 2014), and determine the need for further testing on terrestrial organisms. If you conclude that no further investigation of effects on terrestrial organisms is required, you should update your technical dossier by clearly stating the reasons for adapting the information requirements of section 9.4. of Annex IX, of the REACH Regulation.

ECHA emphasises that the intrinsic properties of soil microbial communities are not addressed through the EPM extrapolation method and therefore the potential adaptation possibility outlined for the information requirement of Annex IX, Section 9.4. does not apply for the present endpoint.

Appendix 2: Procedural history

For the purpose of the decision-making, this decision does not take into account any updates of your registration after the date when the draft decision was notified to you under Article 50(1) of the REACH Regulation.

The compliance check was initiated on 26 November 2015.

The decision making followed the procedure of Articles 50 and 51 of the REACH Regulation:

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.

ECHA notified the draft decision to the competent authorities of the Member States for proposal(s) for amendment.
ECHA received proposals for amendment and modified the draft decision.

ECHA invited you to comment on the proposed amendment(s). You did not provide any comments on the proposed amendment(s).

ECHA referred the draft decision to the Member State Committee.

The Member State Committee reached a unanimous agreement on the draft decision during its MSC-48 meeting and ECHA took the decision according to Article 51(6) of the REACH Regulation

Appendix 3: Further information, observations and technical guidance

1. The substance subject to the present decision is provisionally listed in the Community rolling action plan (CoRAP) for start of substance evaluation in 2017.

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

3. 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 your Member State.

4. 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.