ECHA
EUROPEAN CHEMICALS AGENCY

Decision number: CCH-D-2114311758-46-01/F Helsinki, 08 January 2016

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

For dioctadecyl 3,3'-thiodipropionate, CAS No 693-36-7 (EC No 211-750-5), 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 dioctadecyl 3,3'-thiodipropionate, CAS No 693-36-7 (EC No 211-750-5), submitted by [redacted] (Registrant).

The scope of this compliance check decision is limited to the standard information requirements of Annex VI, Section 3.5., Annex IX, Sections 9.1. and 9.4., Annex X, Sections 9.4 and 9.5.1. of the REACH Regulation. Following the proposal for amendment from a Competent Authority, the scope of this compliance check has been expanded to the standard information requirement of Section 9.1.2. of Annex VII of the REACH Regulation relating to Growth inhibition study aquatic plants. 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 1000 tonnes or more per year. This decision does not take into account any updates submitted after 11 June 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 24 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. That draft decision was based on submission number [redacted].

On 26 November 2014 ECHA received comments from the Registrant on the draft decision.

On 28 January 2015 the Registrant updated his registration dossier with the submission number [redacted].

The ECHA Secretariat considered the Registrant's comments and update.
On basis of this information, Section II was amended. The Statement of Reasons (Section III) was changed accordingly.

On 11 June 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.

Subsequently, proposals for amendment to the draft decision were submitted.

On 17 July 2015 ECHA notified the Registrant of the proposals for amendment to the draft decision and invited him pursuant to Article 51(5) of the REACH Regulation to provide comments on the proposals for amendment within 30 days of the receipt of the notification.

The ECHA Secretariat reviewed the proposals for amendment received and amended the draft decision.

By 17 August 2015 in accordance to Article 51(5), the Registrant provided comments on the proposals for amendment. The Member State Committee took the comments of the Registrant on the proposals for amendment into account.

A unanimous agreement of the Member State Committee on the draft decision was reached on 31 August 2015 in a written procedure launched on 20 August 2015.

ECHA took the decision pursuant to Article 51(6) of the REACH Regulation.

II. Information required

A. Information in the technical dossier derived from the application of Annexes VII to XI

Pursuant to Articles 41(1), 41(3), 10(a)(vii), 12(1)(e), 13 and Annexes VII, 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. Growth inhibition study aquatic plants (Annex VII, Section 9.1.2.; test method: Alga, growth inhibition test, EU C.3./OECD 201);

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

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

4. 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);

5. 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);

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

7. 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).

Notes 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 National Enforcement Authorities.

B. Deadline for submitting the required information

Pursuant to Articles 41(4) and 22(2) of the REACH Regulation the Registrant shall to ECHA by **17 July 2017** an update of the registration dossier containing the information required by this decision, including an update of the Chemical Safety Report.

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 VII to XI

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. Growth inhibition study aquatic plants (EU C.3./OECD 201)

A growth inhibition study on aquatic plants (algae preferred) is a standard information requirement under Annex VII, 9.1.2. of the REACH Regulation. In the registration dossier, the Registrant has provided an algal growth inhibition study as a key study, performed in 1992 according to the corresponding test guideline listed in Annex V to Directive 67/548/EEC (as amended by Directive 87/302/EEC). This study was not conducted in accordance with the principles of good laboratory practice (GLP). ECHA considers that the test is invalid for the following reasons:

> The study summary indicates that "*small parts of the test substance were swimming on the surface of the test water at all test concentrations and a small deposit was observed at the test concentration of 100 mg/L*"potentially causing physical effects and suggesting that concentrations in the study exceeded the water solubility of the substance.
> In addition, the Registrant uses nominal concentrations of the registered substance, but in the robust study summary the Registrant did not provide evidence that the concentrations of the test substance were maintained within [redacted]% of the initial concentration throughout the duration of the test. This is a validation criterion according to the Commission Regulation (EC) No 440/2008 laying down test methods pursuant to Regulation (EC) No 1907/2006 adapted to the technical progress by Commission Regulation (EC) No 761/2009, C.3. Algal inhibition test. Due to the lack of chemical analysis provided, it is not clear what dissolved concentrations the algae were exposed to.
> More specifically, in the study, a very high vehicle concentration of 0.4 mg/L (instead of a maximum of 0.1 mg/L according to the test guideline OECD 201 or equivalent) was used. A [redacted]% inhibition was observed in the vehicle control. The (nominal) test concentrations were far above the water solubility limit of the test substance with the highest test concentration of 100 mg/L (nominal) and a water solubility limit of lower than 1 mg/L .It is not possible to conclude from the test, if the effects observed occurred simply of the massive use of the solvent or due to toxicity of the registered substance.
>
> In addition to the problems with the test concentration, the effects of the test substance on algae are reported to be based on biomass. According to ECHA Guidance R.7b this "*should not be used*", because "*direct use of the biomass concentration without logarithmic transformation cannot be applied to an analysis of results from a system in exponential growth...*" The Guidance also states: "*if only an EbC50 is reported and no primary data are available, it should be considered to perform a new algae study to obtain a valid ErC50 and NOEC or ErC10 especially if algae are the most relevant species for the effects assessment.*"

The reported test for Annex VII 9.1.2. endpoint is invalid due to not fulfilling the validation criteria of the test conditions and the reported study design contrary to the legal requirements.

The Registrant submitted a comment to a Member State Competent Authority's proposal to request a growth inhibition study aquatic plants (algae preferred). In his comment, the Registrant refers to both the key study described above and a supporting read-across study following "the same procedure", but using another vehicle according to the Registrant. No effects were observed in the vehicle control of this study. The Registrant submitted a read-across approach document in his comment entitled "*Appendix 1: Justification and overview of the analogue approach of sulfanediyldipropanoate compounds*".

Concerning the key study, the Registrant states that he has access to the primary data of the study report and will derive effect concentrations based on growth rate. ECHA notes that this will not solve the issues described above, concerning the high vechicle concentration and the lack of evidence on maintaining the substance during testing.

Concerning the supporting read-across study with an analogue substance, the Registrant states that "*both substances have a propanoic ester backbone (3,3'-thiodipropionate) in which the functional side chains are extended with aliphatic groups in place of a hydrogen atom. The different aliphatic side chains are dodecyl for didodecyl-3,3'-thiodipropionate, CAS 123-28-4, and octadecyl for dioctadecyl 3,3'-thiodipropionate, CAS 693-36-7. CAS 123-28-4 has only shorter functional side chains.*" The Registrant's hypothesis for the analogue approach is the following: "*Sulfanediyldipropanoates are large, bulky, non-polar organic compounds used as heat stabilizers in plastic compounds. The substances are poorly water soluble solids. The two substances only differ in the length of their alkyl side chains – either C12H25 or C18H37. Both substances share a very low water solubility (< 1mg/L) and a high log Kow of >> 6 (calculated).*"

The hypothesis for the analogue approach given by the Registrant is based on the fact that the substances are used for the same purpose, are poorly water soluble, have a high log Kow and only differ in the length of their side chains.

REACH Annex XI, 1.5 requires registrants to show that "*...physicochemical, toxicological and ecotoxicological properties are likely to be similar... as a result of structural similarity...*" Although both substances indeed have common functional groups, ECHA notes that the difference in side chains is large (C12 vs. C18) and therefore the substance properties also show large differences. For instance, the molecular weight of the analogue substance is 515 g/mol while that of the target substance (registered substance) is 683 g/mol. In line with this, the (estimated) log Kow values also differ largely. Differences in ecotoxicity are very difficult to assess as only acute studies with aquatic invertebrates and fish are reported (apart from the algae study). Moreover, these acute aquatic tests were conducted with test concentrations far above the maximum water solubility and no measured concentrations are given.

A clear hypothesis is also missing in the justification: no real hypothesis is given, describing how the structural similarity is leading to similar physicochemical, fate and (eco)toxicological properties that would make a read-across for algae plausible.

ECHA also notes that no measured test concentrations are available for the algae study with the analogue substance and that the (nominal) test concentrations were far above the water solubility limit of the test substance. Therefore, this study is not compliant and therefore cannot be used as a basis for read-across.

In the dossier submission on which this decision is based, a justification of the read-across adaptation, based on the above and other adequate and reliable documentation was not provided.

Therefore, since the key and supporting study are not compliant and the Registrant has not provided in his comments to the proposal for amendment, adequate reasoning to support the fulfilment of the criteria pursuant of an adaptation according Annex XI, 1.5 for the supporting study, there is an information gap and it is necessary to provide information for Annex VII, Section 9.1.2. ECHA notes that the registration dossier on which this decision is based (submission number [redacted]) does not contain a read-across justification 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:

Growth inhibition study aquatic plants (EU C.3./OECD 201).

Once the results of the above study are available to the Registrant, he shall revise the chemical safety assessment as necessary according to Annex I of the REACH Regulation, including an updated derivation of the aquatic PNECs.

Note for consideration by the Registrant

Additionally, ECHA notes that during the aquatic toxicity tests, it is particularly important to reach system equilibrium, maintain exposure concentrations throughout the test and verify these concentrations at several time intervals during the test (as for example stated in Chapter R.7b of the ECHA Guidance on information requirements and chemical safety assessment (p. 73 or p. 161) (version 2.0, November 2014). Guidance documents such as the OECD Guidance Document on Aquatic Toxicity Testing of Difficult Substances and Mixtures, ENV/JM/MONO (2000)6 and Guidance on Information Requirements and Chemical Safety Assessment (version 2.0, November 2014) are very relevant for testing this hydrophobic substance and should be consulted by the registrant when conducting the requested tests.

2. and 3. Long-term aquatic toxicity testing on invertebrates and fish (Annex IX, Sections 9.1.5 and 9.1.6.)

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 using the following justification: "*In Annex IX of Regulation (EC) No 1907/2006, it is laid down that long term toxicity test on aquatic invertebrates shall be proposed by the registrant if the chemical safety assessment indicates the need to investigate further the effects on aquatic invertebrates. 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 Dioctadecyl 3,3'-sulfanediyldipropanoate 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, a long term toxicity test on aquatic invertebrates is not provided.*"

ECHA notes further that the Registrant has sought to adapt the long-term toxicity testing on fish using the following justification: *"In Annex IX of Regulation (EC) No 1907/2006, it is laid down that long term toxicity test 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 Dioctadecyl 3,3'-sulfanediyldipropanoate 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, a long term toxicity test on fish is not provided."*

ECHA points out that the justification for waiving provided by the Registrant does not meet the criteria of the general adaptation rules of Annex XI to the REACH Regulation.

ECHA notes that the Registrant has proposed to adapt the standard information requirements of Annex IX, 9.1.5. and Annex X, 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, 9.1.5. and Annex X, 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. ECHA notes that in the dossier with submission number [redacted] based on which the initial draft decision was prepared, the Registrant had not specified the uses of the substance as required by Annex VI, Section 3.5. Following the receipt of the draft decision and the request therein the Registrant submitted on 28 January 2015 an updated dossier (submission number [redacted]) with use descriptors.

However, as the Chemical Safety Report (CSR) submitted by the Registrant 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, the adaptation proposed by the Registrant cannot be accepted.

Furthermore, the ECHA Guidance on information requirements and chemical safety assessment (Version 1.2, November 2012), 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. The Registrant has not demonstrated that a weight-of-evidence approach (Annex XI, 1.2.) would be justified.

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.

In his comments to the draft decision the Registrant has agreed to conduct the long-term toxicity test on aquatic invertebrates. He has further indicated that he will carry out the long-term toxicity test on fish depending on the results of the invertebrate study and subsequently update the Chemical Safety Assessment. ECHA notes that this is in accordance to what is outlined in the Note for consideration by Registrant under III.1. and 2. below. The Registrant has added this testing strategy to the adaptation provided for these endpoints in the latest technical dossier.

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).

Once the results of the above long-term aquatic studies are available to the Registrant, he shall revise the chemical safety assessment as necessary according to Annex I of the REACH Regulation, including an updated derivation of the aquatic PNECs.

Notes 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. ECHA notes that in his comments on the draft decisionand the updated technical dossier, the Registrant has indicated that he will follow this approach.

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.

4., 5. and 6. 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 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: "*In accordance to column 2 of REACh Annex IX, and X, toxicity testing on terrestrial organisms shall be proposed if the result of the Chemical Safety Assessment indicates the need to investigate further the effects of the substance and/or relevant degradation products on terrestrial organisms.*
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 tris(2,4-di-tert-butylphenyl) phosphite reveals neither a need to classify the substance as dangerous for the environment or human health, nor is it a PBT or vPvB substance, nor are there any further indications that the substance may be hazardous to the environment. The substance is used typically as antioxidant and/or stabiliser for polymers in very low concentrations and will be included into the matrix. Therefore, it can be expected that the application of the substance during its life cycle does not result in direct exposure to soil and exposure to soil is regarded as negligible. Indirect exposure to soil via sewage sludge transfer is unlikely since the substance is readily biodegradable. For a substance being considered as „readily biodegradable", it can be assumed that it will be biodegraded within the STP process and as a consequence a transfer to the soil compartment is not expected.
No study on terrestrial organisms is proposed."

ECHA notes that the Registrant has sought to adapt the standard information requirements of Annex IX 9.4.1 and Annex X 9.4.4 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 studies on terrestrial organisms. Furthermore, the Registrant argues that substance uses during its life cycle would not lead to soil exposure. ECHA notes that in the dossier with submission number [redacted] based on which the initial draft decision was prepared,, the Registrant had not specified the uses of the substance as required by Annex VI, Section 3.5. Following the receipt of the draft decision and the request therein the Registrant submitted the use descriptors in the updated dossier. Still, the Chemical Safety Report (CSR) submitted by the Registrant as part of the technical dossier does not contain the Exposure Assessment (EA) and the subsequent Risk Characterisation (RC) sections.

ECHA notes that in order for an adaptation of Annex IX 9.4.1 and Annex X 9.4.4. 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. ECHA hence considers that as no EA/RC have been submitted it is not possible to fully assess whether exposure of the soil environment may occur. No further information on the claim of no exposure was provided in the comments. Therefore, ECHA considers that the Registrant has not justified that the conditions of an adaptation possibility are fulfilled. Therefore, the adaptation proposed by the Registrant cannot be accepted.

In the adaptation the Registrant argues further that as the substance is readily biodegradable no indirect exposure of the soil environment would occur. In his comments to the draft decision the Registrant has discussed the ready biodegradability status of registered substance, and has referred to evaluation carried out by the PBT expert group on the PBT status of the registered substance (ECB – SUMMARY FACT SHEET PBT WORKING GROUP – PBT LIST NO. 96). Regarding persistence the PBT working group summarised that "*Based on the modified OECD 301 D test result, the substance is considered as readily biodegradable without meeting the 10-day window*" and "*The substance is concluded to be not persistent*". ECHA considers this evaluation as appropriate. However, ECHA notes that as the substance has a very high potential to adsorb to soil (log Kow 17.68) exposure of soil cannot be excluded. Furthermore, as fully explained in the Note for consideration at the end of section III."3.,4. and 5" once he has carried out the long-term aquatic test(s) also requested in this decision, the Registrant may allocate the substance to a soil hazard category as per ECHA Guidance on information requirements and chemical safety assessment (Chapter R.7c, version 2.0, November 2014). Due to the high adsorption, this allocation would not be affected by the ready biodegradation/persistence status of the registered substance.

Consequently there is an information gap and it is necessary to provide information for long-term toxicity on terrestrial invertebrates.

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.

ECHA notes that in the comments to the draft decision the Registrant has agreed to carry out the earthworm reproduction test (OECD 222). The agreement to conduct this study has also been provided in the latest technical dossier update.

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 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: "*In accordance to column 2 of REACh Annex IX, and X, toxicity testing on terrestrial organisms shall be proposed if the result of the Chemical Safety Assessment indicates the need to investigate further the effects of the substance and/or relevant degradation products on terrestrial organisms.*
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 tris(2,4-di-tert-butylphenyl) phosphite reveals neither a need to classify the substance as dangerous for the environment or human health, nor is it a PBT or vPvB substance, nor are there any further indications that the substance may be hazardous to the environment. The substance is used typically as antioxidant and/or stabiliser for polymers in very low concentrations and will be included into the matrix. Therefore, it can be expected that the application of the substance during its life cycle does not result in direct exposure to soil and exposure to soil is regarded as negligible. Indirect exposure to soil via sewage sludge transfer is unlikely since the substance is readily biodegradable. For a substance being considered as „readily biodegradable", it can be assumed that it will be biodegraded within the STP process and as a consequence a transfer to the soil compartment is not expected.
No study on terrestrial organisms is proposed."

ECHA notes that the adaptation proposed by the Registrant in the dossier with submission number [redacted], based on which the initial draft decision was prepared, was identical to the one proposed to fulfill the information requirement for testing on terrestrial invertebrates. In his comments to the draft decision and the subsequent dossier update, the Registrant states that he will conduct the plant study depending on the outcome of the long-term terrestrial invertebrate study and the subsequent revision of the chemical safety assessment. ECHA notes that following the aquatic studies and the long-term soil invertebrates study, Registrant may wish to use the Integrated Testing strategy (ITS) as recommended in section R.7.11.6 of Chapter R.7c of the ECHA *Guidance on information requirements and chemical safety assessment* (version 2.0, November 2014) to determine whether the plant study is needed in addition. This possibility is fully discussed in the Note for consideration by the Registrant at the end of section III 3.,4., and 5.

For the same reasons as already explained above under section III."3.,4. and 5."a), the adaptation proposed in the technical dossier for the endpoint terrestrial plants toxicity of the registered substance does not meet the information requirements. Consequently there is an information gap and it is necessary to provide information for long-term toxicity on terrestrial plants.

As is also explained above, ECHA considers that the column 2 adaptation for Annex IX, section 9.4., regarding long-term testing instead of short-term testing are fulfilled for this substance. Even at a lower tonnage level the long-term tests would have been indicated, whereas at the tonnage level of the registration they are a standard information requirement.

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: "*In accordance to column 2 of REACh Annex IX, and X, toxicity testing on terrestrial organisms shall be proposed if the result of the Chemical Safety Assessment indicates the need to investigate further the effects of the substance and/or relevant degradation products on terrestrial organisms.*
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 tris(2,4-di-tert-butylphenyl) phosphite reveals neither a need to classify the substance as dangerous for the environment or human health, nor is it a PBT or vPvB substance, nor are there any further indications that the substance may be hazardous to the environment. The substance is used typically as antioxidant and/or stabiliser for polymers in very low concentrations and will be included into the matrix. Therefore, it can be expected that the application of the substance during its life cycle does not result in direct exposure to soil and exposure to soil is regarded as negligible. Indirect exposure to soil via sewage sludge transfer is unlikely since the substance is readily biodegradable. For a substance being considered as „readily biodegradable", it can be assumed that it will be biodegraded within the STP process and as a consequence a transfer to the soil compartment is not expected.
No study on terrestrial organisms is proposed."

ECHA notes that the adaptation proposed by the Registrant is identical to the one proposed to fulfill the information requirement for testing on terrestrial invertebrates. For the same reasons as already explained above under section III."3.,4. and 5."a), the adaptation proposed 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 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., p115, 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 notes that in his comments on the initial draft decision the Registrant has indicated that he will carry out the terrestrial invertebrate study first, then decide whether the other terrestrial studies are neeeded depending on the outcome of this study and the subsequent update of the chemical safety assessment.

ECHA notes that due to the current absence of information on chronic aquatic toxicity it is not possible to assign the substance to a soil hazard category (Chapter R.7c of the ECHA Guidance on information requirements and chemical safety assessment, version 2.0, November 2014).. Therefore, currently all three terrestrial studies are requested without the possibility of tiered testing. However, ECHA notes that the results from the toxicity test(s) on aquatic invertebrates and fish requested under section II 1., and 2. of the present Decision may allow the subsequent derivation of a PNECwater. In such a case, , the Registrant may consider the ITS as recommended in section R.7.11.6., of the above-mentioned Guidance and determine whether there is still a need for further testing on all three terrestrial organisms. ECHA notes further that if no effects are observed in the aquatic studies, it is not possible to use the soil hazard categorisation table and all three terrestrial studies are required. ECHA notes further that notwithstanding the results of aquatic studies, at least one terrestrial study is required due to high adsorption of the registered substance.

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 2.0, November 2014). 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.

Additionally, ECHA notes that during the terrestrial toxicity tests, it is particularly important to reach system equilibrium, maintain exposure concentrations throughout the test and verify these concentrations at several time intervals during the test (as for example stated in Chapter R.7b of the ECHA Guidance on information requirements and chemical safety assessment (p. 73 or p. 161) (version 2.0, November 2014). Guidance documents such as the OECD Guidance Document on Aquatic Toxicity Testing of Difficult Substances and Mixtures, ENV/JM/MONO (2000)6 and Guidance on Information Requirements and Chemical Safety Assessment (version 2.0, November 2014) are very relevant for testing this hydrophobic substance and should be consulted by the registrant when conducting the requested tests: long-term toxicity testing on terrestrial invertebrates; long-term toxicity testing on plants; effects on soil micro-organisms.

7. 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: "*In accordance to column 2 of REACh Annex X, long term testing on sediment organisms shall be proposaed if the result of the Chemical Safety Assessment indicates the need to investigate further the effects of the substance and/or relevant degradation products on sediment organisms. Due to the low water solubility, release to surface and thereby sediment, is negligible. Furthermore, as presented in IUCLID chapter 5.2.1, the substance can be considered as readily biodegradable but failing 10 window. Therefore, chronic exposure of sediment organisms is unlikely.*"

In his proposed adaptation the Registrant claims that there is no need to investigate the effects on sediment organisms further as the chemical safety assessment does not show the need. 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. ECHA notes that in the dossier with submission number [redacted] based on which the initial draft decision was prepared,the Registrant had not specified the uses of the substance as required by Annex VI, Section 3.5. . Following the receipt of the draft decision and the request therein the Registrant submitted the use descriptors in the updated dossier.

However, as the Chemical Safety Report (CSR) submitted by the Registrant as part of the technical dossier does not contain the Exposure Assessment (EA) and the subsequent Risk Characterisation (RC) sections, ECHA does not consider that the Registrant has demonstrated by means of the CSR that the conditions of an adaptation possibility (Annex XI) are fulfilled. Consequently it is not possible to fully assess whether there may be risks to sediment.

The Registrant claims further that due to low water solubility, release to sediment is negligible. 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) for substances that are highly insoluble and for which no effects are observed in aquatic studies at least one sediment study has to be performed. ECHA notes that as shown in the technical dossier no effects were observed in any of the aquatic studies performed. In addition, as the substance has a reported water solubility of < 1mg/L ECHA considers that long-term sediment testing is indicated for the registered substance.

In the adaptation the Registrant has furthermore stated that the substance is readily biodegradable. ECHA notes that this is not a valid adaptation possibility according to Column 2 of Annex 9.5.1. As already discussed in section III."3., 4. and 5." a) ECHA considers the evaluation outcome of the PBT working group of "*Based on the modified OECD 301 D test result, the substance is considered as readily biodegradable without meeting the 10-day window*" and "*The substance is concluded to be not persistent*" as appropriate. However, ECHA notes that the ready biodegradation/persistence status of the substance does not have an impact on the current request for the sediment study, but rather the request relates to low water solubility, lack of effects observed in the aquatic studies available and high adsorption potential of the registered substance. These are further discussed in the following paragraphs.

In his comments to the draft decision and his updated adaptation for this endpoint in the latest technical dossier, the Registrant has stated that he intents to determine the need for the sediment study based on the results of the aquatic and terrestrial studies and the subsequent chemical safety assessment update. ECHA notes that as indicated above, the sediment study is required based on substance properties and lack of effects in aquatic studies. ECHA notes further that if effects were seen in the long-term aquatic studies requested in this decision, 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). This adaptation possibility is further discussed in the Note for consideration by the Registrant at the end of this section. ECHA notes further that under the REACH Regulation there are separate information requirements for testing sediment and terrestrial organisms as they are defined as two separate compartments and testing uses different organisms. Therefore, the results of the soil organisms testing alone cannot be used to adapt the information requirement of sediment organisms.

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.

Therefore, in this specific case, ECHA notes that the Registrant has not justified an adaptation.

Therefore, pursuant to Article 41(1)(a) and (b) 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)

Note for consideration by the Registrant

According to ECHA *Guidance on information requirements and chemical safety assessment* (R.7.B, version 2.0. November 2014) 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. 139). However, as further explained in Section R.7.8.12.2., p. 150 of the above Guidance, if no effects are seen in aquatic studies, the EPM may not be used, for the reasons also explained in Section R.7.8.10.3, page 145, of the Guidance. 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. Due to a logKow >5 the if the EPM is used, the PECsed/PNECsed ratio is to be increased by a factor of 10 to account for uptake via sediment. 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.

Additionally, ECHA notes that during the Sediment toxicity testing, it is particularly important to reach system equilibrium, maintain exposure concentrations throughout the test and verify these concentrations at several time intervals during the test (as for example stated in Chapter R.7b of the ECHA Guidance on information requirements and chemical safety assessment (p. 73 or p. 161) (version 2.0, November 2014). Guidance documents such as the OECD Guidance Document on Aquatic Toxicity Testing of Difficult Substances and Mixtures, ENV/JM/MONO (2000)6 and Guidance on Information Requirements and Chemical Safety Assessment (version 2.0, November 2014) are very relevant for testing this hydrophobic substance and should be consulted by the registrant when conducting the requested tests: long-term toxicity testing on terrestrial invertebrates; long-term toxicity testing on plants; effects on soil micro-organisms.

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.

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.