EUROPEAN CHEMICALS AGENCY

Helsinki, 22 November 2017

Addressee: [redacted]

Decision number: CCH-D-2114375500-55-01/F
Substance name: (Z)-N-OCTADECYLDOCOS-13-ENAMIDE
EC number: 233-226-5
CAS number: 10094-45-8
Registration number: [redacted]
Submission number: [redacted]
Submission date: 11.06.2015
Registered tonnage band: 100-1000T

## DECISION ON A COMPLIANCE CHECK

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

1. **Name or other identifier (Annex VI, Section 2.1.) of the registered substance;**

2. **Composition (Annex VI, Section 2.3.) of the registered substance;**
   - **Identification and quantification of the impurities;**

3. **Screening for reproductive/developmental toxicity (Annex VIII, Section 8.7.1.; test method: OECD 421/422) in rats, oral route with the registered substance;**

4. **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 with the registered substance;**

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) with the registered substance;**

6. **Long-term toxicity testing on fish (Annex IX, Section 9.1.6.1.; test method: Fish, early-life stage (FELS) toxicity test, OECD TG 210) with the registered substance;**

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 with the registered substance;**

8. **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;**

9. **Identification of degradation products (Annex IX, 9.2.3.) using an appropriate test method with the registered substance;**

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

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

You are required to submit the requested information in an updated registration dossier by **29 November 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 Kevin Pollard, Head of Unit, Evaluation E1.

[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**

**COMPOSITION OF THE SUBSTANCE**

**1. Name or other identifier of the substance (Annex VI, Section 2.1.)**

Pursuant to Article 10(a)(ii) of the REACH Regulation, the technical dossier shall contain information on the identity of the substance as specified in Annex VI, Section 2 of the REACH Regulation. In accordance with Annex VI, Section 2 the information provided shall be sufficient to enable the identification of the registered substance.

Annex VI section 2 of the REACH Regulation requires that each registration dossier contains sufficient information to enable the registered substance to be identified. Therefore, the identifiers used in a registration must be consistent.

According to chapter 4.2.2 of the Guidance for identification and naming of substances under REACH and CLP (Version: 2.0, December 2016) - referred to as "the SID Guidance" thereinafter, a mono-constituent substance is a substance in which one constituent is present at a concentration of at least 80% (w/w) and which contains up to 20% (w/w) of impurities. In contrast, a multi-constituent substance is a substance defined by its composition, for which more than one main constituent is present at a concentration ≥ 10% (w/w) and < 80% (w/w). A mono-constituent substance and a multi-constituent substance are different substances under REACH.

ECHA notes that on the one hand the provided EC number, CAS entry, SMILES notation and the structural formula provided in section 1.1 of the IUCLID dossier refer to mono-constituent substance "(Z)-N-octadecyldocos-13-enamide".

Furthermore, ECHA notes that you have indicated that the type of substance is "mono-constituent substance" in the Composition-field in section 1.1.

On the other hand the provided IUPAC name "N-octadecyldocos-13-enamide" and the InChI code refer to a multi-constituent substance consisting of [redacted] and [redacted] as main constituents.

Given that some of the identifiers refer to a mono-constituent substance "(Z)-N-octadecyldocos-13-enamide"and others refer to a multi-constituent substance consisting of [redacted] as main constituents, you have not used consistent substance identifiers in the naming and identification of your substance.

Therefore you are requested to update the substance identifiers such that all identifier are consistent.

Regarding how to report the identifiers of the substance, the information shall be included in the reference substance assigned in IUCLID section 1.1.

You shall ensure to select the "type of substance" corresponding to the substance subject to this registration from the appropriate dropdown list in section 1.1 of the IUCLID dossier. You shall ensure that the correct identifiers are used throughout the registration whenever reference to the specific substance which is the subject of this registration is made.

If your substance refers to the mono-constituent substance "(Z)-N-octadecyldocos-13-enamide" then please revise the IUPAC name and the InChI code such that they describe the specific Z isomer.

However, if you select "multi-constituent substance" as type of substance, you shall, for technical reasons, do the following in section 1.2 of the IUCLID dossier:

- Include the following statement in the "Brief description" field of the composition currently reported in section 1.2 of the IUCLID dossier: "This composition block does not describe the registered multi-constituent substance and is reported only for technical reasons"; and

- Create a second composition block describing the composition of the multi-constituent substance. For this second composition, ECHA reminds that all the main constituents shall be listed under the "Constituents" header.

If the current identifiers are not appropriate to describe the registered substance, you should not remove or modify at this stage this EC entry for technical reasons, the registration being linked to that EC entry in REACH-IT. To ensure unambiguous identification of the registered substance, you should however indicate, in the "Remarks" field of the reference substance in IUCLID section 1.1, the following: "The EC number 233-226-5 currently assigned does not specifically correspond to the registered substance. This identifier cannot be modified or deleted at this stage in the present registration update for technical reasons". You should also specify, in the same "Remarks" field, any available and appropriate EC number for the substance. Any available CAS entry for the registered substance should be reported under the "CAS information" header of the reference substance in IUCLID section 1.1.

You should note that ECHA has established a process, subject to certain conditions, enabling registrants to adapt the EC identifier of an existing registration, while maintaining the regulatory rights already conferred to the substance concerned.

Pending the resolution of the non-compliances addressed in the present decision, any possible adaptation of the identifier can only become effective once ECHA is in a position to establish unambiguously the identity of the substance intended to be covered by you with this registration. Should the information submitted by you as a result of the present decision enable ECHA to identify the substance unambiguously and result in a need to modify the identifier of the substance, the process of adapting the identifier will be considered relevant. In that case, ECHA will inform you in due time as to when and how the identifier adaptation process shall be initiated.

In any case, you should note that the application of the process of adapting the identifier does not affect your obligation to fulfil the requirements specified in this decision.

In your comments to the draft decision you indicated that you will update your registration dossier and outlined how you intend to address the information requirement, name and other identifiers of the substance (Annex VI, Section 2.1). When you will be preparing the dossier update, ECHA can already point out the following:

You intend to update the description to a UVCB substance and to identify and quantify the composition of the UVCB for known constituents above 10%.

Please note that the "OECD Guidance for characterising oleochemical substances for assessment purposes" (available on the following website: http://www.oecd.org/officialdocuments/publicdisplaydocumentpdf/?cote=env/jm/mono(2014)6&doclanguage=en ) states on page 10 the following: "Substances derived from natural fats or oils (or synthetic sources) are UVCBs due to their variation in the carbon chain length distribution. However, if one constituent with a specific and defined alkyl chain is present at a minimum concentration of 80 %, the substance is considered a well-defined substance and not as an oleochemical UVCB substance."

Furthermore, you have provided in your IUCLID dossier the following information on the manufacturing process: "[redacted]." ECHA notes that according to the literature, naturally occurring fatty acids occur mainly in the cis-configuration. Therefore, if the [redacted] starting material is derived from naturally occurring fatty acid, it is expected that your substance contains mainly the Z isomer (*c.f.* Anneken, D.,Sabine,B., Christoph,R., Fieg,G.,.Steinberne,U., and Westfechte, A. "Fatty Acids" in Ullmann's Encyclopedia of Industrial Chemistry 2006, Wiley-VCH, Weinheim. doi:10.1002/14356007.a10_245.pub2 (chapter 3.4.2.(page 100))).

Please note that if one constituent (such as the Z isomer) is present at a concentration of at least 80% (w/w) and your substance contains up to 20% (w/w) of impurities your substance would be regarded as a mono-constituent substance. If more than one main constituent is present at a concentration ≥ 10% (w/w) and < 80% (w/w) (such as the Z and E isomers), your substance should be regarded as a multi-constituent substance.

If the inherent variability in the composition is large or poorly predictable, the above conditions do not apply to your substance, and you consider your substance falls within the definition of UVCB substances as specified in chapter 4.3 of the SID Guidance you are requested to provide the following information:

Information required to be provided according to Annex VI section 2.1 of the REACH Regulation on the naming of UVCB substances shall consist of two parts: (i) the chemical name and (ii) a more detailed description of the manufacturing process, as indicated in the SID guidance.

(i) The chemical name "N-octadecyldocos-13-enamide" provided in the IUPAC name field of the reference substance in IUCLID section 1.1 and the other substance identifier provided in the same reference substance describe a well-defined substance.

Therefore, if you consider your substance as a UVCB substance you are required to revise the chemical name included in the "IUPAC name" of the reference substance in IUCLID section 1.1. and the other SID identifier according to the naming convention for UVCB substances given in SID Guidance. For substances with variation in the carbon-chain lengths you may consider the naming convention given in chapter 4.3.2.1 of the SID Guidance.
For technical reasons you should not remove or modify at this stage the EC entry. To ensure unambiguous identification of the registered substance, you should however indicate, in the "Remarks" field of the reference substance in IUCLID section 1.1, the following: "The EC number 233-226-5 currently assigned does not specifically correspond to the registered substance. This identifier cannot be modified or deleted at this stage in the present registration update for technical reasons". You should also specify, in the same "Remarks" field, any

available and appropriate EC number for the substance. Any available CAS entry for the registered substance should be reported under the "CAS information" header of the reference substance in IUCLID section 1.1.

You should note that ECHA has established a process, subject to certain conditions, enabling registrants to adapt the EC identifier of an existing registration, while maintaining the regulatory rights already conferred to the substance concerned.

Pending the resolution of the non-compliances addressed in the present decision, any possible adaptation of the identifier can only become effective once ECHA is in a position to establish unambiguously the identity of the substance intended to be covered by you with this registration. Should the information submitted by you as a result of the present decision enable ECHA to identify the substance unambiguously and result in a need to modify the identifier of the substance, the process of adapting the identifier will be considered relevant. In that case, ECHA will inform you in due time as to when and how the identifier adaptation process shall be initiated.

In any case, you should note that the application of the process of adapting the identifier does not affect your obligation to fulfil the requirements specified in this decision.

*(ii)* According to the chapter 4.3.1.2 of the SID Guidance, the information on the manufacturing process should include the origin or source of the substance and the most relevant steps taken during processing. Both the source and process may affect the substance composition and are therefore essential for the identification of the registered substance. You have provided the following manufacturing process description: "[redacted]"

However the provided manufacturing process description is not considered as sufficient for UVCB substances. The following additional information on the process description should be provided in the "Description of composition" field in section 1.2:

- The detailed composition of the starting materials including the carbon number distribution and the upper and lower concentration value for each carbon number.
- All relevant process steps and process parameters
- In case a catalyst is used, the identity of the catalyst needs to be provided.

Therefore, please consider your choice on the type of substance based on the above provided information. If the inherent variability in the composition is large or poorly predictable then you should provide the additional information as outlined above.

**2. Composition of the substance (Annex VI, Section 2.3.)**

Pursuant to Article 10(a)(ii) of the REACH Regulation, the technical dossier shall contain information on the identity of the substance as specified in Annex VI, Section 2 of the REACH Regulation. In accordance with Annex VI, Section 2 the information provided shall be sufficient to enable the identification of the registered substance.

Annex VI, section 2.3. of the REACH Regulation requires that each registration dossier contains sufficient information for establishing the composition of the registered substance and therefore its identity. The identifiers used in a registration must be consistent with the information on composition.

In that respect, according to chapter 4.2 of the SID Guidance, you shall note that, for well-defined substances, the following applies:

- Each main constituent (i.e. the constituent present at ≥80% for mono-constituent substance or each constituent present at ≥10% and 80% for multi-constituent substance) shall be identified and reported individually; and
- Each impurity present at ≥1% or relevant for the classification and/or PBT assessment of the registered substance shall be identified and reported individually.
- For each constituent, the typical, minimum and maximum concentration levels shall be specified regardless of the substance type.

In the present dossier, you identified the registered substance as a well-defined mono-constituent substance. In IUCLID section 1.2 you have included under the "Impurities" section a constituent block "Unidentified components". In the "Remarks" field of this constituent block you have provided the following statement: "*[...]* [redacted]". Furthermore, in the analytical report "[redacted]" you have provided a peak table for the gas chromatographic analysis, which indicates 4 peaks with an area % higher than [redacted]. Three of these peaks where identified as "[redacted]" and one peak was identified as "[redacted]". No further information on the identity and the concentrations of these constituents have been provided in IUCLID section 1.2.
You have reported one main constituent in section 1.2 with EC number 233-226-5, EC name "(Z)-N-octadecyldocos-13-enamide", CAS number 10094-45-8, SMILES notation and structural formula corresponding to "(Z)-N-octadecyldocos-13-enamide". You have assigned IUPAC name "N-octadecyldocos-13-enamide" and InChI code referring to [redacted] for this main constituent.

ECHA concludes that the compositional information has not been provided to the required level of detail, because impurities ≥ 1% (w/w) were not identified and correctly reported in section 1.2.

ECHA observes that the chemical name "N-octadecyldocos-13-enamide" refers to a group of constituents consisting of [redacted]. Similarly to the inconsistency identified in the issue concerning "Name or other identifier of the substance (Annex VI, Section 2.1.)" above, some identifiers refer to a mono-constituent substance "(Z)-N-octadecyldocos-13-enamide" whereas others refer to a group of constituents consisting of ([redacted]. Therefore, you have not used consistent substance identifiers for identification of the main constituent reported in section 1.2.

You are accordingly requested to identify each impurity ≥ 1 % (w/w) that appears in the analytical report and impurities that are relevant for the classification and/or for PBT assessment, irrespective of the concentration.

You are also requested to ensure that the identifiers provided for the reference substance(s) reported in IUCLID section 1.2 are consistent. For this purpose, each main constituent (i.e. the constituent present at ≥80% for mono-constituent substance or each constituent present at ≥10% and 80% for multi-constituent substance) must be identified and reported individually in section 1.2.

- If the substance consists of [redacted] as main constituents, these constituents need to be reported separately in section 1.2, and the typical, minimum and maximum concentration values need to be specified for each constituent.

- If the substance consists of only one main constituent, the main constituent needs to be reported separately in section 1.2, and the typical, minimum and maximum concentration values need to be specified for the constituent.

The reported composition must be consistent with the identifiers reported in section 1.1 of the IUCLID dossier and verifiable by the analytical information provided in section 1.4 of the IUCLID dossier.

Regarding how to report the composition of the registered substance in IUCLID, the following applies: you shall report individually any impurity required to be identified and specify at least one of the following identifiers: chemical name, CAS number, EC number and/or molecular formula, as well as the minimum, maximum and typical concentration, in the appropriate fields in Section 1.2 of the IUCLID dossier.

Further technical details on how to report the composition of well-defined substances in IUCLID are available in the Manual "How to prepare registration and PPORD dossiers" on the ECHA website.

In your comments to the draft decision you indicated that you will update your registration dossier and outlined how you intend to address the information requirement, composition of the substance (Annex VI, Section 2.3.). When you will be preparing the dossier update, ECHA can already point out the following:

You intend to update IUCLID section 1.2 by identifying and quantifying where possible the composition of the UVCB for known constituents above 10%.
You should note that according to chapter 4.3 of the SID Guidance for UVCB substances presenting a large number of constituents the following applies:

- All constituents present in the substance with a concentration of ≥ 10 % shall be identified and reported individually,
- All constituents relevant for the classification and/or PBT assessment of the registered substance shall be identified and reported individually; and
- Other constituents shall be identified by a generic description of their chemical nature.

Therefore, if it is not possible to report all individual constituents of your substance due to their number or complexity, these constituents shall be grouped according to their structural similarity and identified by a generic description of their chemical nature.

Furthermore for each constituent required to be reported individually, the IUPAC name, CAS name and CAS number (if available), molecular and structural formula, as well as the

minimum, maximum and typical concentration, should be reported in the appropriate fields in IUCLID.

For the other constituents to be reported under a generic description, a generic chemical name describing the group of constituents, generic molecular and structural information (if applicable), as well as the minimum, maximum and typical concentration, should be reported in the appropriate fields in IUCLID.

## PROPERTIES OF THE SUBSTANCE

### *Grouping of substances and read-across approach*

Article 13(1) of the REACH Regulation provides that information on intrinsic properties of substances may be generated by means other than tests. Such other means include the use of information from structurally related substances (grouping of substances and read-across), "provided that the conditions set out in Annex XI are met".
In the registration, you have adapted the standard information requirements for

- Reproductive toxicity (Annex VIII, Section 8.7.1)
- Pre-natal developmental toxicity study (Annex IX, Section 8.7.2.) in a first species

by applying a read-across adaptation following REACH Annex XI, Section 1.5.

Annex XI, Section 1.5. requires a structural similarity among the substances within a group or category such that relevant properties of a substance within the group can be predicted from the data on reference substance(s) within the group by interpolation. The following analysis presents your justification for the proposed grouping approach and read-across hypothesis, together with ECHA's analysis concerning the justification in both a generic and an property-specific context.

- ***Description of the grouping and read-across approach***

*"The toxicological properties show that the target substance (Z)-N-octadecyldocos-13-enamide (CAS 10094-45-8) and the source substances N-octadecylstearamide (CAS 13276-08-9) and (Z)-N-octadec-9-enylhexadecan-1-amide (CAS 16260-09-6) have similar toxicokinetic behaviour, including low bioavailability of the parent substance, but anticipated hydrolysis of the amide bond followed by absorption, distribution, metabolism and excretion of the breakdown products ammonia as well as free long-chain, saturated or mono-unsaturated fatty acids (C16:0, C18:0, C18:1 or C22:1_9). Based on the common metabolic fate, which is irrespective of the degree of fatty acid saturation and carbon chain length, the target and source substance show no acute oral, dermal or inhalative toxicity, no potential for skin and eye irritation and no skin sensitisation properties."*

ECHA understands this as the hypothesis under which you make predictions for the properties listed above.

- ***Support of the grouping and read-across approach***

You have provided a read-across justification as a separate attachment in the technical dossier. You have also provided read-across justifications in relevant sections of the technical dossier and in the CSR. In summary you provide the following arguments to support the read-across approach:

- Structural similarity between the target substance (Z)-Noctadecyldocos-13-enamide (stearyl erucamide, CAS 10094-45-8) and the analogue substances (Z)-N-octadec-9-enylhexadecan-1-amide (oleyl palmitamide, CAS 16260-09-6) and *N-octadecylstearamide (stearyl stearamide, CAS 13276-08-9).*
- The target substance and the source substances share a similar manufacturing process ([redacted]).
- The target substance and the source substances share common physical-chemical characteristics in terms of physical state (solid), high boiling points (> 400°C), similar densities (0.9g/cm$^3$), high Log Kow values (>5) and low water solubility (< 0.01 g/cm$^3$).
- The target substance and the source substances share a similar ecotoxicological and toxicological profile.
- The target substance and the source substances are not classified in Annex I of Directive 67/548/EEC, and do not have to be self-classified according to the available experimental data.

ECHA observes that you have not provided any study summaries for reproductive toxicity for the analogous substances, but that a testing proposal for pre-natal developmental toxicity has been submitted to ECHA with the analogue substance oleyl palmitamide (CAS no. 16260-09-6).

- ***ECHA analysis of the grouping and read-across approach in light of the requirements of Annex XI, 1.5.***

With regard to the proposed predictions ECHA has the following observations:

(i) Substance characterisation of source and target substances

The substance characterisation of the source substance(s) need to be sufficiently detailed in order to assess whether the attempted prediction is not compromised by the composition and/or impurities. In the ECHA practical guide 6 "*How to report on Read-Across*" it is recommended to follow the ECHA *Guidance for identification and naming of substances under REACH and CLP* (version 1.3, February 2014) also for the source substances. This ensures that the identity of the source substance and its impurity profile allows an assessment of the suitability of the substances for read-across purposes.

In your read-across justification you state:

"*The target substance (Z)-N-octadecyldocos-13-enamide (stearyl erucamide, CAS 10094-45-8) and the source substances, (Z)-N-octadec-9-enylhexadecan-1-amide (oleyl palmitamide,CAS 16260-09-6) and N-octadecylstearamide (stearyl stearamide, CAS 13276-08-9), are mono-constituent substances with a purity of more than 80% and do not include any impurities or other constituents which could have an effect on classification and labelling.*
*Neither are there impurities which will require a classification as carcinogenic, mutagenic or toxic to reproduction, nor are there impurities which will require a classification as persistent, bio-accumulating or toxic to the environment.*"

ECHA notes the following: As stated in Section 1.2 above purity and impurity profile of the target substance has been provided although at a rather general level. Also the information on the purity of the source substances given above is insufficient as no detailed impurity profiles have been provided. Hence, ECHA considers that the provided information is insufficient to conclude that the attempted prediction is not compromised by the composition and/or impurities of the target and source substances.

(ii) Explanation on why and how the structural similarities allow predictions

In order to meet the provisions in Annex XI, Section 1.5. to predict human health effects from data for a reference substance within the group by interpolation to other substances in the group, ECHA considers that structural similarity alone is not sufficient. It has to be justified why such prediction is possible in view of the identified structural differences and the provided evidence has to support such explanation. In particular, the structural similarities must be linked to a scientific explanation of how and why a prediction is possible.

ECHA notes the following:

a. Common origin. You state that "*The target substance, (Z)-N-octadecyldocos-13-enamide (stearyl erucamide, CAS 10094-45-8), and the source substances, (Z)-N-octadec-9-enylhexadecan-1-amide (oleyl palmitamide, CAS 16260-09-6) and N-octadecylstearamide (stearyl stearamide, CAS 13276-08-9),* [redacted] *(March, 1992). It should be noted that the original raw materials used to* [redacted]."

b. Structural similarity. You state that "*The target substance, (Z)-N-octadecyldocos-13-enamide (stearyl erucamide, CAS 10094-45-8) and the source substances, N-octadecylstearamide (stearyl stearamide, CAS 13276-08-9) and (Z)-N-octadec-9-enylhexadecan-1-amide (oleyl palmitamide, CAS 16260-09-6), are secondary amides which belong to the chemical class of N-Fatty Alkyl Amides of Saturated and Unsaturated Fatty Acids. Their structures consist of two linear carbon chains (i.e. not branched but* [redacted] *containing a C=C double bond)* [redacted] *linked by an amide moiety -C(=O)NH-, and* [redacted]

c. Similar physico-chemical properties. You state that "*The target and source substances share the physical similarities in terms of physical state (solid), high boiling points (> 400°C), similar densities (0.9 g/cm3), high Log Kow values (>5) and low water solubility (< 0.01 g/cm3). For a number of endpoints the experimental values could be only estimated and were supported by valid predictive methods, for example, ACD/LAB calculations (ChemSpider, 2013). In the case of vapour pressure, the predicted value of 0 Pa for the source substance is imprecise. However, this may be taken to be indicative that the source substance, like the target substance, has an extremely low vapour pressure.*"

ECHA concludes that whilst you have explained the common origin, similar chemical structure and similar physico-chemical properties of the target and source substances you have not explained why the structural difference would not lead to differences in the toxicity profile of target and source substances.

(iii) Support of a similar or regular pattern as a result of structural similarity

Annex XI, Section 1.5. provides that "*substances whose physicochemical, toxicological and eco-toxicological properties are likely to be similar or follow a regular pattern as result of structural similarity may be considered as a group or 'category' of substances.* One prerequisite for a prediction based on read-across therefore is that the substances involved are structurally similar and are likely to have similar properties. One important aspect in this regard is the analysis of the data matrix to compare the properties of source and target substances and to establish whether indeed they are similar or follow a regular pattern.

ECHA notes the following observations:

a. For human health endpoints comparisons of the toxicological profiles of target and source substance can only be done for genetic toxicity *in vitro* and repeated dose toxicity.

b. For reproductive toxicity only a testing proposal for a "pre-natal developmental toxicity study" (OECD TG 414) with the source substance (Z)-N-octadec-9-enylhexadecan-1-amide has been submitted. No OECD TG 421 or 422 screening study is available.

Hence, supporting information related to reproductive toxicity is missing. ECHA concludes that the presented evidence does not support a similar or regular pattern of reproductive toxicity as a result of structural similarity. Therefore it cannot be verified that the proposed analogue substances can be used to predict reproductive properties of the registered substance.

(iv) Reliability and adequacy of the source studies

Annex XI, Section 1.5 provides, with regard to the reliability and adequacy of the source studies, that in all cases the results of the read-across should:

- *be adequate for the purpose of classification and labelling and/or risk assessment,*
- *have adequate and reliable coverage of the key parameters addressed in the corresponding test method referred to in Article 13(3),*
- *cover an exposure duration comparable to or longer than the corresponding test method referred to in Article 13(3) if exposure duration is a relevant parameter, and*
- *adequate and reliable documentation of the applied method shall be provided.*

ECHA notes that the only higher tier study provided for the analogue substances is a repeated dose toxicity study (90 day). As studies related to reproductive toxicity are lacking for the source substances ECHA concludes that there is no basis for accepting read-across for the endpoints reproductive toxicity (Annex VIII, Section 8.7.1) and pre-natal developmental toxicity in a first species (Annex IX, Section 8.7.2).

(iii) Toxicokinetics

One important aspect in establishing that substances have similar effects or follow a regular pattern is the comparison of absorption, distribution, metabolism and elimination of source and target substances. This allows assessing the qualitative and quantitative internal systemic exposure of the test organism when exposed to source and target, respectively.

Regarding your information about toxicocinetics ECHA notes the following:

You state that: "*based on the available information, the physicochemical properties and molecular weight of the target substance (Z)-N-octadecyldocos-13-enamide (CAS 10094-45- 8) and the source substances N-octadecylstearamide (CAS 13276-08-9) and (Z)-N-octadec-9-enylhexadecan-1-amide (CAS 16260-09-6) suggest poor oral absorption. However, due to the strong structural similarity, both substances are anticipated to undergo enzymatic hydrolysis in the gastrointestinal tract and absorption of the hydrolysis products may also be relevant*".

However, the only test which specifically studies the toxicocinetics of the registered substances seems to be the "*in vitro digestion of Stearyl Erucamide*" (1963), measuring the acidic enzymatic hydrolysis. As comparable data for the source substances are not presented it is not possible to conclude that the target and source substances are hydrolysed in a similar manner. Taken together the information on metabolism is mainly general and does not contain information that can give substantial support to the read-across hypothesis.

You have also predicted the potential metabolites of the target substance using the OECD QSAR toolbox. However, no such information was provided for the source substance and comparisons between metabolism profiles of the target and source substances are not made. Hence, the provided information is not sufficient to support the hypothesis of the similar metabolic fate of the target and source substances.
ECHA considers that due to the general level of the information you provide, i.e. the lack of solid substance-specific information and missing information, it is not possible to compare the toxicocinetics, with specific emphasis on metabolism, of the target and source substances. Consequently, the information provided does not demonstrate that information on the source substances can be used to predict the hazard profile of the target substance.

- ***Conclusion on the read-across approach***

ECHA considers that structural similarity alone is not sufficient for predicting toxicological properties. It has to be justified why such prediction is possible in view of the identified structural differences and the provided evidence has to support such explanation. ECHA notes that in view of the issues listed above it has not been demonstrated that the source and read-across substances have the same properties or follow a similar pattern with regard to studies on screening for reproductive/developmental toxicity (Annex VIII, Section 8.7.1.) and pre-natal developmental toxicity study (Annex IX, Section 8.7.2.) in a first species.
ECHA concludes that you have failed to meet the requirement of Annex XI, Section 1.5. that human health effects may be predicted from data for reference substance(s) within the group by interpolation to other substances in the group (read-across approach).
In your comments to the draft decision according to Article 50(1) of the REACH Regulation you indicate that you intend to strengthen the weight of evidence to further justify your read-across approach. In particular you will use weight of evidence to demonstrate that the source and the target substance can be expected to give similar responses with regard to potential reproductive and developmental effects. Furthermore, you assert that the composition of the two substances will be clarified from data already within the characterization reports when the dossier is updated to reflect the true classification of the two substances; both will be updated to be UVCBs.

To support why the structural differences would not lead to differences in the toxicity profile of target and source substances you propose to generate QSAR data for the source substance which will then be evaluated alongside the target substance QSAR data. You also

propose *in vitro* metabolism data be generated for both the source and target substances to further enable comparisons of the metabolism of the target and the source substance.

ECHA acknowledges that you will provide more detailed information on the composition of the target and source substances. ECHA has further taken note of the proposed way forward to strengthen the scientific basis for your read-across by generating QSAR and *in vitro* data. However, while *in vitro* information may contribute to conclusions on metabolism, QSAR and *in vitro* data are generally not on their own sufficient to replace experimental data in substantiating a read-across hypothesis. ECHA expects therefore that you add experimental toxicological data confirming the similarity in effects of the source and target substances for the endpoints in question.Pursuant to Article 41(1) of the REACH Regulation, ECHA concludes that the adaptation of the standard information requirements for the endpoints screening for reproductive/developmental toxicity and pre-natal developmental toxicity in the technical dossier based on the proposed read-across approach does not currently comply with the general rules of adaptation as set out in Annex XI, Section 1.5. Therefore, ECHA rejects all adaptations in the technical dossier that are based on Annex XI, 1.5.

### 3. Screening for reproductive/developmental toxicity (Annex VIII, Section 8.7.1.)

Pursuant to Articles 10(a) and 12(1) of the REACH Regulation, a technical dossier registered at 100 to 1000 tonnes per year shall contain as a minimum the information specified in Annexes VII to IX of the REACH Regulation. The information to be generated for the dossier must fulfil the criteria in Article 13(4) of the same regulation.

"Screening for reproductive/developmental toxicity" (test method OECD TG 421 or 422) is a standard information requirement as laid down in Annex VIII, Section 8.7.1. of the REACH Regulation if there is no evidence from available information on structurally related substances, from (Q)SAR estimates or from *in vitro* methods that the substance may be a developmental toxicant. No such evidence is presented in the dossier. Therefore, adequate information on this endpoint needs to be present in the technical dossier for the registered substance to meet this information requirement.

You have not provided any study record of a screening for reproductive/developmental toxicity in the dossier that would meet the information requirement of Annex VIII, Section 8.7.1. Instead you have sought to adapt this information requirement according to Annex XI, Section 1.5. of the REACH Regulation by providing a testing proposal for a pre-natal developmental toxicity study (OECD guideline 414) with the analogue substance (Z)-N-octadec-9-enylhexadecan-1-amide (CAS 16260-09-6). However, as explained above in section "*Grouping of substances and read-across approach*" of this Appendix of this decision, your adaptation of the information requirement is rejected.

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

According to the test methods OECD TG 421 and 422, the test is designed for use with rats. On the basis of this default assumption ECHA considers testing should be performed with rats.

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 6.0, July 2017) R.7a, chapter R.7.6.2.3.2. Since the substance to be tested is a solid, ECHA concludes that testing should be performed by the oral route.

Therefore, pursuant to Article 41(1) and (3) of the REACH Regulation, you are requested to submit the following information derived with the registered substance subject to the present decision: Reproductive/developmental toxicity screening test (test method: OECD TG 421) *or* Combined repeated dose toxicity study with the reproduction/developmental toxicity screening test (test method: OECD TG 422) in rats by the oral route.

*Notes for your considerations*

For the selection of the appropriate test, please consult ECHA *Guidance on information requirements and chemical safety assessment*, Chapter R.7a, section R.7.5 and 7.6 (version 6.0, July 2017). You should also carefully consider the order of testing especially the requested screening (OECD TG 421/422) and the developmental toxicity studies (OECD TG 414) to ensure unnecessary animal testing is avoided, paying particular attention to ECHA's end point specific guidance document[2].

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

Pursuant to Articles 10(a) and 12(1) of the REACH Regulation, a technical dossier registered at 100 to 1000 tonnes per year shall contain as a minimum the information specified in Annexes VII to IX of the REACH Regulation. The information to be generated for the dossier must fulfil the criteria in Article 13(4) of the same regulation.

A "pre-natal developmental toxicity study" (test method EU B.31./OECD TG 414) for a first species is a standard information requirement as laid down in Annex IX, Section 8.7.2. of the REACH Regulation. Adequate information on this endpoint needs to be present in the technical dossier for the registered substance to meet this information requirement.

You have not provided any study record of a pre-natal developmental toxicity study in the dossier that would meet the information requirement of Annex IX, Section 8.7.2. Instead you have sought to adapt this information requirement according to Annex XI, Section 1.5. of the REACH Regulation by providing a testing proposal for a pre-natal developmental toxicity study (OECD guideline 414) with the analogue substance (Z)-N-octadec-9-enylhexadecan-1-amide (CAS 16260-09-6). However, as explained above in this Appendix of this decision, section *"Grouping of substances and read-across approach"*, your adaptation of the information requirement is rejected.

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

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

[2] ECHA Guidance on Information Requirements and Chemical Safety Assessment, Chapter R.7a: Endpoint specific guidance Version 6.0, July 2017, R.7.6.2.3.2, p 486.

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 6.0, July 2017) R.7a, chapter R.7.6.2.3.2. Since the substance to be tested is a solid, ECHA concludes that testing should be performed by the oral route.

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

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

Pursuant to Articles 10(a) and 12(1) of the REACH Regulation, a technical dossier registered at 100 to 1000 tonnes per year shall contain as a minimum the information specified in Annexes VII to IX of the REACH Regulation. The information to be generated for the dossier must fulfil the criteria in Article 13(4) of the same 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. Adequate information on this endpoint needs to be present in the technical dossier for the registered substance to meet this information requirement.

You have sought to adapt this information requirement according to Annex IX, Section 9.1., column 2. You provided the following justification for the adaptation:

*"According to Regulation (EC) No. 1907/2006, Annex IX, Column 2, 9.1.6, long-term toxicity testing shall be proposed by the registrant if the chemical safety assessment according to Annex I indicate the need to investigate further effects on aquatic organisms.*

*The substance does not need further investigations due to the following reasons. As the test substance is highly insoluble in water (< 0.01 mg/L), if at all, only very small amounts of the test substance are expected in water. Furthermore, no effects were observed to aquatic algae, daphnia and fish in the range of water solubility. Since only low amounts of the test substance can be expected in the aquatic environment and no adverse effects of the substance are expected no long-term tests on invertebrates should be performed."*

ECHA notes that the ECHA Guidance on information requirements and chemical safety assessment (Version 4., June 2017), Chapter R7b, indicates that the need to conduct further testing according to column 2 of Annex IX, section 9.1., may be triggered e.g. when due to low water solubility of a substance, short term toxicity tests do not reveal any toxicity. The absence of toxicity observed in the short-term tests with the registered substance having a low water solubility can, therefore, not be used as an argument for adaptation of long-term tests.

Therefore, ECHA notes that as no effects were observed in any of the short-term aquatic studies submitted as part of the technical dossier and the substance has a low water solubility the available data does not allow to conclude on aquatic toxicity.

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

In your comments to the draft decision according to Article 50(1) of the REACH Regulation you recognise "*that some chronic ecotoxicology data for the aquatic compartment should be generated*". Furthermore, you noted that "*a chronic Daphnia magna study will be conducted using a WAF preparation [...] As it is highly unlikely that verification of the test substance would be achieved by conventional analytical techniques or TOC analysis which has an LOQ of around 1 mg/L, no analytical verification will be undertaken. [...] analytical determination of achieved concentration for highly insoluble UVCB's is extremely difficult and often impossible [...] the test will be undertaken in a semi-static manner [...] the test will likely be undertaken as a limit test without range-finding*".

ECHA notes that ECHA's Guidance on Information Requirements and Chemical Safety Assessment, Chapter R.7.13 reminds that "*it is therefore necessary to develop a specific testing strategy to ensure that the composition of the sample to be tested in the laboratory reflects fully the composition of the likely human or environmental exposure*". It should be noted that when the Water Accommodated Fraction (WAF) approach is used with a test substance containing several constituents, the toxicity cannot be allocated to specific constituents directly and interpretation of the results in the risk assessment requires careful consideration taking into account differences in fate of the constituents in the environment. When constituents of varying solubility are present there can be partitioning effects which limit dissolution in the water. These effects should be minimised and appropriate loadings selected accordingly to allow an appropriate determination of the toxicity of the different constituents. In that respect, it is critical that a robust chemical analysis is carried out to identify those constituents present in the water to which the test organisms are exposed.

Additionally, chemical analysis to demonstrate attainment of equilibrium in WAF preparation and stability during the conduct of the test is required. Methods capable of identifying at least gross changes in the composition of WAFs with time are therefore also required.

ECHA notes that a Member State Competent Authority submitted a Proposal for Amendment (PfA) indicating that the aquatic integrated testing strategy (ITS) may be applicable in this case and that the long-term toxicity testing on fish may only be needed following the long-term daphnia study. In your comments on the PfA you propose a tiered testing strategy for aquatic testing. ECHA has addressed your proposed strategy and the MSCA's PfA fully in section 6. below, and concludes that the long-term toxicity testing on both aquatic invertebrates and fish is required.

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

According to ECHA *Guidance on information requirements and chemical safety assessment, Chapter R.7b* (version 4.0, June 2017) *Daphnia magna* reproduction test (test method EU C.20. / OECD TG 211) is the preferred test to cover the standard information requirement of Annex IX, Section 9.1.5.

Therefore, pursuant to Article 41(1) and (3) of the REACH Regulation, you are requested to submit the following information derived with the registered substance subject to the present decision: Daphnia magna reproduction test (test method: EU C.20./OECD TG 211).

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

Pursuant to Articles 10(a) and 12(1) of the REACH Regulation, a technical dossier registered at 100 to 1000 tonnes per year shall contain as a minimum the information specified in Annexes VII to IX of the REACH Regulation. The information to be generated for the dossier must fulfil the criteria in Article 13(4) of the same regulation.

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

You have sought to adapt this information requirement according to Annex IX, Section 9.1., column 2. You provided the following justification for the adaptation : *"According to Regulation (EC) No. 1907/2006, Annex IX, Column 2, 9.1.6, long-term toxicity testing shall be proposed by the registrant if the chemical safety assessment according to Annex I indicate the need to investigate further effects on aquatic organisms.*

*The substance does not need further investigations due to the following reasons. As the test substance is highly insoluble in water (< 0.01 mg/L), if at all, only very small amounts of the test substance are expected in water. Furthermore, no effects were observed to aquatic algae, daphnia and fish in the range of water solubility. Since only low amounts of the test substance can be expected in the aquatic environment and no adverse effects of the substance are expected no long-term tests on fish should be performed."*

ECHA notes that the ECHA Guidance on information requirements and chemical safety assessment (Version 4.0, June 2017), Chapter R7b, indicates that the need to conduct further testing according to column 2 of Annex IX, section 9.1., may be triggered e.g. when due to low water solubility of a substance, short term toxicity tests do not reveal any toxicity. The absence of toxicity observed in the short-term tests with the registered substance having a low water solubility can, therefore, not be used as an argument for adaptation of long-term tests.

Therefore, ECHA notes that as no effects were observed in any of the short-term aquatic studies submitted as part of the technical dossier and the substance has a low water solubility the available data does not allow to conclude on aquatic toxicity.

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

In your comments to the draft decision according to Article 50(1) of the REACH Regulation you note that you reserve "*the right to comment on the requirement for the Fish Early Life Stage test following the outcome of the chronic Daphnia test. It is likely that the PEC/PNEC ratio will be less than 1. In the event that PEC/PNEC ≥1 a further proposal will be issued*".

ECHA notes that according to ECHA's Guidance on Information Requirements and Chemical Safety Assessment, Chapter R.7b (version 4.0, June 2017) "*The Chemical Safety Assessment (CSA) is based on all available toxicity information. The information should at least cover species of three trophic levels: algae/aquatic plants, invertebrates (Daphnia preferred), and fish.*" Furthermore, it is specified in this Guidance document that "*If there is compelling evidence, using these methods, to suggest that the fish value is likely to be at least a factor of about 10 less sensitive than invertebrates or algae there are no further requirements for fish testing.*"

As on the basis of the information available for the substance, it is not possible to conclude that the fish is likely to be less sensitive than invertebrates or algae, information on the long-term fish toxicity is necessary for the Chemical Safety Assessment (CSA), including PBT assessment, and classification and risk characterisation of the substance.

ECHA notes that a Member State Competent Authority submitted a Proposal for Amendment (PfA) indicating that the aquatic ITS may be applicable in this case and that further advice on possible alternatives for animal testing should be provided in the decision. Concerning possible alternatives for animal testing ECHA refers you to the updated note for consideration at the end of this section. However, ECHA considers that the aquatic ITS cannot be applied in this case as further discussed below, also in response to your comments on the PfAs.

ECHA understands that in your comments on the PfA you propose a stepwise approach to fulfil the information requirements for long-term aquatic toxicity testing, starting with a long-term daphnia study on a proposed read-across substance olelyl palmitade (CAS 16260-09-6). However, ECHA notes that the long-term daphnia data on the proposed read-across substance is not available. ECHA notes further that under the current, compliance check (CCH) process according to Article 41 of the REACH Regulation the Agency is required "to verify (...) that the information in the technical dossier (...) complies with the requirements of Article 10". Hence under a CCH only the quality of the current dossier/information is assessed. As no data on the proposed read-across substance is yet available ECHA considers that the conditions of Annex XI, 1.5. are not met and the proposed read-across can therefore not be accepted.

Nevertheless ECHA notes the following concerning the information you have submitted to support the proposed read-across. You included results from terrestrial toxicity studies conducted on the registered substance stearyl erucimade and on the proposed analogue substance olelyl palmitade (CAS 16260-09-6). You indicate that the results are from a "*finalised study but not yet submitted*". You consider the data to show that "*there is a lack of effect in the ecotoxicology compartment which may be attributed to a lack of exposure due to very low solubility*". You also indicate that "*analytical verification was successful in the Algal study for oleyl palmitamide and so the lack of toxicity observed, across the board of environmental compartments and over the two substances indicates that both substances are biologically inert*".

ECHA notes that as only effect values are provided it is not possible for ECHA to assess the acceptability of the terrestrial data submitted and whether it could be used to justify lack of toxicity. Furthermore, ECHA notes that while aquatic data can be used to extrapolate effects in the terrestrial compartment using the Equilibrium Partitioning Method, no such method to extrapolate from terrestrial data to aquatic organisms exists.

Furthermore, ECHA notes that as discussed previously in this section, short-term aquatic tests do not provide a true measure of the toxic potential of low water solubility substances. Poorly soluble substances require longer time to be significantly taken up by the test organisms and consequently steady state conditions are likely not to be reached within the duration of a short-term toxicity test. For this reason, short-term tests may not give a true measure of toxicity for poorly soluble substances and toxicity may not even occur at the water solubility limit of the substance if the test duration is too short.

In your technical dossier a read-across approach has been applied on short-term aquatic endpoints. Due to the low water solubility of both the registered substance and the

proposed source substance, for the reasons given above ECHA considers this short-term data meaningless to assess the aquatic toxicity potential of the registered substance. Therefore, the read-across used for the acute aquatic endpoints has not been addressed in this decision. ECHA notes now that the proposed source substances, (Z)-N-octadec-9-enylhexadecan-1-amide (oleyl palmitamide, CAS 16260-09-6) added in your comments on the PfAs and N-octadecylstearamide (stearyl stearamide, CAS 13276-08-9), proposed source substance in short-term aquatic endpoints, are the same source substances addressed in the read-across approach rejected for human health endpoints (please refer to section "Grouping of substances and read-across approach" above). ECHA hence emphasises that if you wish to pursue a read-across approach also for long-term aquatic endpoints you should note the general limitations identified in the read-across rejection for human health endpoints above. Furthermore, you should refer to ECHA's Read-Across Assessment Framework, in particular to section "Scientific assessment of environmental fate and effects" (https://echa.europa.eu/support/registration/how-to-avoid-unnecessary-testing-on-animals/grouping-of-substances-and-read-across). ECHA does highlight that in the absence of any aquatic chronic toxicity data to use as bridging studies on proposed target and source substances with low water solubilities, proving similar aquatic toxicities is challenging.

Dossier updates and any adaptations therein will be checked by ECHA during the follow-up phase. Any read-across adaptations need to fulfil the requirements of Annex XI section 1.5, while any QSAR adaptations, which you also intend to apply, need to fulfil the requirements of Annex XI, section 1.3.

ECHA notes further that in your stepwise testing approach you indicate that if it is not feasible to carry out the long-term daphnia test on the proposed read-across substance, you would study the feasibility of carrying out the test with the registered substance. You indicate that you would analyse the water solubility; if the water solubility was <0.001 mg/L or not determined, no aquatic testing would be undertaken, while if the water solubility was above 0.001 mg/L you would go forward with long-term toxicity testing of daphnia either by direct addition and evaluating exposure based on loading rates, or with measured effect values depending on the sensitivity of the analytical method and the observed water solubility. Long-term fish study would then be initiated only if the substance was shown to be toxic to daphnia and if risks were shown in the chemical safety assessment.

ECHA notes that you consider testing not needed if the water solubility is shown to be below 0.001 mg/L or not determined. However, Annex VIII 9.1.3. and Annex VII 9.1.1. of the REACH Regulation explicitly recommend that long-term aquatic toxicity tests be considered if the substance is poorly water soluble. In *ECHA Guidance on information requirements and chemical safety assessment*, Chapter R.7b (version 4.0, June 2017), Section R.7.8.5. it is further defined that a substance is poorly water soluble when water solubility below 1 mg/L or below the detection limit of the analytical method of the test substance based on, while no lower limit on when long-term testing is not needed is not defined. ECHA hence considers it not justified to state that no aquatic testing is needed if water solubility is shown to be below 0.001 mg/L. Due to the substance being difficult to test ECHA refers you to consult the OECD Guidance Document on Aquatic Toxicity Testing of Difficult Substances and Mixtures, ENV/JM/MONO (2000)6 and ECHA *Guidance on information requirements and chemical safety assessment* (version 4.0, June 2017), Chapter R7b, Table R.7.8-3 summarising aquatic toxicity testing of difficult substances for choosing the design of the requested ecotoxicity test(s) and for calculation and expression of the result of the test(s).

Furthermore, ECHA notes that you consider that the need to carry out the long-term fish study is conditional on the results of the long-term daphnia study. ECHA considers this approach and the aquatic integrated testing strategy (ITS) given in *ECHA Guidance on information requirements and chemical safety assessment*, Chapter R.7b (version 3.0, February 2016), Section R.7.8.5.3.) not applicable in this case for the reasons set out below.

ECHA notes that for the derivation of the $PNEC_{aquatic}$ data on three trophic levels, on aquatic invertebrates, fish and aquatic plants, is required (ECHA Guidance on information requirements and chemical safety assessment, v.4.0, June 2017, Chapter R7b, Section R.7.8.5.3). As discussed above, the short-term data is not applicable in this case due to the substance being considered poorly soluble in water. Therefore long-term data on all three trophic levels is needed for the derivation of $PNEC_{aquatic}$ and to perform the chemical safety assessment.

Furthermore, ECHA notes that due to the low water solubility the short-term data cannot serve as a compelling evidence to predict relative differences (or lack of) in species sensitivity required to apply the aquatic ITS (*ECHA Guidance on information requirements and chemical safety assessment*, Chapter R.7b (version 4.0, June 2017), Section R.7.8.5.3.).

For the reasons stated above, the integrated testing strategy (*ECHA Guidance on information requirements and chemical safety assessment*, Chapter R.7b (version 4.0, June 2017), Section R.7.8.5.3.) is not applicable and it is necessary to provide long-term data on both aquatic invertebrates and on fish.
As explained above, the information provided on this endpoint for the registered substance in the technical dossier does not meet the information requirement. Consequently there is an information gap and it is necessary to provide information for this endpoint.

According to ECHA *Guidance on information requirements and chemical safety assessment, Chapter R.7b* (version 4.0, June 2017) fish early-life stage toxicity test (test method OECD TG 210), fish short-term toxicity test on embryo and sac-fry stages (test method EU C.15. / OECD TG 212) and fish juvenile growth test (test method EU C.14. / OECD TG 215) are the preferred tests to cover the standard information requirement of Annex IX, Section 9.1.6.

Regarding the long-term toxicity testing on fish pursuant to Annex IX, section 9.1.6.1, ECHA considers that the FELS toxicity test according to OECD TG 210 is the most sensitive of the standard fish tests available as it covers several life stages of the fish from the newly fertilised egg, through hatch to early stages of growth and should therefore be used (see ECHA *Guidance on information requirements and chemical safety assessment* (version 4.0, June 2017), Chapter R7b). The test method OECD TG 210 is also the only suitable test currently available for examining the potential toxic effects of bioaccumulation (ECHA Guidance Chapter R7b, version 4.0, June 2017). For these reasons, ECHA considers the FELS toxicity test using the test method OECD TG 210 as most appropriate and suitable.

ECHA notes that in your comments on the PfA you indicate that if a long-term fish study is conducted you would choose between the OECD 210, the OECD 212 and the OECD 215. As explained above, ECHA considers the OECD 210 the most appropriate and suitable test method.

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

*Notes for your consideration for requests 5 and 6*

Before conducting the above test you are advised to consult the ECHA Guidance on information requirements and chemical safety assessment, Chapters R.4 (v.1.1, December 2011), R.5 (v.2.1, December 2011), R.6 (May 2008), R.7b (v 4.0, June 2017) and R.7c (v 3.0, June 2017). If you decide to adapt the testing requested according to the specific rules outlined in Annexes VI to X and/or according to general rules contained in Annex XI of the REACH Regulation, you are referred to the advice provided in practical guides on "How to use alternatives to animal testing to fulfil your information requirements for REACH registration".

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), if based on acute aquatic toxicity data neither fish nor invertebrates are shown to be substantially more sensitive, long-term studies may be required on both.

Due to the low solubility of the substance in water and high partition coefficient you should consult OECD Guidance Document on Aquatic Toxicity Testing of Difficult Substances and Mixtures, ENV/JM/MONO (2000)6 and ECHA *Guidance on information requirements and chemical safety assessment* (version 4.0, June 2017), Chapter R7b, Table R.7.8-3 summarising aquatic toxicity testing of difficult substances for choosing the design of the requested ecotoxicity test(s) and for calculation and expression of the result of the test(s).

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

Pursuant to Articles 10(a) and 12(1) of the REACH Regulation, a technical dossier registered at 100 to 1000 tonnes per year shall contain as a minimum the information specified in Annexes VII to IX of the REACH Regulation. The information to be generated for the dossier must fulfil the criteria in Article 13(4) of the same regulation.

"Soil simulation testing" is a standard information requirement as laid down in Annex IX, section 9.2.1.3. of the REACH Regulation for substances with a high potential for adsorption to soil. Column 2 indicates that the study does not need to be conducted if the substance is readily biodegradable or if direct and indirect exposure of soil is unlikely, and if the chemical safety assessment indicates that there is no need to investigate the degradation of the substance or its degradation products. Adequate information on this endpoint needs to be present in the technical dossier for the registered substance to meet this information requirement.

You have sought to adapt this information requirement according to Annex IX, Section 9.2.1.3., column 2. You provided the following justification for the adaptation: "*In accordance with column 2 of Regulation (EC) No 1907/2006 Annex VIII, IX and X further biotic degradation tests shall be proposed if the result of the Chemical Safety Assessment indicates the need to investigate further the degradation of (Z)-N-octadecyldocos-13-enamide (CAS No. 10094-45-8) and its degradation products. The substance is not readily biodegradable and therefore it could be not excluded that the substance has a potential to persist in the environment if it is exposed to soil.*

*However the release to surface waters, and thereby indirect exposure of soil, is considered as marginally as the substance will be physically removed in sewage treatment plants due to the low water solubility and high adsorption potential. An extensive discharge via a STP effluent is unlikely. Furthermore the substance is assessed to be neither acutely or chronically toxic nor to accumulate in organisms. Thus, it is not expected to pose a risk on soil organisms (long term study is planed). Considering this information, testing for this endpoint is not deemed necessary since the substance is not expected to cause an environmental risk."*

However, ECHA notes that your adaptation does not meet the specific rules for adaptation of Annex IX, Section 9.2.1.3., column 2). More specifically, ECHA notes that the registered substance has low water solubility (<0.01 mg/L), high partition coefficient (log Kow > 5.7) and high adsorption coefficient (log Koc,soil = 10.4), indicating high adsorptive properties. In addition, based on the uses reported in the technical dossier, ECHA considers that such uses are reported for which soil exposure cannot be excluded (wide dispersive professional and consumer uses), and also that there is no exposure estimation available in the Chemical Safety Report (CSR) as the substance is not classified, indicates that the possible exposure to soil compartment in number of your exposure scenarios cannot be ruled out. Hence, ECHA considers that the Chemical Safety Assessment does not demonstrate and conclude that there is no need to further investigate the degradation of the substance and its degradation products and that you have not demonstrated that soil exposure is unlikely.

Due to existing data gaps in aquatic toxicity and bioaccumulation it is not possible to conclude on those properties.
Therefore, your adaptation of the information requirement cannot be accepted.

In your comments to the draft decision according to Article 50(1) of the REACH Regulation you note that "*the substance is classified as a UVCB [...] a risk assessment for this substance is not considered necessary and there is no indication for a risk [...] technical difficulties connected with the test performance of poorly soluble substances in sediment and soil simulation tests and the difficulties for interpretation due to the formation of non-extractable residues (NER) should also be considered [...] investigation into the degradability of this substance with a further screening test aiming to increase bioavailability and with a prolonged duration is proposed [...] standard simulation tests for this endpoint are intended for single substances and are not appropriate for this substance*".

ECHA notes that the CSA includes a number of steps as described in the REACH Regulation. Information on the substance and its degradation products, including persistence, for instance is used for the PBT/vPvB assessment, classification, exposure assessment and risk characterisation of substances. As addressed under various sections of the decision, there is uncertainty on toxicity and environmental fate/behaviour of the substance. Thus, generation of the missing information on the properties of the substance is necessary before conclusions on the classification, PBT/vPvB status and risks posed by the use of the substance can be made.

ECHA acknowledges that degradation simulation testing can encounter a number of technical difficulties which should be considered before testing is initiated. The OECD 307 provides that the test "*is applicable to slightly volatile, non-volatile, water-soluble or water-insoluble compounds*". Furthermore, the high potential for adsorption to soil justifies the need for this endpoint to be addressed in the technical dossier. ECHA considers that OECD degradation simulation test guidelines can be applied for the testing of multi-constituent and UVCB substances. The biodegradation of each relevant constituent present in

concentration at or above 0.1% (w/w) or, if not technically feasible, in concentrations as low as technically detectable shall be assessed. This can be done simultaneously during the same study. When reporting the non-extractable residues (NER) in your test results you are requested to explain and scientifically justify the extraction procedure and solvent used obtaining a quantitative measure of NER.

Furthermore, ECHA notes that the test guidelines for ready biodegradability address standard information requirement of Annex VII, section 9.2.1.1 and such testing can be carried out without submitting a testing proposal. If new results of a prolonged ready biodegradability tests are available, relevant and adequate to adapt information requirement for soil simulation testing, it is noted in the decision above that the testing requested may still be adapted 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.

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 4.0, June 2017) Aerobic and anaerobic transformation in soil (test method EU C.23. / OECD TG 307) is the preferred test to cover the standard information requirement of Annex IX, Section 9.2.1.3.

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 4.0, June 2017) 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 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 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 and anaerobic transformation in soil (test method: EU C.23./OECD TG 307). The biodegradation of each relevant constituent present in concentration at or above 0.1% (w/w) or, if not technically feasible, in concentrations as low as technically detectable shall be assessed. This can be done simultaneously during the same study.

*Notes for your consideration*

Before conducting the requested tests you are advised to consult the ECHA Guidance on information requirements and chemical safety assessment, Chapter R7b, Sections R.7.9.4 and R.7.9.6 (version 4.0, June 2017) and Chapter R.11, Section R.11.4.1.1 (version 3.0,

November 2017) on PBT assessment to determine the sequence in which the simulation tests are to be conducted and the necessity to conduct all of them. The order in which the simulation biodegradation tests are performed needs to take into account the intrinsic properties of the registered substance and the identified use and release patterns which could significantly influence the environmental fate of the registered substance.

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 3.0, June 2017), Chapter R.11, Section R.11.4.1.1. and Figure R. 11-3 on PBT assessment for the integrated testing strategy for persistency assessment in particular taking into account the degradation products of the registered substance.

## 8. Sediment simulation testing (Annex IX, Section 9.2.1.4.)

Pursuant to Articles 10(a) and 12(1) of the REACH Regulation, a technical dossier registered at 100 to 1000 tonnes per year shall contain as a minimum the information specified in Annexes VII to IX of the REACH Regulation. The information to be generated for the dossier must fulfil the criteria in Article 13(4) of the same regulation.

"Sediment simulation testing" is a standard information requirement as laid down in Annex IX, section 9.2.1.4. of the REACH Regulation for substances with a high potential for adsorption to sediment. Column 2 indicates that the study does not need to be conducted if the substance is readily biodegradable or if direct and indirect exposure of soil is unlikely, and if the chemical safety assessment indicates that there is no need to investigate further the degradation of the substance and its degradation products. Adequate information on this endpoint needs to be present in the technical dossier for the registered substance to meet this information requirement.

You have sought to adapt this information requirement according to Annex IX, Section 9.2.1.4., column 2. You provided the following justification for the adaptation: *"In accordance with column 2 of Annex IX 9.2.1.2 of EC 1907/2006 the testing is not required as the substance is highly insoluble in water. The water solubility of (Z)-N-octadecyldocos-13-enamide (CAS No. 10094-45-8) is <0.01 mg/L."*

However, ECHA notes that your adaptation does not meet the specific rules for adaptation of Annex IX, Section 9.2.1.4., column 2. ECHA notes that the registered substance has low water solubility (<0.01 mg/L), high partition coefficient (log Kow > 5.7) and high adsorption coefficient (log Koc,soil = 10.4), indicating high adsorptive properties. Low water solubility is not one of the elements that allow an adaptation under Annex IX, Section 9.2.1.4., column 2. In addition, based on the uses reported in the technical dossier, ECHA considers that such uses are reported for which sediment exposure cannot be excluded (wide dispersive professional and consumer uses), and also that there is no exposure estimation available in the Chemical Safety Report (CSR) as the substance is not classified, indicates that the possible exposure to sediment compartment in number of your exposure scenarios cannot be ruled out. Hence, ECHA considers that the Chemical Safety Assessment does not demonstrate and conclude that there is no need to further investigate the degradation of the substance and its degradation products and that that you have not demonstrated that sediment exposure is unlikely.

Due to existing data gaps in aquatic toxicity and bioaccumulation it is not possible to conclude on those properties.

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

In your comments to the draft decision according to Article 50(1) of the REACH Regulation you refer to the comments provided for the soil simulation testing request.

As noted under section 7 above, generation of the missing information on the properties of the substance is necessary before conclusions on the classification, PBT/vPvB status and risks of the substance can be made.

The biodegradation of each relevant constituent present in concentration at or above 0.1% (w/w) or, if not technically feasible, in concentrations as low as technically detectable shall be assessed. This can be done simultaneously during the same study. Furthermore, when reporting the NER in your test results you are requested to explain and scientifically justify the extraction procedure and solvent used obtaining a quantitative measure of NER.

It is noted in the OECD 308 that the test "*is applicable to slightly volatile, non-volatile,* water-soluble or poorly water-soluble compounds". Furthermore, the high potential for adsorption to sediment justifies the need for this endpoint to be addressed in the technical dossier.

Moreover, if new results of a prolonged ready biodegradability test are available, relevant and adequate to adapt information requirement for sediment simulation testing, it is noted in the decision above that the testing requested may still be adapted 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.

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 4.0, June 2017) Aerobic and anaerobic transformation in aquatic sediment systems (test method EU C.24. / OECD TG 308) is the preferred test to cover the standard information requirement of Annex IX, Section 9.2.1.4.

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 4.0, June 2017) 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 June 2017) 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 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 and anaerobic transformation in aquatic sediment systems (test method: EU C.24./OECD TG 308).
The biodegradation of each relevant constituent present in concentration at or above 0.1% (w/w) or, if not technically feasible, in concentrations as low as technically detectable shall be assessed. This can be done simultaneously during the same study.

*Notes for your consideration*

Before conducting the requested tests you are advised to consult the ECHA Guidance on information requirements and chemical safety assessment, Chapter R7b, Sections R.7.9.4 and R.7.9.6 (version 4.0, June 2017) and Chapter R.11, Section R.11.4.1.1 (version 3.0, June 2017) on PBT assessment to determine the sequence in which the simulation tests are to be conducted and the necessity to conduct all of them. The order in which the simulation biodegradation tests are performed needs to take into account the intrinsic properties of the registered substance and the identified use and release patterns which could significantly influence the environmental fate of the registered substance.

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 3.0, June 2017), Chapter R.11, Section R.11.4.1.1. and Figure R. 11-3 on PBT assessment for the integrated testing strategy for persistency assessment in particular taking into account the degradation products of the registered substance.

## 9. Identification of degradation products (Annex IX, 9.2.3.)

Pursuant to Articles 10(a) and 12(1) of the REACH Regulation, a technical dossier registered at 100 to 1000 tonnes per year shall contain as a minimum the information specified in Annexes VII to IX of the REACH Regulation. The information to be generated for the dossier must fulfil the criteria in Article 13(4) of the same regulation.

The 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 information does not need to be provided if the substance is readily biodegradable.

You have not provided any study record of identification of degradation products in the dossier that would meet the information requirement of Annex IX, Section 9.2.3.

In your comments to the draft decision according to Article 50(1) of the REACH Regulation you note that "a*n extended OECD 301B may provide additional information on this point and is proposed to be undertaken.*"

Moreover, if new results of a prolonged ready biodegradability test are available, relevant and adequate to adapt this information requirement, as it is noted in the decision above, the testing requested may still be adapted 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.

As explained above, there is no information provided on this endpoint for the registered substance in the technical dossier. Consequently there is an information gap and it is necessary to provide information for this endpoint.

Regarding appropriate and suitable test method, the methods will have to be substance-specific. When analytically possible, identification, stability, behaviour, molar quantity of metabolites relative to the parent compound should be evaluated. In addition degradation half-life, log Kow and potential toxicity of the metabolite may be investigated.

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

Identification of the degradation products (Annex IX, Section 9.2.3.) by using an appropriate and suitable test method, as explained above in this section.

*Notes for your consideration*

Before providing the above information you are advised to consult the ECHA *Guidance on information requirements and chemical safety assessment* (version 4.0, June 2017), Chapter R.7b., Sections R.7.9.2.3 and R.7.9.4. These guidance documents explain that the data on degradation products is only required if information on the degradation products following primary degradation is required in order to complete the chemical safety assessment. Section R.7.9.4. further states that when substance is not fully degraded or mineralised, degradation products may be determined by chemical analysis.

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

Pursuant to Articles 10(a) and 12(1) of the REACH Regulation, a technical dossier registered at 100 to 1000 tonnes per year shall contain as a minimum the information specified in Annexes VII to IX of the REACH Regulation. The information to be generated for the dossier must fulfil the criteria in Article 13(4) of the same regulation.

"Bioaccumulation in aquatic species, preferably fish" is a standard information requirement as laid down in Annex IX, Section 9.3.2.of the REACH Regulation. Adequate information on this endpoint needs to be present in the technical dossier for the registered substance to meet this information requirement.

You have sought to adapt this information requirement according to Annex XI, Section 1.2 (Weight of Evidence). You provided the following justification for the adaptation :
"*Experimental data on bioaccumulation of (Z)-N-octadecyldocos-13-enamide (CAS No. 10094-45-8) is not available.*

*The evaluation of the bioaccumulation potential of the substance is therefore based on all available related data. This is in accordance to the REACh Regulation (EC) No 1907/2006, Annex XI General rules for adaptation of the standard testing regime set out in Annexes VII to X, 1.2, to cover the data requirements of Regulation (EC) No. 1907/2007 Annex IX and X (Guidance on information requirements and chemical safety assessment Chapter R.7c: Endpoint specific guidance, R.7.11.5.3, page 123 ff (ECHA, 2012)).*

*The bioaccumulation potential of a substance is driven by the physic-chemical properties of the substance triggering the bioavailability as well as by metabolism and excretion. As the*

*test substance is highly insoluble in water (< 0.01 mg/L) the bioavailability of the substance in water is negligible. Though the substance has a high partition coefficient (log Kow of > 5.7) indicating the potential to bioaccumulate a significant accumulation is not expected based on the environmental fate and on BCF/BAF calculation.*
*The log Koc values of >10 indicates that the substance will adsorb to suspended organic particles, dissolved organic matter and to some degree biota in the aquatic environment. If available, a potential uptake of the substance by organisms of the pelagic zone is expected to occur mainly via food ingestion since the substance may adsorb to solid particles.*
*Despite that the substance is not readily biodegradable elimination in sewage treatment plants is expected due to the high adsorption potential and the very low water solubility. Insoluble substances are largely removed in the primary settling tank and fat trap during the clarification and sedimentation process of waste water treatment (according to the Guidance on information requirements and chemical safety assessment, Chapter R7. b (ECHA, 2012)). Only small amounts of the substance may enter the secondary treatment and thus get in contact with activated sludge. Due to the high log Koc calculated for the substance an extensive adsorption to sewage sludge is expected. Thus the substances is expected to be removed from the water column to a significant degree (Guidance on information requirements and chemical safety assessment, Chapter R.7a (ECHA, 2012)). Thus a significant uptake of the substance by aquatic organisms through the water phase is not expected. Considering this, one can assume that the availability of the substance in the aquatic environment is generally very low, which reduces the probability of uptake by aquatic organisms*
*This assumption is supported by QSAR calculations. A calculated BCF/BAF of 0.89 L/kg (SRC BCFBAF v3.01 Arnot Gobas, upper trophic level) indicates that the substance has a low bioaccumulation potential ([redacted], 2012)."*

However, ECHA notes that your adaptation does not meet the general rule for adaptation of Annex XI; Sections 1.2 and 1.3., because ECHA guidance R.11 notes that: "*If a Log Kow value indicates that the substance screens as B/vB, but a registrant concludes it is not B/vB based on other data, there should be specific reference to the REACH guidance indicating how such a conclusion was drawn. It should be noted that neither a high Koc value nor low water solubility value can be used to argue that a substance lacks significant bioaccumulation potential. Instead these properties may influence the form of PBT testing required.*"

ECHA notes that you have provided QSAR calculations to estimate the bioaccumulation potential of the substance. As there are no QMRF nor QPRF documents provided in the dossier to support the provided QSAR calculations and the log Kow of 17.26 that has been used for both calculations is according to the endpoint study records outside of the used model's applicability domain (log kow 0.31-8.7 for Arnot-Grobas Model and log kow 1-11.26 for BCFBAF model), ECHA considers that the provided data does not fulfil Annex XI Section 1.3 requirements.
ECHA underlines that according to Annex XI, Section 1.3. of the REACH Regulation the results of (Q)SARs may be used instead of testing when the following conditions are met:

- results are derived from a (Q)SAR model whose scientific validity has been established,
- the substance falls within the applicability domain of the (Q)SAR model,
- results are adequate for the purpose of classification and labelling and/or risk assessment, and
- adequate and reliable documentation of the applied model is provided.

Moreover, there is no justification available in the waiving statement proving that the substance would not be bioavailable for bioaccumulation via dietary exposure.

You did not provide the adequate and reliable documentation of the applied models referred to under the second and fourth bullet point above. Without such documentation ECHA is not in a position to assess whether the other conditions outlined in the first and third bullet points are fulfilled. As you have not demonstrated that the conditions of the adaptation of Annex XI, Section 1.3. of the REACH Regulation are fulfilled, the adaptation cannot be accepted.

ECHA also notes, that you have not provided exposure assessment (as the substance is not classified) to prove that the aquatic exposure would be unlikely. The range of wide dispersive uses provided in the dossier indicate the potential exposure to aquatic compartment. Even though, it is true that elimination from STP due to high adsorption properties is likely, and therefore aquatic exposure is expected to be minimal, it is not necessarily true for exposure via dietary route and therefore the potential uptake of the substance via dietary route cannot be excluded.

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

In your comments to the draft decision according to Article 50(1) of the REACH Regulation you note that "*ECHA guidance R 11 states if the log Kow > 10 and there are no indications for chronic mammalian toxicity these can be used as indicators for a lack of high bioaccumulation [...]* the physicochemical properties and molecular weight of the substance Stearyl erucamide (CAS 16260-09-6) suggest poor oral absorption [...] *it is proposed to wait for the outcome of the "P" assessment based on the enhanced biodegradation test, and the results of the mammalian chronic studies proposed for the source substance before any new bioaccumulation data is proposed to be generated experimentally*".

ECHA notes that due to the general level of the information you provided, *i.e.* the lack of solid substance-specific information and missing information, it is not possible to compare the toxicocinetics, with specific emphasis on metabolism, of the target and source substances. Moreover, ECHA notes that further information on long-term aquatic and on mammalian toxicity is requested in the decision. Thus, there is uncertainty about long-term toxicity of the substance.

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

According to ECHA *Guidance on information requirements and chemical safety assessment, Chapter R.7c* (version 3.0, June 2017) bioaccumulation in fish: aqueous and dietary exposure (test method EU C.13. / OECD TG 305) is the preferred test to cover the standard information requirement of Annex IX, Section 9.3.2.

As the substance has very low water solubility and very high partition coefficient, the dietary route would be more appropriate for testing.

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

Bioaccumulation in fish: dietary exposure bioaccumulation fish test (test method: OECD TG 305-III).

*Notes for your consideration*

Before conducting the above test you are advised to consult the ECHA *Guidance on information requirements and chemical safety assessment* (version 3.0, June 2017), Chapter R.11.4. and Figure R.11-4 on the PBT assessment for further information on the integrated testing strategy for the bioaccumulation assessment of the registered substance. You should revise the PBT assessment when information on bioaccumulation is available.

## Appendix 2: Procedural history

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

The compliance check was initiated on 12 July 2016.

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 did not amend the request(s).

ECHA notified the draft decision to the competent authorities of the Member States for proposals for amendment.

ECHA received proposal(s) for amendment and modified the draft decision.

ECHA invited you to comment on the proposed amendment(s).

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-55 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 compliance check decision does not prevent ECHA from initiating further compliance checks on the present 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 your Member State.

3. In relation to the information required by the present decision, the sample of the substance used for the new test(s) must be suitable for use by all the joint registrants. Hence, the sample should have a composition that is suitable to fulfil the information requirement for the range of substance compositions manufactured or imported by the joint registrants. It is the responsibility of all joint registrants who manufacture or import the same substance to agree on the appropriate composition of the test material and to document the necessary information on their substance composition. In addition, it is important to ensure that the particular sample of the substance tested in the new test(s) is appropriate to assess the properties of the registered substance, taking into account any variation in the composition of the technical grade of the substance as actually manufactured or imported by each registrant. If the registration of the substance by any registrant covers different grades, the sample used for the new test(s) must be suitable to assess these grades. Finally, there must be adequate information on substance identity for the sample tested and the grade(s) registered to enable the relevance of the test(s) to be assessed.