Helsinki, 16 December 2016

Addressee: [redacted]

Decision number: TPE-D-2114350076-55-01/F
Substance name: N-octadecylstearamide
EC number: 236-276-6
CAS number: 13276-08-9
Registration number: [redacted]
Submission number: [redacted]
Submission date: 29.09.2015
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.

While your originally proposed test for Pre-natal developmental toxicity study (OECD TG 414), using the analogue substance **Oleyl palmitamide** (CAS no 16260-09-6) is rejected, you are requested to perform:

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

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

2. **Biotic degradation testing**

   a) **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 with the registered substance;**

   b) **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 with the registered substance;**

You are requested to perform as additional test:

c) **Simulation testing on ultimate degradation in surface water (Annex IX, Section 9.2.1.2.; test method: Aerobic mineralisation in surface water – simulation biodegradation test, EU C.25./OECD TG 309) at a temperature of 12°C with the registered substance;**

d) **Including the identification of the degradation products (Annex IX, Section 9.2.3.) by means of one of the above test methods.**

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

3. **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 requested to perform as additional test:

4. **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 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:

5. **Long-term toxicity on terrestrial invertebrates (Annex IX, Section 9.4.1., column 2; test method: Earthworm reproduction test, OECD TG 222) OR Long-term toxicity on terrestrial invertebrates (Annex IX, Section 9.4.1., column 2; test method: Enchytraeid reproduction test, OECD TG 220) using the registered substance.**

You are additionally requested to perform:

6. **Long-term toxicity testing on plants (Annex IX, Section 9.4.3., column 2; test method: Terrestrial plants, growth test, OECD TG 208) OR Long-term toxicity testing on plants (Annex IX, Section 9.4.3., column 2; test method: Soil Quality –Biological Methods – Chronic toxicity in higher plants, ISO 22030) using the registered substance.**

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

7. **Effects on soil micro-organisms**

a) **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 requested to perform as additional test:

b) 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 **3 January 2019**. You shall also update the chemical safety report, where relevant.

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

Appeal

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

Authorised[1] by Leena Ylä-Mononen, Director of Evaluation

[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.

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Appendix 1: Reasons

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

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

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.

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

You have submitted a testing proposal for a pre-natal developmental toxicity study according to OECD TG 414 to be performed with the proposed analogue substance oleyl palmitamide (CAS 16260-09-6; hereinafter referred to as the "source substance").

ECHA has considered first the scientific validity of the read-across hypothesis for the pre-natal developmental toxicity study endpoint before assessing the testing proposed.

Grouping of substances and read-across

Article 13(1) of the REACH Regulation requires information on intrinsic properties of substances on human toxicity to be generated whenever possible by means other than vertebrate animal tests, including from information from structurally related substances (grouping or read-across), *"provided that the conditions set out in Annex XI are met"*.

According to Annex XI, Section 1.5., there needs to be structural similarity among the substances within a group or a category and furthermore, it is required that the relevant properties of a substance within the group can be predicted from the data for reference substance(s) by interpolation, and the data should be adequate for the purpose of classification and labelling and/or risk assessment. Furthermore, Annex XI, Section 1.5. lists several additional requirements, including that adequate and reliable documentation of the applied method is to be provided.

Under developmental toxicity endpoint of IUCLID dossier and respective section of the Chemical Safety Report (CSR) you have outlined the read-across hypothesis and justification with general statements such as:

- *"The registration of n- octadecylstearamide, UVCB (CAS RN 13276-08-9) employs a combined approach for addressing the required endpoints. The required endpoints are addressed using data on the substance subject to registration, n-octadecylstearamide, UVCB, when available."*
- *"Oleyl palmitate is a C16 fatty amide with a C18 unsaturated amine. The chain lengths are within the C16-18 range of n- octadecylstearamide, UVCB. The sole difference is the unsaturation in the C18 chain."*

- *"These substances are structurally similar to n-octadecylstearamide, UVCB, the target substance subject to registration. The substance and the proposed structural analogues are predominantly C32 – C40 secondary alkanamides. These substances are expected to be metabolised by fatty acid amide hydrolase and esterases. Any differences among the substance structures are not expected to result in any significant differences in the toxicological effects or degradation products."*
- *"A read across matrix is appended to provide further information on read across justification."*

ECHA notes that no read-across justification document was provided.

ECHA notes further that the above statements are not sufficient to justify the read-across approach for the following reasons:

Structural similarity and dissimilarity

Apart from the identified structural dissimilarity (i.e. unsaturation in the C18 chain), the differences in structure and composition between the target (registered) and source substances have not been established (UVCB and mono constituent substances, respectively). Furthermore, the composition or impurity profile of the suggested source substance is not reported in the technical dossier.

Therefore, ECHA considers that you have not addressed the structural differences between the target (registered) and the source substance and you did not explain why those differences would not lead to differences in the toxicity profile of target (registered) and source substances.

Toxicokinetic properties

ECHA notes that no toxicokinetic information or hydrolysis data of the target (registered) substance and the source substance have been provided.

Toxicological data

ECHA notes that you have not explained how predicting the developmental toxicity of the registered substance would be possible based on the provided supporting information. Furthermore, ECHA notes that no higher tier studies have been provided for the target (registered) and source substance.

Therefore, ECHA considers that the systemic toxicity profiles of the registered and the source substances, in general, cannot be compared and that further prediction of the developmental toxicity of the registered substance is not possible.

Conclusion of your read-across adaptation

The proposed adaptation of the standard information requirements for a pre-natal developmental toxicity study (Annex IX, Section 8.7.2.) in a first species in the technical dossier is based on the proposed read-across approach examined above. ECHA considers that you did not provide sufficient information to establish a basis whereby relevant human health properties of the target (registered) substance may be predicted from source substance data.

In the comments on the draft decision, you have provided the following information:

> [redacted] *wishes to clarify its proposed read-across approach and asks ECHA to reconsider* [redacted] *proposed approach for addressing this study requirement.* [redacted] *clarifies that the analogue substance is part of a separate registration and that* [redacted] *is working cooperatively with the lead registrant of the analogue substance as its testing proposal for an OECD TG 414 study is being reviewed by ECHA. At this time,* [redacted] *is unaware of the status of the testing proposal for the analogue substance, but asks ECHA to defer a final decision on the testing proposal for the subject substance until a final decision on the testing proposal for the proposed analog source substance is taken.*
>
> [redacted] *intends to build a robust justification for using read-across from the OECD TG 414 study on the analogue substance in support of its registered substance.* [redacted] *provides below further details in support of a read-across approach as an alternative to testing the registered substance. This approach is in accordance with Article 13(1) of the REACH Regulation, as it provides information on intrinsic properties by means other than testing and reduces the number of tests to be performed using vertebrate animals, in accordance with Article 25.*
>
> *As detailed in the confidential description of the registered substance, N-octadecylstearaminde is a UVCB consisting of* [redacted] *constituents:* [redacted] *All constituents* [redacted] *Each* [redacted] *The proposed analogue substance, oleyl palmitamide, is a mono-constituent substance that is also* [redacted]*. The primary difference between the registered substance and the analogue substance is the unsaturation in the C18 chain.*
>
> *The published literature supports the metabolism in mammals of both the source and target substances in a manner common to secondary fatty acid amides. This includes hydrolysis into fatty acids and amines by fatty acid amide hydrolase (FAAH), with further metabolism for the resulting fatty acid and amine moieties. Metabolism of fatty acids to acetyl CoA, primarily by β-oxidation, and of the amines to carboxylic acids or alcohols are well established.*

ECHA notes that the information on the read-across approach as provided within the comments does not address the shortcomings listed above by ECHA. More specifically, the reference to "published literature" is not sufficient to adequately justify the approach as you have the obligation to make the information available in your dossier. ECHA notes that you did not update your registration dossier accordingly with new information including an appropriate read-across justification by 27 July 2016. ECHA informed you in the notification letter of 18 May 2016 that it will examine any later updates only after expiry of the date given in the adopted decision for providing the missing information.

ECHA considers that the explanations concerning the missing information on the strutrural, toxikinetic and toxicological dissimilarities provided above have not adequately been addressed and are still valid, thus the read-across approach as currently provided in the dossier cannot be accepted.

In the absence of further information supporting the proposed read-across approach, ECHA is not in a position to evaluate the proposed read-across adaptation according to REACH Annex XI, Section 1.5. which could allow establishing that relevant properties of the registered substance can be predicted from those of the source substance. The proposed read-across has therefore to be rejected as not acceptable. Accordingly, it is necessary to perform testing on 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.

Testing required

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.

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)(c) of the REACH Regulation, you are requested to carry out the following 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). Your originally proposed test for Pre-natal developmental toxicity study (EU B.31./OECD TG 414) oral route, using the analogue substance Oleyl palmitamide (CAS 16260-09-6) is rejected according to Article 40(3)(d) of the REACH Regulation.

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.

2. Biotic degradation (Annex IX, Section 9.2.1.)

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

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

"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. As the substance has a high potential for adsorption to soil, soil simulation testing is a standard information requirement for the substance. 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 for an aerobic and anaerobic transformation in soil simulation biodegradation study (OECD TG 307 / EU C.23) with the following justification:
'An OECD Guideline 307 (Aerobic Soil Metabolism Study in Four Soils) study is proposed for the substance n-octadecylstearamide, UVCB (CAS RN 13276-08-9).
The Lead Registrant proposes to conduct an OECD 307 study to address loss or transformation in the environment due to the use pattern of end products containing n-octadecylstearamide, UVCB.
The non-European Union (non-EU) manufacturer, represented in the EU by 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 considers that the proposed study is appropriate to fulfil the information requirement of Annex IX, Section 9.2.1.3. of the REACH regulation. The information currently available in the technical dossier and the Chemical Safety Assessment (CSA) is not sufficient to conclude on the biodegradation potential and consequently the persistence of the registered substance or its degradation products in the soil compartment and thus, it is necessary to generate additional information for this endpoint.

ECHA notes that the information from the simulation study may also be needed for the purposes of the PBT, vPvB assessment as based on available information in the technical dossier and the CSA the PBT, vPvB status of registered substance is unclear.

In the testing proposal you have not specified the temperature at which the test shall be performed. One of the purposes of the simulation test is to provide the information that must be considered for assessing the P/vP properties of the registered substance in accordance with Annex XIII of REACH regulation to decide whether it is persistent in the environment. Annex XIII also indicates that "*the information used for the purposes of assessment of the PBT/vPvB properties shall be based on data obtained under relevant conditions*". The Guidance on information requirements and chemical safety assessment R.7b (version 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.16-9 (version 2.1 October 2012) 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.

Simulation tests performed in sediment or in soil possibly imply the formation of non-extractable residues (NER). These residues (of the parent substance and/or transformation products) are bound to the soil or to the sediment particles. NERs may potentially be re-mobilised as parent substance or transformation product unless they are irreversibly bound by covalent bonds or incorporated into the biomass. The amount and kind of NER is operationally defined by the extraction method employed.

Strong extractions methods, for example soxhlet-extraction with apolar solvents, should be used in order to qualify the remaining NER as irreversibly bound residues. You are therefore requested to justify scientifically that the extraction method you will apply is appropriate to identify non-extractable residues (NER) as residues irreversibility bound to the soil.

In the comments on the draft decision, you have provided the following information:

[...] "[redacted] *agrees to carry out the following proposed studies once a final decision is adopted:*

- *Soil simulation testing aerobic and anaerobic transformation in soil at a temperature of 12°C with identification of degradation products when practicable (Aerobic and anaerobic transformation in aquatic sediment systems, EC Method C.24/OECD Guideline No. 308)".* [...]

Therefore, pursuant to Article 40(3)(a) of the REACH Regulation, you are requested to carry out the proposed 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.

Notes for your consideration

In accordance with Annex I, Section 4, of the REACH Regulation you should revise the PBT assessment when results of the test detailed above is available. You are also advised to consult the ECHA Guidance on information requirements and chemical safety assessment (version 2.0, November 2014), Chapter R.11.1.3. and Figure R. 11-1 on PBT assessment for the integrated testing strategy for persistency assessment in particular taking into account the degradation products of the registered substance, and the order in which the simulation studies requested should be performed to best assess the persistency of the substance.

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

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

"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. As the substance has a high potential for adsorption to sediment, sediment simulation testing is a standard information requirement for the substance. 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 testing the registered substance in a Sediment simulation testing (OECD TG 308 / EU C.24) with the following justification: *An OECD Guideline 308 (Aerobic Degradation and Metabolism in Aquatic System) study is proposed for the substance n-octadecylstearamide, UVCB (CAS RN 13276-08-9).*
The Lead Registrant proposes to conduct an OECD 308 study to address potential loss or transformation in the environment due to the use pattern of end products containing n-octadecylstearamide, UVCB.
The non-European Union (non-EU) manufacturer, represented in the EU by 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 considers that the proposed study is appropriate to fulfil the information requirement of Annex IX, Section 9.2.1.2. of the REACH Regulation.

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

ECHA notes that the information from the simulation study may also be needed for the purposes of the PBT, vPvB assessment as based on available information in the technical dossier and the CSA the PBT, vPvB status of registered substance is unclear.

In the testing proposal you have not specified the temperature at which the test shall be performed. One of the purposes of the simulation test is to provide the information that must be considered for assessing the P/vP properties of the registered substance in accordance with Annex XIII of REACH regulation to decide whether it is persistent in the environment. Annex XIII also indicates that "*the information used for the purposes of assessment of the PBT/vPvB properties shall be based on data obtained under relevant conditions*".

The Guidance on information requirements and chemical safety assessment R.7b (version 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.16-9 (version 2.1 October 2012) 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.

Simulation tests performed in sediment or in soil possibly imply the formation of non-extractable residues (NER). These residues (of the parent substance and/or transformation products) are bound to the soil or to the sediment particles. NERs may potentially be re-mobilised as parent substance or transformation product unless they are irreversibly bound by covalent bonds or incorporated into the biomass. The amount and kind of NER is operationally defined by the extraction method employed. Strong extractions methods, for example soxhlet-extraction with apolar solvents, should be used in order to qualify the remaining NER as irreversibly bound residues. You are therefore requested to justify scientifically that the extraction method you will apply is appropriate to identify non-extractable residues (NER) as residues irreversibility bound to the sediment.

In the comments on the draft decision, you have provided the following information:

[...] "[redacted] *agrees to carry out the following proposed studies once a final decision is adopted:*

- *Sediment simulation testing aerobic and anaerobic transformation in aquatic sediment systems at a temperature of 12°C with identification of degradation products when practicable (Aerobic and anaerobic transformation in aquatic sediment systems, EC Method C.24/OECD Guideline No. 308).*" [...]

Therefore, pursuant to Article 40(3)(a) of the REACH Regulation, you are requested to carry out the proposed 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.) at a temperature of 12°C.

Notes for your consideration

In accordance with Annex I, Section 4, of the REACH Regulation you should revise the PBT assessment when results of the test detailed above is available. You are also advised to consult the ECHA Guidance on information requirements and chemical safety assessment (version 2.0, November 2014), Chapter R.11.1.3. and Figure R. 11-1 on PBT assessment for the integrated testing strategy for persistency assessment in particular taking into account the degradation products of the registered substance, and the order in which the simulation studies requested should be performed to best assess the persistency of the substance.

c) Simulation testing on ultimate degradation in surface water (Annex IX, Section 9.2.1.2)

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

"Simulation testing on ultimate degradation in surface water" is a standard information requirement as laid down in Annex IX, Section 9.2.1.2. of the REACH Regulation. The information on this endpoint is not available for the registered substance but needs to be present in the technical dossier to meet the information requirements.

You have not provided any study record of simulation testing on ultimate degradation in water in the dossier that would meet the information requirement of Annex IX, Section 9.2.1.2. The technical dossier does also not contain an adaptation in accordance with column 2 of Annex IX, Section 9.2.1.2. or with the general rules of Annex XI for this standard information requirement.

The information currently available in the technical dossier and the CSA is not sufficient to conclude on the biodegradation potential and consequently the persistence of the registered substance or its degradation products in the aquatic compartment and thus, it is necessary to generate additional information for this endpoint. ECHA notes that the OECD 309 study is the preferred method for concluding on the persistency of a substance.

ECHA notes that the information from the simulation study may also be needed for the purposes of the PBT, vPvB assessment as based on available information in the technical dossier and the CSA the PBT, vPvB status of registered substance is unclear.

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

According to ECHA *Guidance on information requirements and chemical safety assessment, Chapter R.7b* (version 3.0, February 2016) Aerobic mineralisation in surface water – simulation biodegradation (test method EU C.25. / OECD TG 309) is the preferred test to cover the standard information requirement of Annex IX, Section 9.2.1.2.

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.16-9 (version 2.1 October 2012) indicates 12°C (285K) as the average environmental temperature for the EU to be used in the chemical safety assessment. Performing the test at the temperature of 12°C is within the applicable test conditions of the Test Guideline OECD TG 309. Therefore, the test should be performed at the temperature of 12°C.

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

Therefore, pursuant to Article 41(1) and (3) of the REACH Regulation, you are requested to submit the following information derived with the registered substance subject to the present decision: Aerobic mineralisation in surface water – simulation biodegradation test (test method: EU C.25./OECD TG 309).

Notes for your consideration

In accordance with Annex I, Section 4, of the REACH Regulation you should revise the PBT assessment when results of the test detailed above is available. You are also advised to consult the ECHA Guidance on information requirements and chemical safety assessment (version 2.0, November 2014), Chapter R.11.1.3. and Figure R. 11-1 on PBT assessment for the integrated testing strategy for persistency assessment in particular taking into account the degradation products of the registered substance, and the order in which the simulation studies requested should be performed to best assess the persistency of the substance.

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

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

According to Section 9.2.3 in Annex IX of the REACH Regulation identification of degradation products is a standard information requirement. You have not justified an adaptation of this requirement.

As explained fully in sections 2. a) to c) 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.

Consequently there is an information gap and it is necessary to provide information for this information requirement. The identification of degradation products should therefore be included in the requested degradation simulation tests. It is also noted that the OECD TG 307, OECD TG 308 and OECD TG 309 Test Guidelines feature the formation and identification of the degradation products.

Notes for your consideration

In accordance with Annex I, Section 4, of the REACH Regulation you should revise the PBT assessment when results of the tests detailed above is available. You are also advised to consult the ECHA Guidance on information requirements and chemical safety assessment (version 2.0, November 2014), Chapter R.11.1.3. and Figure R. 11-1 on PBT assessment for the integrated testing strategy for persistency assessment in particular taking into account the degradation products of the registered substance.

3. and 4. Fish, early-life stage (FELS) toxicity test (Annex IX, Section 9.1.6.1.) and Long-term toxicity testing on aquatic invertebrates (Annex IX, Section 9.1.5.)

Pursuant to Article 40(3)(a) of the REACH Regulation, ECHA may require the Registrant to carry out the proposed test, i.e. long-term toxicity testing on fish. In addition, 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 fish" and "Long-term toxicity testing on aquatic invertebrates" are standard information requirement as laid down in Annex IX, Sections 9.1.6. and 9.1.5., column 1, of the REACH Regulation respectively.

You have submitted a testing proposal for testing the registered substance for long-term toxicity testing on fish, OECD 210 with the following justification: *"An OECD 210 (Fish, Early-Life Stage Toxicity Test) study with fathead minnow (Pimephales promelas) is proposed for the substance n-octadecylstearamide, UVCB (CAS RN 13276-08-9).*
The Lead Registrant proposes to conduct an OECD 210 study to address the fish toxicity endpoint based on the data requirements of REACH Annex IX and in place of an OECD 203 (Fish, Acute Toxicity) study required according to Annex VIII. According to Column 2 of Annex VIII, a long-term toxicity to fish study should be considered if the substance is water insoluble; the water solubility of n-octadecylstearamide, UVCB, is less than 0.05 mg/L. This alternate study design covers several life stages of the fish, from hatch of the newly fertilized eggs through early growth stages, and is considered the most sensitive of the fish tests.
The non-European Union (non-EU) manufacturer, represented in the EU by 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 considers that there is an information gap and it is necessary to provide information for this endpoint. The proposed study is appropriate to fulfil the information requirement of Annex IX, Section 9.1.6 of the REACH Regulation.

ECHA notes that you have not submitted a testing proposal on a "Long-term toxicity testing on invertebrates", which is a standard information requirement as laid down in Annex IX, Section 9.1.5., column 1 of the REACH Regulation. Instead you have provided the following justification: "*According to 9.1.Column 2 of Annex IX of of Regulation (EC) 1907/2006 concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH) the long-term toxicity testing on aquatic invertebrates is proposed if the chemical safety assessment indicates the need to investigate further the effects on aquatic organisms; the choice of appropriate test depends on the results of the chemical safety assessment. Due to the very low water solubility of (less than 0.0506 mg/L), a Fish early life stage (FELS) toxicity study is proposed to address fish toxicity in place of a short term fish toxicity study. In addition, due to the mitigating factors indicating that aquatic toxicity is unlikely to occur, very low water solubilityer and the short term toxicity to aquatic invertebrate result of EL50 WAF greater than 100 mg/L, aquatic toxicity is unlikely to occur. Given the proposed study and the lack of toxicity, chronic testing to aquatic invertebrates is waived.*"

ECHA points out that long-term toxicity testing on invertebrates is indeed a standard information requirement of Annex IX, Section 9.1.5., column 1 of the REACH Regulation. In addition, ECHA notes that the water solubility of the registered substance is low and considers that the substance is poorly water soluble. Due to the low solubility of the registered substance, the short-term toxicity testing with aquatic invertebrates would not be relevant and conclusive. Therefore, ECHA considers that it is necessary to provide information on long-term toxicity with invertebrates and, consequently, there is an information gap for the long-term toxicity testing on aquatic invertebrates (Annex IX, Section 9.1.5. of the REACH Regulation). Thus, your justification for adaptation does not meet the criteria of either the specific adaptation rules of Column 2 of Annex IX, section 9.1.5. or of the general adaptation rules of Annex XI.

ECHA notes that no information on short or long-term toxicity to fish is available in the registration dossier. In the absence of information on short-term toxicity to fish, it cannot be concluded if fish or invertebrates or algae/aquatic plants are shown to be substantially more sensitive.

In the comments on the draft decision, you have provided the following information:

[...] "[redacted] *agrees to carry out the following proposed studies once a final decision is adopted:*

- *Long-term toxicity testing on fish (Fish, early-life stage (FELS) toxicity test, OECD Guideline No. 210).* "[...] and [...] "[redacted] *is considering ECHA's comments regarding the following requested data and agrees to complete the requested studies once the final decision is adopted:*
- *Long-term toxicity testing on aquatic invertebrates (Daphnia magna reproduction test, EC Method C.20/OECD Guideline No. 211).*" [...]

Therefore, pursuant to Article 40(3)(a) and (c)of the REACH Regulation, you are requested to carry out the following studies 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 210) and Long-term toxicity testing on aquatic invertebrates (Annex IX, 9.1.5.; test method: *Daphnia magna* reproduction test, EU C.20/OECD 211).

Notes for your consideration

Due to the low solubility of the substance in water you should consult OECD Guidance Document on Aquatic Toxicity Testing of Difficult Substances and Mixtures, ENV/JM/MONO (2000)6 and ECHA Guidance, 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 this test.

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

The information on "short-term and long-term toxicity to terrestrial 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: *"An OECD Guideline 207 (Earthworm, Acute Toxicity Tests) study is proposed for the substance n-octadecylstearamide, UVCB (CAS RN RN 13276-08-9).*
The Lead Registrant proposes to conduct an OECD 207 study with Eisenia fetida to address potential exposure to soil-dwelling organisms due to the use pattern of end products containing n-octadecylstearamide, UVCB.
The non-European Union (non-EU) manufacturer, represented in the EU by 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."

However, according to section R.7.11.5.3., Chapter R.7c of the ECHA *Guidance on information requirements and chemical safety assessment* (version 2.0, November 2014), substances that are ionisable or have a log K_{ow}/K_{oc} >5 are considered highly adsorptive, whereas substances with a half-life >180 days are considered very persistent in soil. ECHA notes that, according to the evidence presented within the Registration dossier, the substance has a high potential to adsorb to soil ($logK_{ow}$ is 6,5) and is considered very persistent which is default setting for not readily biodegradable substances, when value of the half-life in soil is not available and therefore 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) 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, as in this case, the test OECD 232 is not appropriate as the dominant route of exposure for Collembolans is via pore water.

In the comments on the draft decision, you have provided the following information:

[...] "[redacted] *is considering ECHA's comments regarding the following requested data and agrees to complete the requested studies once the final decision is adopted:*

Long-term toxicity testing on terrestrial invertebrates (Earthworm reproduction test, OECD Guideline No. 222)". [...]

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: Earthworm reproduction test (*Eisenia fetida/Eisenia andrei*) OECD 222, or Enchytraeid reproduction test OECD 220, while the proposed short-term toxicity test on terrestrial invertebrates (OECD 207) is rejected pursuant to Article 40(3)(d) of the REACH Regulation.

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

The information on "short-term or long-term toxicity to terrestrial plants" is not available for the registered substance but needs to be present in the technical dossier to meet the information requirements. The test required by ECHA under point (5) above is not sufficient by itself to address the standard information requirements of Annex IX, section 9.4.3.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 with the following justification: *"According to 9.4.Column 2 of Annex IX of Regulation (EC) 1907/2006 concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH) a short term toxicity to plants does not need to be conducted if direct or indirect exposure to the soil compartment is unlikely. In addition, in the absence of toxicity for soil organisms, the equilibrium partitioning method may be applied to assess the hazard to soil organisms; the choice of the appropriate test depends on the outcome of the Chemical Safety Assessment. Although soil exposure is likely given n-octadecylstearamide, UVCB (CAS RN 13276-08-9) is primarily used as a dedusting agent on agricultural fertilisers within the EU and will be available as a dedusting agent (coating) for potential uptake by crops and is expected to be metabolised by plants into biological substances and materials, based on the historic use of the substance as a dedusting agent (coating) within the fertiliser market and the low soil mobility (log Koc greater than or equal to 5.63), plant toxicity is not considered a concern and testing is waived."*

You have considered that it is unfeasible, with the currently available information, to derive a PNEC for aquatic organisms. Consequently, it is not possible to adapt the standard information requirements for the terrestrial compartment through an initial screening assessment based upon the Equilibrium Partitioning Method (EPM), mentioned in Column 2 of Annex IX, section 9.4. Consequently there is an information gap and it is necessary to provide information for the standard information requirement of Annex IX, Section 9.4.3.

Based on the substance properties as discussed under point (1) above, ECHA considers that the substance has a high potential to adsorb to soil (the value for logK_{ow} is 6,5) and is very persistent, which is default setting for not readily biodegradable substances, when value of the half-life in soil is not available. Moreover, the substance has intended releases to the environment as it is primarily used as a dedusting agent on agriculturul fertilisers. 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.

In the comments on the draft decision, you have provided the following information:

[...] "[redacted] *is considering ECHA's comments regarding the following requested data and agrees to complete the requested studies once the final decision is adopted:*

- *Long-term toxicity testing on terrestrial plants (Terrestrial plant test: seedling emergence and seedling growth test, OECD Guideline No. 208 with at least six species tested, including a minimum of two monocotyledonous species and four dicotyledonous species)".* [...]

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).

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

Pursuant to Article 40(3)(a) of the REACH Regulation, ECHA may require the Registrant to carry out the proposed test. In addition, 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. The Registrant must address the standard information requirements set out in Annex IX, Section 9.4., for different taxonomic groups: short-term toxicity testing on invertebrates (Annex IX, Section 9.4.1.), effects on soil micro-organisms (Annex IX, Section 9.4.2.), and short-term toxicity testing on plants (Annex IX, Section 9.4.3.).

You have submitted a testing proposal for testing the registered substance for effects on soil microorganisms, EU C.21/OECD 216 with the following justification: "*An OECD Guideline 216 (Soil Microorganisms: Nitrogen Transformation Test) study is proposed for the substance n-octadecylstearamide, UVCB (CAS RN RN 13276-08-9).*
The Lead Registrant proposes to conduct an OECD 216 study to address potential effects on nitrogen mineralization and nitrification in soils due to the use pattern of end products containing n-octadecylstearamide, UVCB.
The non-European Union (non-EU) manufacturer, represented in the EU by 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."

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.

ECHA notes that the tests required under points 5 and 6 above and the test proposed in this point alone are not sufficient to address this standard information requirement. ECHA concludes that the effects on soil microorganisms need to be ascertained by performing a relevant test.

According to ECHA *Guidance on information requirements and chemical safety assessment,* Chapter R.7c (version 2.0, November 2014) "*The carbon and nitrogen transformation tests are both designed to detect long-term adverse effects of a substance on the process of carbon or nitrogen transformation in aerobic soils over at least 28 days. For most non-agrochemicals the nitrogen transformation test is considered sufficient as nitrate transformation takes place subsequent to the degradation of carbon-nitrogen bonds.*"

As the substance has an intended use in agrochemicals, ECHA considers that the proposed study alone is not appropriate to fulfil the information requirement of Annex IX, Section 9.1.5 of the REACH Regulation.

To address this endpoint, both a nitrogen transformation test (test method: EU C.21/OECD TG 216) and a carbon transformation test (test method: EU C.22/OECD TG 217) should be performed. According to Section R.7.11.3.1, Chapter R.7c of the ECHA *Guidance on information requirements and chemical safety assessment* (version 2.0, November 2014), ECHA considers the nitrogen transformation test (EU C.21/OECD TG 216) suitable for non-agrochemicals. For agrochemicals the carbon transformation test (EU: C.22/OECD TG 217) is also required.

In the comments on the draft decision, you have provided the following information:

[...] "[redacted] *agrees to carry out the following proposed studies once a final decision is adopted:*
Effects on soil microorganisms:

- *Nitrogen transformation (Soil microorganisms: nitrogen transformation test, EC Method C.21/OECD Guideline No. 216); and*

- *Carbon transformation (Soil microorganisms: carbon transformation test, EC Method C.22/OECD Guideline No. 217."* [...]

Therefore, pursuant to Article 40(3) (a) and (c) of the REACH Regulation, you are requested to carry out the following proposed and additional tests using the registered substance subject to the present decision: Soil microorganisms: nitrogen transformation test, EU C.21/OECD TG 216 **and** carbon transformation test, EU C.22/OECD TG 217.

8. Deadline to submit the requested information

In the draft decision communicated to you, the time indicated to provide the requested information was 18 months from the date of adoption of the decision. In your comments on the draft decision, you requested an extension of the timeline to 24 months due to the limited laboratory space for testing this substance in aquatic environments. ECHA acknowledges the limited capacities and therefore grants the extension of the deadline to 24 months.

Appendix 2: Procedural history

ECHA received your registration containing the testing proposal(s) for examination pursuant to Article 40(1) on 3 June 2014.

ECHA held a third party consultation for the testing proposal(s) from 17 April 2015 until 2 June 2015. ECHA did not receive information from third parties.

This decision does not take into account any updates after **27 July 2016**, 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 on 18 May 2016 and invited you to provide comments.

On 26 June 2016, ECHA received your comments a) agreeing to requests 2-7 in the draft decision, b) on the read across from a pre-natal developmental toxicity study on oleyl palmitamide and c) requesting an extension of the timeline for provision of the information from 18 to 24 months.

The ECHA Secretariat considered your comments.

As a result, ECHA amended the deadline for providing the information and changed Appendix 1 (Reasons).

ECHA notified the draft decision on 8 September 2016 to the competent authorities of the Member States for proposals 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.

The Member State Committee reached a unanimous agreement on the draft decision in its MSC-51 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.