EUROPEAN CHEMICALS AGENCY

Helsinki, 14 December 2016

Addressee: [redacted]

Decision number: TPE-D-2114349030-64-01/F
Substance name: Phosphoric acid, octadecyl ester
EC number: 254-466-7
CAS number: 39471-52-8
Registration number: [redacted]
Submission number: [redacted]
Submission date: 20.11.2013
Registered tonnage band: 100-1000T

DECISION ON A TESTING PROPOSAL

Based on Article 40 of Regulation (EC) No 1907/2006 (the 'REACH Regulation'), ECHA has taken the following decision.

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

1. Sub-chronic toxicity study (90-day), oral route (Annex IX, Section 8.6.2.; test method: EU B.26./OECD TG 408) in rats using the registered substance.

2. Pre-natal developmental toxicity study (Annex IX, Section 8.7.2.; test method: EU B.31./OECD TG 414) in a first species (rat or rabbit), oral route using the registered substance.

Your following testing proposal is rejected:

3. Reproductive toxicity study (Annex IX, Section 8.7.3.).

While your originally proposed test for Fish, Prolonged Toxicity Test: 14-Day Study, OECD 204 using the registered substance is rejected, you are requested to perform:

4. 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) using the registered substance.

You are additionally requested to perform:

5. 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) using the registered substance

While your originally proposed test for Simulation Test - Aerobic Sewage Treatment. A: Activated Sludge Units, OECD 303 A using the registered substance is rejected, you are requested to perform:

6. Sediment simulation testing (Annex IX, Section 9.2.1.4.; test method: Aerobic and anaerobic transformation in aquatic sediment systems, EU C.24. / OECD TG 308) at a temperature of 12°C using the registered substance

While your originally proposed test for Inherent Biodegradability in Soil, OECD 304 A using the registered substance is rejected, you are requested to perform:

7. Soil simulation testing (Annex IX, Section 9.2.1.3.; test method: Aerobic and anaerobic transformation in soil, EU C.23./OECD TG 307) at a temperature of 12°C using the registered substance

You are additionally requested to provide:

8. Identification of degradation products (Annex IX, Section 9.2.3.; test method as for items 6 and 7 above) of the registered substance.

While your originally proposed test for Short-term toxicity to terrestrial invertebrates (Annex IX, Section 9.4.1.; test method: Earthworm acute toxicity test, EU C.8/OECD TG 207) using the registered substance is rejected, you are requested to perform:

9. Long-term toxicity to terrestrial invertebrates (Annex IX, Section 9.4.1., column 2; test method: Earthworm reproduction test (OECD TG 222) or Enchytraeid reproduction test (OECD TG 220) or Collembolan reproduction test in soil (OECD TG 232)

While your originally proposed test for Short-term toxicity to plants (Annex IX, Section 9.4.3.; test method: Terrestrial plant test: seedling emergence and seedling growth test, OECD TG 208) using the registered substance is rejected, you are requested to perform:

10. Long-term toxicity to terrestrial plants (Annex IX, Section 9.4.3., column 2; test method: Terrestrial plant test: seedling emergence and seedling 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) using the registered substance.

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

11. Effects on soil micro-organisms (Annex IX, Section 9.4.2.; test method: Soil microorganisms: nitrogen transformation test, EU C.21./OECD TG 216) using the registered substance.

You are additionally requested to perform:

12. Effects on soil micro-organisms (Annex IX, Section 9.4.2.; test method: Soil microorganisms: carbon transformation test, EU C.22./OECD TG 217) using the registered substance.

You may adapt the testing requested above according to the specific rules outlined in Annexes VI to X and/or according to the general rules contained in Annex XI of the REACH Regulation. In order to ensure compliance with the respective information requirement, any such adaptation will need to have a scientific justification, referring and conforming to the appropriate rules in the respective Annex, and an adequate and reliable documentation.

You are required to submit the requested information in an updated registration dossier by **21 June 2019**. You shall also update the chemical safety report, where relevant. The timeline has been set to allow for sequential testing.

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

Appeal

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

Authorised[1] by Claudio Carlon, Head of Unit, Evaluation E2

[1] As this is an electronic document, it is not physically signed. This communication has been approved according to ECHA's internal decision-approval process.

Appendix 1: Reasons

The decision of ECHA is based on the examination of the testing proposal(s) submitted by you.

1. **Sub-chronic toxicity study (90-day) (Annex IX, Section 8.6.2.)**

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

A sub-chronic toxicity study (90 day) is a standard information requirement as laid down in Annex IX, Section 8.6.2. of the REACH Regulation. The information on this endpoint is not available for the registered substance but needs to be present in the technical dossier to meet the information requirements. Consequently there is an information gap and it is necessary to provide information for this endpoint.

You have submitted a testing proposal for a sub-chronic toxicity study (90 day) in rats by the oral route according to EU B.26/OECD TG 408 with the registered substance.

You proposed testing by the oral route. Based on the information provided in the technical dossier, human exposure to the registered substance by the inhalation route seems to be likely. However, due to the missing information in the technical dossier (i.e, the concentration used as spary application in the non industrial setting (PROC 11), and granulometry information on the registered substance) and in the absence of any repeated dose toxicity study by the oral route, it is not possible for ECHA to evaluate the most appropriate route of administration. Since the proposed oral route is the preferred one as indicated in ECHA Guidance on information requirements and chemical safety assessment (version 4.1, October 2015) Chapter R.7a, section R.7.5.4.3, the test shall be performed by the oral route using the test method EU B.26./OECD TG 408..

You proposed testing in rats. According to the test method EU B.26./OECD TG 408 the rat is the preferred species. ECHA considers this species as being appropriate and testing should be performed with the rat.

Therefore, pursuant to Article 40(3)(a) of the REACH Regulation, you are requested to carry out the proposed study with the registered substance subject to the present decision: Sub-chronic toxicity study (90-day) in rats, oral route (test method: EU B.26./OECD TG 408).

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

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

A pre-natal developmental toxicity study for a first species is a standard information requirement as laid down in Annex IX, Section 8.7.2. of the REACH Regulation. The information on this endpoint is not available for the registered substance but needs to be present in the technical dossier to meet the information requirements. Consequently there is an information gap and it is necessary to provide information for this endpoint.

You have submitted a testing proposal for a pre-natal developmental toxicity study according to EU B.31./OECD TG 414 with the registered substance.

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

You did not specify the species to be used for testing. 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 consideration, ECHA considers testing should be performed with the rat or rabbit as a first species.

You did not specify the route for testing. ECHA considers that the oral route is the most appropriate route of administration for substances except gases to focus on the detection of hazardous properties on reproduction as indicated in ECHA *Guidance on information requirements and chemical safety assessment* (version 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 40(3)(a) of the REACH Regulation, you are requested to carry out the proposed study with the registered substance subject to the present decision: Pre-natal developmental toxicity study in a first species (rats or rabbits), oral route (test method: EU B.31./OECD TG 414).

Notes for your consideration

For the selection of the appropriate species you are advised to consult ECHA *Guidance on information requirements and chemical safety assessment* (version 4.1, October 2015), Chapter R.7a, section R.7.6.2.3.2.

3. Reproductive toxicity study (Annex IX, Section 8.7.3.)

Pursuant to Article 40(3)(d) of the REACH Regulation, ECHA may reject a proposed test.

You have submitted a testing proposal for a two-generation reproductive toxicity study according to EU B.35./OECD TG 416 with the following justification:*" if the available repeated dose toxicity studies (e.g. 28-day or 90- day studies, OECD 421 or 422 screening studies) indicate adverse effects on reproductive organs or tissues or reveal other concerns in relation with reproductive toxicity*".

According to Annex IX, Section 8.7.3., as amended by Commission Regulation (EU) 2015/282 (entered into force on 13 March 2015), a two-generation reproductive toxicity study is no information requirement any longer. Furthermore, the current requirement according to Annex IX, Section 8.7.3., i.e. the extended one-generation reproductive toxicity study, is only an information requirement if adverse effects on reproductive organs or tissues have been observed in the available repeated dose toxicity studies (e.g. a 28-day or 90-day repeated dose toxicity study, OECD TG 421 or 422 screening studies) or if they reveal other concerns in relation with reproductive toxicity.

ECHA notes that there is no repeated dose toxicity study available in the registration dossier, while you have proposed to perform a sub-chronic toxicity study (90 days).

ECHA notes further that you have not included any justification why to perform a reproductive toxicity study at tonnage level 100 – 1000 tonnes per year. ECHA considers that the proposed study is at this stage not necessary to fulfil the information requirement of Annex IX, Section 8.7.3. of the REACH Regulation because no repeated dose toxicity study is currently available to evaluate if performance of such a reproductive toxicity study is required at that tonnage level.

ECHA concludes that at this stage there is no information gap for the information requirement of Annex IX, Section 8.7.3. Therefore, pursuant to Article 40(3)(d) of the REACH Regulation, the proposed two-generation reproduction toxicity study (OECD TG 416) is rejected.

Notes for your consideration

Once the results from the sub-chronic toxicity study (Section II, 1. above) are available, you should reconsider the information requirement of Annex IX, Section 8.7.3. If the sub-chronic toxicity study indeed indicates adverse effects on reproductive organs or tissues, or reveals other concerns in relation with reproductive toxicity, you need – in accordance with the REACH Regulation – to submit a new testing proposal for the present endpoint, unless compliance with this information requirement is scientifically justified and documented by means of specific or general rules of adaptation.

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

Pursuant to Article 40(3)(d) and (c) of the REACH Regulation, ECHA may reject a proposed test and require the Registrant to carry out other tests in cases of non-compliance of the testing proposal with Annexes IX, X or XI.

"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. Reliable information on this endpoint is not available for the registered substance and needs to be present in the technical dossier to meet the information requirements. Consequently there is an information gap and it is necessary to provide information for this endpoint.

You have submitted a testing proposal for testing the registered substance for long-term toxicity testing on fish: Fish, Prolonged Toxicity Test: 14-Day StudyFish, early-life stage toxicity test, OECD TG 204 with the following justification:"*The Lead Registrant proposes an OECD 204 to address this endpoint based on the data requirements of REACH Annex IX; the final use of the substance (as part of a product) is as a Fertilizer, therefore exposure to the environmental compartment is likely. In addition, based on a weight of evidence approach using QSAR data on the constituents of phosphoric acid, octadecyl ester, ChV to fish is predicted to be 0.003 mg/l. Due to this prediction, and the liklihood of exposure, further investigation is required.*".

ECHA agrees with your conclusion that further investigation is required. However, ECHA considers that the proposed test cannot fulfil the information requirement as it is not mentioned in Annex IX 9.1.6 as one of the valid tests that can cover the specific information requirement. More specifically, the Annex IX, 9.1.6 mentions that the information shall be provided for one of the Sections 9.1.6.1 (OECD Guideline 210: Fish early-life stage (FELS) toxicity test), 9.1.6.2 (OECD Guideline 212: Fish short-term toxicity test on embryo and sac-fry stages) or 9.1.6.3 (OECD Guideline 215: Fish, juvenile growth test).

Furthermore, the ECHA *Guidance on information requirements and chemical safety assessment* (version 3.0, February 2016; Chapter R7b Section R.7.8.4.1, page 30) states that "*only such studies can be regarded as long-term fish test, in which sensitive life-stages (juveniles, eggs, larvae) are exposed. Thus, tests performed according to OECD 204 (Fish, Prolonged Toxicity Test: 14-Day Study (OECD 1984)) or similar guidelines cannot be considered suitable long-term tests. They are, in effect, prolonged acute studies with fish mortality as the major endpoint examined.*".

ECHA considers that for the endpoint of long-term toxicity testing on fish pursuant to Annex IX, section 9.1.6.1, 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 R7b, version 3.0, February 2016). For these reasons, ECHA considers the FELS toxicity test using the test method OECD TG 210 as appropriate and suitable.

Therefore, pursuant to Article 40(3)(c)of the REACH Regulation, you are requested to carry out the proposed test using the registered substance subject to the present decision: Fish, early-life stage (FELS) toxicity test (Annex IX, 9.1.6.1.; test method: Fish, early-life stage toxicity test, OECD TG 210). Your testing proposal for Fish, Prolonged Toxicity Test: 14-Day StudyFish, early-life stage toxicity test, OECD TG using the registered substance is rejected pursuant to Article 40(3)(d) of the REACH Regulation.

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

Pursuant to Article 40(3)(c) of the REACH Regulation, ECHA may require the Registrant to carry out one or more additional tests in case of non-compliance of the testing proposal with Annexes IX, X or XI of the REACH Regulation.

"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.

According to Annex XI, 1.3 of the REACH Regulation, one of the conditions for using (Q)SARs instead of test data is that adequate and reliable documentation of the applied method is provided. You have sought to adapt the long-term toxicity testing on aquatic invertebrates by providing non-justified QSARs. ECHA notes that the general form of the (Q)SAR Model Reporting Format (QMRF) and (Q)SAR Prediction Reporting Format (QPRF), as described in the ECHA Guidance on information requirements and chemical safety assessment Chapter R.6: (Q)SARs and grouping of chemicals (ECHA, May 2008), are missing. Therefore, ECHA cannot be certain about the provided long-term aquatic invertebrate toxicity data.

ECHA notes that there is no reliable information on short and long term aquatic toxicity to indicate the species sensitivity difference. According to ECHA *Guidance on information requirements and chemical safety assessment* (version 3.0, February 2016), Chapter R7b (Section R.7.8.5 including Figure R.7.8-4), in the absence of the short-term aquatic toxicity information, species sensitivity differences cannot be established and the need for long-term toxicity testing on aquatic invertebrates cannot be excluded.

According to ECHA *Guidance on information requirements and chemical safety assessment* (May 2008), Chapter R10 (Section R.10.3.1 including Table R.10-4) and in Chapter R7b (Section R.7.8.5.3), in order to derive $PNEC_{aquatic}$, it is necessary to provide toxicity information from each of the three trophic levels: Primary producers (plants), represented by algae; plant eating animals, represented by invertebrates (e.g. *Daphnia*) and predators, represented by fish. From the available information, ECHA notes that two trophic levels, invertebrates and fish, are missing. Consequently, there is an information gap and it is necessary to provide information also for this endpoint.

Based on information provided in the dossier the substance appears to have low solubility in water and highly adsorptive properties. According to ECHA *Guidance on information requirements and chemical safety assessment* (version 3.0, February 2016), Chapter R7b (Section R.7.8.5.3), and according to column 2, Annex VII, a long-term study shall be considered if the substance is poorly water soluble, i.e. solubility is below 1 mg/L. Therefore, ECHA considers that the short-term toxicity data is not relevant and information on long-term toxicity in Daphnia is needed for the PNEC derivation. The preferred test to assess long-term toxicity to aquatic invertebrates is OECD TG 211, *Daphnia magna* reproduction test.

Therefore, pursuant to Article 40(3)(c) of the REACH Regulation, you are requested to carry out the following test using the registered substance subject to the present decision: *Daphnia magna* reproduction test (test method: EU C.20/OECD TG 211).

Note for your consideration in relation to Sections 4 and 5:

Based on information provided in the dossier the substance appears to have low solubility in water and highly adsorptive properties. Therefore, you should consult the 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 for choosing the design of the requested long-term ecotoxicity tests and for calculation and expression of the result of both tests.

6. Sediment simulation testing (Annex IX, Section 9.2.1.4.)

Pursuant to Article 40(3)(d) and (c) of the REACH Regulation, ECHA may reject a proposed test and require the Registrant to carry out other tests in cases of non-compliance of the testing proposal with Annexes IX, X or XI.

"Sediment simulation testing" is a standard information requirement for substances with a high potential for adsorption to sediment as laid down in Annex IX, Section 9.2.1.4. of the REACH Regulation. The information on this endpoint is not available for the registered substance but needs to be present in the technical dossier to meet the information requirements. Consequently there is an information gap and it is necessary to provide information for this endpoint.

You have submitted a testing proposal for Simulation Test – Aerobic Sewage Treatment A: Activated Sludge Units (OECD 303A) to cover this endpoint with the following justification: "*The Lead Registrant proposes an OECD 303A to address this endpoint based on the data requirements of REACH Annex IX; the final use of the substance (as part of a product) is as a Fertilizer, therefore exposure to soil and sediment is likely.*".

ECHA notes that the substance is used as agrochemical and therefore natural aquatic systems will likely be subject to exposure of the registerd substance. Based on information provided in the dossier the substance appears to have low solubility in water and highly adsorptive properties. Therefore, potential persistence in the water compartment, and specifically sediments, should be investigated. The information currently available in the technical dossier and Chemical Safety Assessment (CSA) is not considered as sufficient to conclude on the biodegradation potential and consequently the persistence of the registered substance or its degradation products in the water compartment and thus, it is necessary to generate additional information for this endpoint.

However, the proposed OECD Test Guideline 303A test cannot be used to cover the simulation biodegradation endpoint, as indicated in the ECHA Guidance on Information requirements (R7b, version 3.0, February 2016). This Guidance (R.7.9.5.1, page 210) states that "*Results from tests simulating the conditions in a sewage treatment plant (STP) (e.g. the OECD 303) cannot be used for assessing the degradation in the aquatic environment*". The results from the OECD 303A test cannot be used for classification purposes either (Guidance R.7.9.5.1, page 222).

Based on the information provided in the dossier on the physico chemical properties of the substance the preferred test method is Aerobic and anaerobic transformation in aquatic sediment systems (test method: EU C.24/OECD TG 308). Furthermore, according to the guidance document R11, the OECD 303 studies are not considered as relevant tests to assess persistence in the environment (R.7.9.5.2); whereas the preferred test method EU C.24/OECD TG 308 mentioned above can be used for the PBT assessment, as indicated in the Guidance on Information requirements (R11, v.2.0, November 2014, Section R11.4.1.1 and Table R.11.5). ECHA notes that the information from the simulation study requested may also be needed for the purposes of the PBT, vPvB assessment as based on available information in the technical dossier and CSA the PBT, vPvB status of registered substance is unclear.

One of the purposes of the simulation test is to provide the information that must be considered for assessing the P/vP properties of the registered substance in accordance with Annex XIII of the REACH Regulation to decide whether it is persistent in the environment. Annex XIII also indicates that "*the information used for the purposes of assessment of the PBT/vPvB properties shall be based on data obtained under relevant conditions*". The Guidance on information requirements and chemical safety assessment R.7b (version 3.0, February 2016) specifies that simulation tests "attempt to simulate degradation in a specific environment by use of indigenous biomass, media, relevant solids [...], and a typical temperature that represents the particular environment". The Guidance on information requirements and chemical safety assessment Chapter R.16 on Environmental Exposure Estimation, Table R.16-8 (version 3.0, February 2016) indicates 12°C (285K) as the average environmental temperature for the EU to be used in the chemical safety assessment. Performing the test at the temperature of 12°C is within the applicable test conditions of the Test Guideline OECD TG 308. Therefore, the test should be performed at the temperature of 12°C.

Therefore, pursuant to Article 40(3)(c) of the REACH Regulation, you are requested to carry out the following additional study using the registered substance subject to the present decision: Aerobic and anaerobic transformation in aquatic sediment systems (test method: EU C.24/OECD TG 308), including the identification of the degradation products (Annex IX, Section 9.2.3.). Your testing proposal for Simulation Test – Aerobic Sewage Treatment A: Activated Sludge Units (OECD 303A) is rejected pursuant to Article 40(3)(d) of the REACH Regulation.

7. Soil simulation testing (Annex IX, Section 9.2.1.3.)

Pursuant to Article 40(3)(d) and (c) of the REACH Regulation, ECHA may reject a proposed test and require the Registrant to carry out other additional tests in cases of non-compliance of the testing proposal with Annexes IX, X or XI.

"Soil simulation testing" is a standard information requirement for substances with a high potential for adsorption to soil as laid down in Annex IX, Section 9.2.1.3. of the REACH Regulation. The information on this endpoint is however not available for the registered substance. Consequently there is an information gap and it is necessary to provide information for this endpoint.

You have submitted a testing proposal Inherent Biodegradability in Soil (OECD 304A) to cover this endpoint with the following justification: "*The Lead Registrant proposes an OECD 304 A to address this endpoint based on the data requirements of REACH Annex IX; the final use of the substance (as part of a product) is as a Fertilizer, therefore exposure to soil and sediment is likely.*".

ECHA notes that the substance is used as agrochemical and therefore natural soil systems will be subject to direct exposure of the registered substance. Besides, based on information provided in the dossier, the substance appears to have low solubility in water and highly adsorptive properties. Therefore, potential persistence in the soil compartment should be investigated.

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

However, the proposed OECD Test Guideline 304A test cannot be used to cover the simulation biodegradation endpoint, as indicated in the Guidance on Information requirements (R7b, version 3.0, February 2016). This Guidance (R.7.9.5.1, page 223) states that the inherent degradability tests do not provide suitable degradation data for its use on classification. Furthermore, it states that "*Substances that are degraded more than 70% in tests for inherent biodegradability have the potential for ultimate biodegradation (OECD Test Guidelines). However, because of the optimum conditions in these tests, the rapid biodegradability of inherently biodegradable substances in the environment cannot be assumed.*" and "*Therefore, positive results in these tests should not be interpreted as evidence for rapid degradation in the environment.* ". Furthermore, according to the guidance document the OECD 304 study is not considered as a relevant test to assess persistence in the environment. Therefore, the preferred test method is OECD TG 307, Aerobic and anaerobic transformation in soil which can be used for the PBT assessment (Guidance R11, v.2.0, November 2014, Section R11.4.1.1 and Table R.11.5). ECHA notes that the information from the simulation study requested may also be needed for the purposes of the PBT, vPvB assessment as based on the information available in the technical dossier and CSA the PBT, vPvB status of registered substance is unclear.

One of the purposes of the simulation test is to provide the information that must be considered for assessing the P/vP properties of the registered substance in accordance with Annex XIII of the REACH Regulation to decide whether it is persistent in the environment. Annex XIII also indicates that "*the information used for the purposes of assessment of the PBT/vPvB properties shall be based on data obtained under relevant conditions*". The Guidance on information requirements and chemical safety assessment R.7b (version 3.0, February 2016) specifies that simulation tests "*attempt to simulate degradation in a specific environment by use of indigenous biomass, media, relevant solids [...], and a typical temperature that represents the particular environment*". The Guidance on information requirements and chemical safety assessment Chapter R.16 on Environmental Exposure Estimation, Table R.16-8 (version 3.0, February 2016) indicates 12°C (285K) as the average environmental temperature for the EU to be used in the chemical safety assessment. Performing the test at the temperature of 12°C is within the applicable test conditions of the Test Guideline OECD TG 307. Therefore, the test should be performed at the temperature of 12°C.

Therefore, pursuant to Article 40(3)(c) of the REACH Regulation, you are requested to carry out the following study using the registered substance subject to the present decision: Aerobic and anaerobic transformation in soil (test method: EU C.23/OECD TG 307) at a temperature of 12°C. Your testing proposal for Inherent Biodegradability in Soil (OECD 304A) is rejected pursuant to Article 40(3)(d) of the REACH Regulation.

Note for your consideration in relation to Sections 6 and 7 above:

You are advised to consult the ECHA Guidance on information requirements and chemical safety assessment (version 2.0, November 2014), Chapter R.11.4. and Figure R.11—3 on the PBT/vPvB assessment for further information on the integrated testing strategy for the persistence assessment of the registered substance. You shall revise the PBT/vPvB assessment when information on persistence is available.

The registered substance is deemed to form non-extractable residues because of the strong adsorption potential of the constituents in the registered substance to soil/sediment (log Koc = 4.35-9.9 for the four constituents of the registered substance). For studying the pathway of transformation, for establishing a mass balance and for interpreting the formation of non-extractable residues, a labelled substance may be used as test material (according to OECD 308 / OECD 307).

The registered substance contains four main constituents. Due to possible technical problems it might be difficult to manufacture a ^{14}C-labelled complex substance. Therefore, if there are such reasons, the Registrant needs to consider, the physico-chemical properties (e.g. Koc, log Pow, water solubility) and typical concentrations of the constituents in the registered substance when deciding on the relevant and representative composition of the test item for the degradation simulation testing.

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

Pursuant to Article 40(3)(c) of the REACH Regulation, ECHA may require the Registrant to carry out other tests in cases of non-compliance of the testing proposal with Annexes IX, X or XI.

"Identification of the degradation products" is a standard information requirement according to column 1, Section 9.2.3. of Annex IX of the REACH Regulation. Column 2 of Section 9.2.3. of Annex IX further states that the study does not need to be conducted if the substance is readily biodegradable.

In the present dossier, ECHA notes that the information on this endpoint is not available. The technical dossier does not contain a valid adaptation for this standard information requirement in accordance with Column 2 of Section 9.2.3 of Annex IX or Annex XI to the REACH Regulation either.

As explained fully in sections (7) and (8) above, ECHA considers that with the current information the CSA cannot be used to justify that there is no need to investigate further the degradation of the substance and its degradation products. ECHA notes further that the information requested here may be needed for the PBT/vPvB assessment and for the identification of the degradation products in relation to the PBT/vPvB assessment.

ECHA notes that the degradation products can be identified when performing the tests already required above under points 7 and 8 of the present decision (test methods EU C.24./OECD TG 308 and EU C.23./OECD TG 307). Thus, there is no need for other tests in order to provide information for this endpoint.

Therefore, pursuant to Article 41(1)(3)(c) of the REACH Regulation, you are requested to submit the following information derived with the registered substance subject to the present decision: Identification of degradation products (Annex IX, Section 9.1.3.; test method as for points 6 and 7 above) of the registered substance.

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

Pursuant to Article 40(3)(d) and (c) of the REACH Regulation, ECHA may reject a proposed test and require the Registrant to carry out other tests in cases of non-compliance of the testing proposal with Annexes IX, X or XI.

"Effects on terrestrial organisms" is a standard information requirement as laid down in Annex IX, Section 9.4. of the REACH Regulation. You must address the standard information requirements set out in Annex IX, Section 9.4., for different taxonomic groups: short-term toxicity testing on invertebrates (Annex IX, Section 9.4.1.), effects on soil micro-organisms (Annex IX, Section 9.4.2.), and short-term toxicity testing on plants (Annex IX, Section 9.4.3.). Furthermore, Annex IX, Section 9.4., column 2 specifies that long-term toxicity testing shall be considered by you, instead of short-term testing, in particular for substances that have a high potential to adsorb to soil or that are very persistent.

The information on "short-term and long-term toxicity to invertebrates" is not available for the registered substance but needs to be present in the technical dossier to meet the information requirements. Consequently there is an information gap and it is necessary to provide information for this endpoint.

You have submitted a testing proposal for a short-term toxicity test on terrestrial invertebrates Earthworm, Acute Toxicity Tests (EU C.8/OECD TG 207) with the following justification: *"The Lead Registrant proposes an OECD 207 to address this endpoint based on the data requirements of REACH Annex IX; the final use of the substance (as part of a product) is as a Fertilizer, therefore exposure to the environmental compartment is likely."*.

ECHA notes that the substance is used as agrochemical and therefore natural soil systems will be subject to direct exposure of the registered substance. Therefore, toxicity to terrestrial invertebrates should be investigated.
Based on information provided in the dossier, the substance appears to have low solubility in water and highly adsorptive properties. Therefore the substance meets the column 2 adaptation criteria of Annex IX, section 9.4. concerning the use of long-term testing instead of short-term. Therefore, considering the properties of the substance, ECHA concludes that only a long-term toxicity test on invertebrates (and not the short-term test) will provide the adequate information.

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. You are to apply the most appropriate and suitable test guideline among those listed above. However, ECHA notes that when log Kow >5 and log Koc >4, the test OECD 232 is not appropriate as the dominant route of exposure for Collembolans is via pore water.

Therefore, pursuant to Article 40(3)(c) of the REACH Regulation, you are required to carry out additionally one of the following studies using the registered substance subject to the present decision: Earthworm reproduction test (*Eisenia fetida/Eisenia andrei*) OECD 222, or Enchytraeid reproduction test OECD 220, or Collembolan reproduction test in soil OECD 232), while the short-term toxicity test on terrestrial invertebrates (OECD 207) is rejected pursuant to Article 40(3)(d) of the REACH Regulation.

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

Pursuant to Article 40(3)(c) of the REACH Regulation, ECHA may require the Registrant to carry out one or more additional tests in case of non-compliance of the testing proposal with Annexes IX, X or XI of the REACH Regulation.

"Effects on terrestrial organisms" is a standard information requirement as laid down in Annex IX, Section 9.4. of the REACH Regulation. You must address the standard information requirements set out in Annex IX, Section 9.4., for different taxonomic groups: short-term toxicity testing on invertebrates (Annex IX, Section 9.4.1.), effects on soil micro-organisms (Annex IX, Section 9.4.2.), and short-term toxicity testing on plants (Annex IX, Section 9.4.3.). Furthermore, Annex IX, Section 9.4., column 2 specifies that long-term toxicity testing shall be considered by you, instead of short-term testing, in particular for substances that have a high potential to adsorb to soil or that are very persistent.

The information on "short-term or long-term toxicity to plants" is not available for the registered substance but needs to be present in the technical dossier to meet the information requirements. Consequently there is an information gap and it is necessary to provide information for this endpoint.

You have proposed to adapt this standard information requirement by considering it being a study scientifically unjustified : "*Phosphoric acid, octadecyl ester is primarily used as an agricultural fertiliser wthin the EU. As such phosphoric acid, octadecyl ester will be applied to agricultural fields for uptake by crops and is expected to be metabolised by plants into biological substances and materials. Based on the historic use of the substance within the fertiliser market, toxicity to plants is not a concern, and therefore waived.*"

ECHA notes that the substance is used as agrochemical and therefore natural soil systems will be subject to direct exposure of the registered substance. Therefore, toxicity to terrestrial plants should be investigated.

Based on the information provided in the dossier the substance appears to have low solubility in water and highly adsorptive properties. High absorbance potential and persistence of the substance indicates the need for long-term testing to be performed (Column 2 of Section 9.4. of Annex IX). No argument has been provided in the dossier as to why, despite the potential to adsorb and persistence of the substance, long-term testing is not appropriate. Therefore ECHA concludes that only a long-term toxicity test on plants (and not the short-term) will provide the necessary useful information. Furthermore, ECHA *Guidance on information requirements and chemical safety assessment* Chapter R10, section R.10.6.2., (version May 2008) allows the potential application of a lower assessment factor (AF) if information on additional long-term terrestrial toxicity test of two trophic levels were available. In contrast, the Guidance does not allow for a lower AF to be applied if information on a short-term study were to become available in addition to the long-term invertebrate study.

Therefore, pursuant to Article 40(3)(c) of the REACH Regulation, you are required to carry out one of the following additional studies using the registered substance subject to the present decision: Terrestrial plants, growth test (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).

Notes for your consideration in relation to Sections 9 and 10 above:

ECHA notes that you have also proposed a toxicity test on fish and you have a request on aquatic invertebrates toxicity test, and the results of these tests may subsequently allow the derivation of $PNEC_{water}$. If the results of the proposed toxicity test on fish and aquatic invertebrates allow the subsequent derivation of a $PNEC_{water}$, 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.

11. Effects on soil micro-organisms: Nitrogen transformation test (Annex IX, Section 9.4.2.)

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

"Effects on terrestrial organisms" is a standard information requirement as laid down in Annex IX, Section 9.4. of the REACH Regulation. You must address the standard information requirements set out in Annex IX, Section 9.4., for different taxonomic groups: short-term toxicity testing on invertebrates (Annex IX, Section 9.4.1.), effects on soil micro-organisms (Annex IX, Section 9.4.2.), and short-term toxicity testing on plants (Annex IX, Section 9.4.3.). Furthermore, Annex IX, Section 9.4., column 2 specifies that long-term toxicity testing shall be considered by you instead of short-term, in particular for substances that have a high potential to adsorb to soil or that are very persistent.

The information on "effects on soil micro-organisms" is not available for the registered substance but needs to be present in the technical dossier to meet the information requirements. Consequently there is an information gap and it is necessary to provide information for this endpoint.

You have submitted a testing proposal for a nitrogen transformation test (OECD Guideline 216) with the following justification: "*An OECD Guideline 216 (Soil Microorganisms: Nitrogen Transformation Test) study is proposed for the substance phosphoric acid, octadecyl ester (CAS number 39471-52-8). The Lead Registrant proposes an OECD 216 to address this endpoint based on the data requirements of REACH Annex IX; the final use of the substance (as part of a product) is as a Fertilizer, therefore exposure to the environmental compartment is likely. The Lead Registrant is a multi-national company with world-wide distribution, therefore, study results will be used to meet the data requirements for multiple regulatory programs.*".

ECHA notes that the substance is used as agrochemical and therefore natural soil systems will be subject to direct exposure of the registered substance. ECHA agrees with your assessment.

Therefore, pursuant to Article 40(3)(a) of the REACH Regulation, you are requested to carry out the proposed test using the registered substance subject to the present decision: Soil microorganisms: nitrogen transformation test, EU C.21/OECD TG 216.

12. Effects on soil micro-organisms: Carbon transformation test (Annex IX, Section 9.4.2.)

Pursuant to Article 40(3)(c) of the REACH Regulation, ECHA may require the Registrant to carry out one or more additional tests in case of non-compliance of the testing proposal with Annexes IX, X or XI of the REACH Regulation.

"Effects on terrestrial organisms" is a standard information requirement as laid down in Annex IX, Section 9.4. of the REACH Regulation. You must address the standard information requirements set out in Annex IX, Section 9.4., for different taxonomic groups: short-term toxicity testing on invertebrates (Annex IX, Section 9.4.1.), effects on soil micro-organisms (Annex IX, Section 9.4.2.), and short-term toxicity testing on plants (Annex IX, Section 9.4.3.).

ECHA notes that the substance is used as agrochemical and therefore natural soil systems will be subject to direct exposure of the registered substance. According to the ECHA Guidance on information requirements and chemical safety assessment, R.7c, R..7.11.3.1., p.112, the nitrogen transformation test (OECD guideline 216) is considered sufficient for most non-agrochemicals, whereas the carbon transformation test (OECD guideline 217) is needed for subtances in agrochemical use. As the substance is applied directly to soil as a fertilizer, ECHA considers this is an agrochemical use and the carbon transformation test is required in addition to the nitrogen transformation test.

Therefore, pursuant to Article 40(3)(c) of the REACH Regulation, you are requested to carry out the following additional test using the registered substance subject to the present decision: Soil microorganisms: carbon transformation test, EU C.22/OECD TG 217.

Notes for your consideration in relation to Sections 11 and 12 above:

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 9.4.3. does not apply for the present endpoint

13. Deadline to submit the requested Information

In the draft decision communicated to you the time indicated to provide the requested information was 24 months from the date of adoption of the decision. In your comments on the draft decision, you stated that "*Due to the difficult nature of testing this substance in aquatic environments, Acta anticipates possible issues with completing the testing within the 24 months specified.*" ECHA notes that the deadline needs to be adjusted to accommodate for the difficult to test properties of the substance. In such cases an extra 6 months can be granted. Therefore, ECHA has set the deadline to 30 months.

Appendix 2: Procedural history

ECHA received your registration containing the testing proposals for examination pursuant to Article 40(1) on 20 November 2013.

ECHA held a third party consultation for the testing proposal(s) from 17 April 2015 until 4 June 2015. ECHA did not receive information from third parties.

This decision does not take into account any updates after **01 July 2016**, e.g. 30 calendar days after the end of the commenting period.

The decision making followed the procedure of Articles 50 and 51 of the REACH Regulation, as described below.

ECHA notified you of the draft decision and invited you to provide comments.
ECHA took into account your comments and amended the deadline.

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 amendments.

ECHA referred the draft decision to the Member State Committee.

Your comments on the proposed amendment(s) were taken into account by the Member State Committee.

In addition, you provided comments on the draft decision. These comments were not taken into account by the Member State Committee as they were considered to be outside of the scope of Article 51(5).

The Member State Committee reached a unanimous agreement on the draft decision in its MSC-50 written procedure and ECHA took the decision according to Article 51(6) of the REACH Regulation.

Appendix 3: Further information, observations and technical guidance

1. This decision does not imply that the information provided in your registration dossier is in compliance with the REACH requirements. The decision does not prevent ECHA from initiating a compliance check on the registration at a later stage.

2. Failure to comply with the request(s) in this decision, or to fulfil otherwise the information requirement(s) with a valid and documented adaptation, will result in a notification to the Enforcement Authorities of the Member States.

3. In carrying out the test(s) required by the present decision it is important to ensure that the particular sample of substance tested 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. If the registration of the substance covers different grades, the sample used for the new test(s) must be suitable to assess these. Furthermore, 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.

4. In case the required test(s) is/are conducted with an analogue substance in the context of a read-across approach, the identity of the test material used to perform the test should be specified in line with the ECHA's Practical Guide 6 "How to report on read-across". This is required to demonstrate that the test material is representative of the analogue substance identified in the read-across approach and used to predict the properties of the registered substance.