ECHA
EUROPEAN CHEMICALS AGENCY

Helsinki, 24 October 2017

Addressee: [redacted]

Decision number: CCH-D-2114375451-50-01/F
Substance name: (Z)-N-OCTADEC-9-ENYLHEXADECAN-1-AMIDE
EC number: 240-367-6
CAS number: 16260-09-6
Registration number: [redacted]
Submission number: [redacted]
Submission date: 08.07.2015
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 of the substance (Annex VI, Section 2.1.);**

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

3. **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;**

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

5. **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;**

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

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

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

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 **31 July 2020**. 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.

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Appendix 1: Reasons

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.

The identifiers used in a registration must therefore be consistent in order to enable the registered substance to be identified unequivocally.

According to chapter 4.2.2 of the Guidance for identification and naming of substances under REACH and CLP (Version: 2.1, May 2017) - 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 therefore different substances under REACH.

In your registration dossier, you provided on the one hand an EC number, CAS entry, SMILES notation and a structural formula in section 1.1 of the IUCLID dossier referring to the mono-constituent substance (Z)-N-octadec-9-enylhexadecan-1-amide. Furthermore, you have indicated that the type of substance is "mono-constituent substance" in the Composition-field in section 1.1.

On the other hand you provided an IUPAC name "N-octadec-9-en-1-ylhexadecanamide" and an InChI code that 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-octadec-9-enylhexadecan-1-amide" and others refer to a multi-constituent substance consisting of [redacted] and [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 identifiers are consistently and correctly describing your substance.

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 [redacted] then please revise the IUPAC name and the InChI code such that they describe the specific [redacted].

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 240-367-6 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 change the type of the substance to a UVCB substance and have provided the following reasoning: "Due to the variable ratio isomeric nature of the substance, the unidentifiable nature of some of the components (variable chain length) and the biological origin, the description will be updated to a UVCB." Furthermore you intend to list in IUCLID section 1.2 "[redacted])".

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.[2] Therefore, if the [redacted] starting material is derived from naturally occurring [redacted], it is expected that your substance contains mainly the [redacted].

Please note that if one constituent (such as the [redacted]) 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 [redacted]), 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 for defining whether a substance is to be considered a mono- or multi-constituent substance do not apply to your substance, and if you consider your substance falls within the definition of UVCB substances as specified in chapter 4.3 of the SID Guidance, then 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-octadec-9-en-1-ylhexadecanamide" 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 substance identifier according to the naming convention for UVCB substances given in the 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.

[2]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))

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 240-367-6 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 carefully 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.

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 registration 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 analytical report "[redacted]" you have provided a peak table for the gas chromatographic analysis, which indicates 3 peaks with an area % higher than [redacted]. While one of these peaks was reported in section 1.2 as the impurity "[redacted]", the other two peaks were reported with an area of [redacted] % and [redacted] % are not reported in section 1.2. On the peak table these two peaks are identified as "Intermediates".

Furthermore, two peaks on the peak table were identified as "[redacted]" and "[redacted]" but not reported in section 1.2.

You have reported one main constituent in section 1.2 with EC number [redacted], EC name "[redacted]", CAS number [redacted], SMILES notation and structural formula corresponding to [redacted]. 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.

You have assigned as IUPAC name "*N-octadec-9-en-1-ylhexadecanamide*" and InChI code referring to [redacted] for this main constituent.

ECHA observes that the chemical name "*N-octadec-9-en-1-ylhexadecanamide*" refers to a group of constituents consisting of [redacted] and [redacted].

Given that some of the identifiers refer [redacted] and others refer to a group of constituents consisting of [redacted] and [redacted], you have not used consistent substance identifiers in the naming and 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 all 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 a mono-constituent substance or each constituent present at ≥ 10 % and < 80 % for a multi-constituent substance) must be identified and reported individually in section 1.2.

- If the substance consists of both [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 including "[redacted])". There is no indication that these concentration ranges for the constituents are representative and, therefore, these concentration ranges appear to be too broad to identify your substance.

The minimum and maximum concentrations should be representative for each constituent and therefore should reflect the actual concentration ranges of the substance as manufactured and/or imported. Broad concentration ranges should be explained either by analytical data recorded on the substance or by the manufacturing process description.

3. 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 - as indicated in the ECHA Guidance on information requirements and chemical safety assessment (Version 4, June 2017), Chapter R7b, - 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 accepted to conduct a chronic *Daphnia magna* study using direct addition according to OECD Series on Testing and Assessment Number 23, and you proposed to use volume displacement to measure the achieved concentration in the test. ECHA notes that this method would show not only the dissolved fraction of the substance, but also the adsorbed and suspended forms. Thus, it is a less accurate method than other existing analytical methods.

However, ECHA notes that you can first perform a limit test by direct addition up to the water solubility limit of the registered substance. If no effects are seen, there will not be a need to analytically verify and quantify the dissolved concentration.

ECHA notes that the competent authority of a Member State proposed to amend the decision indicating that the aquatic integrated testing strategy 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 proposed amendment you suggested a tiered testing strategy for aquatic testing. ECHA has addressed your suggested strategy and the Member State's proposal fully in section 4. 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).

4. 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, as indicated in the ECHA Guidance on information requirements and chemical safety assessment (Version4, June 2017), Chapter R7b, 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.

In your comments to the draft decision according to Article 50(1) of the REACH Regulation, you provide reasoning not to perform the long term toxicity test on fish, mainly based on the results from the short-term fish toxicity test. As explained below, the absence of toxicity observed in the short-term tests with the registered substance having a low water solubility cannot be used as an argument for adaptation of long-term tests.

Based on the information provided in your dossier, ECHA considers that the registeresd substance is poorly soluble (water solubility < 0.01 mg/L*).* Poorly soluble substances require longer time to be significantly taken up by the test organisms and so 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 actually not even occur at the water solubility limit of the substance if the test duration is too short. Still, long-term toxicity cannot be excluded and should be investigated. 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.

ECHA considers that the available information in your chemical safety assessment does not rule out long-term effects to aquatic organisms and that further long-term effects on aquatic organisms need to be investigated. Consequently ECHA concludes that your adaptation does not meet the specific rules for adaptation of Annex IX, Section 9.1.6., column 2 and cannot be accepted.

Regarding your comment on the analytical sensitivity, ECHA would like to remind you the possibility of performing a limit test first (See above, Appendix I Section 3).

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.

ECHA notes that the competent authority of a Member State proposed to amend the decision indicating that the aquatic integrated testing strategy 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 integrated testing strategy cannot be applied in this case as further discussed below, also in response to your comments on the proposed amendment.

ECHA understands that in your comments on the proposed amendment you suggest a stepwise approach to fulfil the information requirements for long-term aquatic toxicity testing, starting with the long-term daphnia study. You propose two different study designs depending on the sensitivity of the analytical method available.

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).

You consider that the need to carry out the long-term fish study is conditional to 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 due to the following.

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 earlier in this section the registered substance has low water solubility. ECHA notes that 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. Furthermore, 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. Therefore long-term data on all three trophic levels is needed for the derivation of $PNEC_{aquatic}$ and to perform the chemical safety assessment. ECHA notes that data on aquatic microorganisms is not considered for the derivation of the $PNEC_{aquatic}$.

In your comments you discuss that as the algal toxicity represent both acute and chronic endpoints toxicity in aquatic environment is known. You state that there was "*no algal toxicity at 0.015 mg/L over 72 hours*", you also state that "*algae is by default, the most sensitive species (based on solubility and analytical verification)*". While ECHA notes that chronic data on algae is availbale it refers to the discussion in the previous paragraph on the need to have long-term data on three trophic levels. 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. ECHA hence considers it not justified to claim that alage is the most sensitive species. Furthermore, ECHA notes that due to the reasons outlined above it is not possible to define the order of sensitivities of the three species as would be 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.).

In your comments on the PfAs you included results from terrestrial toxicity studies conducted on the registered substance. You indicate that the terrestrial results have not yet been submitted in a dossier update. You conclude the data to show that there is no significant terrestrial toxicity. ECHA notes that as only effect values are provided it is not possible for ECHA to assess the compliance of the terrestrial data submitted and whether it could be used to justify lack of aquatic 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. ECHA hence considers that the terrestrial toxicity data is of limited value to prove absence of effects in the aquatic environment.

For the reasons stated above, ECHA considers that 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.

ECHA also notes that dossier updates and any adaptations therein will be checked by ECHA during the follow-up phase. Any QSAR adaptations, which you also intend to apply based on your comments on the PfAs, need to fulfill the requirements of Annex XI, section 1.3.

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 proposed amendment 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 request 3 and 4

Before conducting the above test under request 4, 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".

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 3.0, February 2016), Chapter R7b, Table R.7.8-3 summarising aquatic toxicity testing of difficult substances for choosing the design of the requested ecotoxicity test(s) and for calculation and expression of the result of the test(s).

5. 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. 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 > 5.6), indicating high adsorptive properties. Hence, 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., 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-Octadec-9-enylhexadecan-1-amide (CAS No. 16260-09-6) and its degradation products. The substance is only partly biodegradable in water according to an OECD guideline 301 D and a repetitive die away test following DGXI/400/84, EEC 1984 ([redacted], 1989) but 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 neither meet the adaptation rule of Annex IX, Section 9.2.1., column 2, according to which further testing may not be indicated on the basis of the chemical safety assessment according to Annex I, nor the specific rule for adaptation of Annex IX, Section 9.2.1.3., column 2, second indent, according to which the study does not need to be conducted if direct and indirect exposure of soil is unlikely. 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). Moreover, as there is no exposure estimation available in a Chemical Safety Report (CSR) as the substance is not classified, the possible exposure to soil compartment in a 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.

ECHA notes further that 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 provide reasoning not to perform the soil simulation test: "*Thus further biotic degradation testing is only required if the CSA indicates a need for this.*" and to perform the extended OECD TG 301B instead. 9.2.1.3., Soil simulation testing, is, however, a standard requirement and therefore this should be addressed unless the CSA would allow an adaptation.

ECHA notes that the CSA includes a number of steps as described in the REACH Regulation. Information on the degradation of a substance and its degradation products, including their 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 of the substance can be made.

As explained above, the physicochemical properties of the substance and the reported uses, justifies the need for this endpoint to be included in the technical dossier. Specifically, 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 included in the technical dossier.

ECHA acknowledges that degradation simulation testing can encounter a number of technical difficulties which should be considered before testing is initiated. 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.

Moreover, ECHA notes that performing a soil simulation test can result on formation of non-extractable residues (NER). These should be addressed properly: when reporting the NERs in the test results you are requested to explain and scientifically justify the extraction procedure and solvent used obtaining a quantitative measure of NER.

ECHA notes that the extended OECD TG 301B test can assist in persistency assessments (confirming a potential for degradation, and thus concluding on not P/vP) although it is not to be used in Classification and Labelling (ECHA Guidance R7b R.7.9.4.1).

Further, you may adapt the testing requested 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, providing adequate and reliable justification.

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) at a temperature of 12 °C.

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.

According to Annex XIII of the REACH Regulation, the identification of PBT/vPvB substances shall take account of the PBT/vPvB-properties of relevant constituents of the substance. Section R.11.4.1 of REACH Guidance document R.11 on PBT/vPvB assessment (version 3.0, June 2017) further indicates that "constituents, impurities and additives are relevant for the PBT/vPvB assessment when they are present in concentration of ≥ 0.1% (w/w). This limit of 0.1% (w/w) is set based on a well-established practice recognised in European Union legislation".

Therefore persistancy shall be concluded for each constituents, impurities and additives present in the registered substance in concentrations at or above 0.1% (w/w) or, if not technically feasible, in concentrations as low as technically detectable.

6. 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. 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 > 5.6), indicating high adsorptive properties. Hence, 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-Octadec-9-enylhexadecan-1-amide (CAS No. 16260-09-6) 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. 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, ECHA considers that you have not demonstrated that direct and indirect exposure of sediment is unlikely. The uses reported in the technical dossier indicate potential for exposure for sediment (wide dispersive professional and consumer uses). There is also no exposure estimation available in the Chemical Safety Report (CSR), as the substance is not classified. Hence, the possible exposure to sediment compartment in number of your exposure scenarios cannot be ruled out.

ECHA notes further that 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 provide reasoning not to perform the sediment simulation test: *"Thus further biotic degradation testing is only required if the CSA indicates a need for this."* and to perform the extended OECD TG 301B instead. 9.2.1., Sediment simulation testing, is, however, a standard requirement and therefore this should be addressed unless the CSA would allow an adaptation.

ECHA notes that the CSA includes a number of steps as described in the REACH Regulation. Information on the degradation of a substance and its degradation products, including their 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 of the substance can be made.

As explained above, the physicochemical properties of the substance and the reported uses, justifies the need for this endpoint to be included in the technical dossier. Specifically, the OECD 308 provides that the test "*is applicable to slightly volatile, non-volatile,* water-soluble or poorly water-soluble compounds". You stated that the water solubility is virtually insoluble but the reported water solubility is <0.01 mg/L, which could also correspond to poor water soluble substances. Furthermore, the high potential for adsorption to sediment justifies the need for this endpoint to be included in the technical dossier.

ECHA acknowledges that degradation simulation testing can encounter a number of technical difficulties which should be considered before testing is initiated. 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.

Moreover, ECHA agrees you that performing a sediment simulation test can result on formation of non-extractable residues (NER). These should be addressed properly: when reporting the NERs in the test results you are requested to explain and scientifically justify the extraction procedure and solvent used obtaining a quantitative measure of NER.

ECHA notes that the extended OECD TG 301B test can assist in persistency assessments (confirming a potential for degradation, and thus concluding on not P/vP) although it is not to be used in Classification and Labelling (ECHA Guidance R7b R.7.9.4.1).

Further, you may adapt the testing requested 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, providing adequate and reliable justification.

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 Februaryr 2016) indicates 12°C (285K) as the average environmental temperature for the EU to be used in the chemical safety assessment. Performing the test at the temperature of 12°C is within the applicable test conditions of the Test Guideline OECD TG 308. Therefore, the test should be performed at the temperature of 12°C.

Therefore, pursuant to Article 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) at a temperature of 12 °C.

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.

According to Annex XIII of the REACH Regulation, the identification of PBT/vPvB substances shall take account of the PBT/vPvB-properties of relevant constituents of the substance. Section R.11.4.1 of REACH Guidance document R.11 on PBT/vPvB assessment (version 3.0, June 2017) further indicates that "constituents, impurities and additives are relevant for the PBT/vPvB assessment when they are present in concentration of ≥ 0.1% (w/w). This limit of 0.1% (w/w) is set based on a well-established practice rooted in a principle recognised in European Union legislation". Therefore persistancy shall be concluded for each constituents, impurities and additives present in the registered substance in concentrations at or above 0.1% (w/w) or, if not technically feasible, in concentrations as low as technically detectable.

7. 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.

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.

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.

In your comments to the draft decision according to Article 50(1) of the REACH Regulation, you state that "*identification of degradation products is like further biotic degradation testing only required if the CSA indicates a need for this.*" Section 9.2.3. of Annex IX of the REACH Regulation, Identification of degradation products, is a standard requirement and therefore this should be addressed unless the CSA would allow an adaptation.

In your comments to the draft decision, you suggested a biodegradation pathway for the registered substance. There is no supporting adequate and reliable justification document and, therefore, this adaptation cannot be accepted.

This decisions requests identification of degradation products "*using an appropriate and suitable test method*". ECHA notes that, although the preferred study to identify the degradation products are simulation tests, the extended OECD 301B may be used to identify the degradation products, if the registered substance is fully mineralised during this test.

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.

According to Annex XIII of the REACH Regulation, the identification of PBT/vPvB substances shall take account of the PBT/vPvB-properties of relevant constituents of the substance. Section R.11.4.1 of REACH Guidance document R.11 on PBT/vPvB assessment (version 3.0, June 2017) further indicates that "constituents, impurities and additives are relevant for the PBT/vPvB assessment when they are present in concentration of ≥ 0.1% (w/w). This limit of 0.1% (w/w) is set based on a well-established practice recognised in European Union legislation". Therefore degradation products shall be identified for each constituents, impurities and additives present in the registered substance in concentrations at or above 0.1% (w/w) or, if not technically feasible, in concentrations as low as technically detectable.

8. 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-Octadec-9-enylhexadecan-1-amide (CAS No. 16260-09-6) 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 the main components of > 5 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 components 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 using BCFBAF v3.01. BCF/BAF values calculated for the substance exhibit a low bioaccumulation potential ([redacted]*, 2012). 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.*

But it supports the tendency that substances with high log Kow values (> 10) have a lower potential for bioconcentration as summarized in the ECHA Guidance R.11 (ECHA, 2012) and they are not expected to meet the B/vB criterion, which is also in accordance with Annex IX of Regulation (EC) No 1907/2006.

The substance is characterised by a low water solubility and high log Koc leading to a low bioavailability. Due to its higher molecular weight, no extensive metabolism of the substance is expected but rather direct elimination. In conclusion, a bioaccumulation or biomagnification through the food chain of the substance is not expected.
It can hence be concluded that the high log Kow, which indicates a potential for bioaccumulation, overestimates the bioaccumulation potential of the substance."

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*[3]*. Instead these properties may influence the form of PBT testing required."*

ECHA notes further that you have provided QSAR calculations to estimate the bioaccumulation potential of the substance. However, there are no QMRF nor QPRF documents provided in the dossier to enable ECHA to assess the reliability of the provided QSAR calculations, while the log Kow of 14.31 that has apparently been used for both calculations is according to the information provided 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 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.

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.

Therefore, ECHA considers that the provided data does not fulfil Annex XI Section 1.3 requirements.

3 emphasis added

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

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.
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) and bioaccumulation in sediment-dwelling benthic oligochaetes 315 (test method OECD TG 315) are 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 potential uptake of the substance by aquatic organisms is expected to occur mainly via food ingestion, therefore the fish dietary route would be more appropriate for testing bioaccumulation.

In your comments to the draft decision according to Article 50(1) of the REACH Regulation, you suggested to conduct the OECD TG 315. ECHA notes that Annex IX Section 9.3.2. states that bioaccumulation should preferably be performed on fish. However, ECHA agrees with you that due to the physicochemical properties and uses of the substance, sediment and soil would be the main target compartments and so, sediment dwelling organisms could be used for the screening and as part of the weigh-of-evidence assessment of bioaccumulation properties (ECHA Guidance R11v 3.0, June 2017).

However, it should be noted it is not possible to give any threshold values for using sediment BSAF values in PBT assessment. A case-by-case assessment based on expert judgement of the reliability and relevance of the available information is required in order to be able to give BSAF values an appropriate weight in the B and vB assessment (ECHA Guidance R11v 3.0, June 2017).

You further propose to withdraw the bioaccumulation study from the present decision, and submit a testing proposal if the registered substance concludes to be P/vP. ECHA notes that information on bioaccumulation is already requested in the decision. Thus, there will be no need for providing a testing proposal.

Following Member State Competent Authorities Proposals for Amendment (PfAs) the option to fulfil the present standard information requirement by carrying out the OECD 315 test (bioaccumulation in sediment-dwelling benthic oligochates) was removed due to the limitations of using the results derived from the OECD 315 study for the B/vB assessment.

In your comments on the PfA you propose a step-wise approach whereby you would first review the PBT assessment based on extended biodegradation study. ECHA acknowledges that data on bioaccumulation is only needed if the substance is confirmed to be P or vP and if information on bioaccumulation is needed to complete the PBT/vPvB assessment. However, ECHA refers you to consult the ECHA *Guidance on information requirements and chemical safety assessment* (version 3.0, June 2017), Chapter R.11.4. on the usability of the extended degradation test for P/vP assessment.

You would follow by assessing QSAR data and producing in silico data to assess the aquatic and dietary route for bioaccumulation potential. You consider that if the conditions set in Annex XI section 1.3. are not fulfilled you would consider read-across to EC Number 240-367-6. ECHA notes that the EC number you only use to identify is the EC number of the registered substance. Nevertheless ECHA notes that any read-across adaptation needs to fulfil the requirements set in Annex XI section 1.5. Similarly any QSAR approach needs to fulfil the requirements of Annex XI section 1.3. Any adaptations included in the updated technical dossier will be assessed by ECHA at the follow-up stage.

You propose to also use modelling "*to support the hypothesis that the majority of the substance will deposit to the sediment compartment*". You consider for bioaccumulation testing to test most relevant environmental compartment. Hence if the sediment is shown to be the compartment of concern, you would conduct an OECD 315 study and the OECD 305 study via the dietary route as requested if the aquatic environment is compartment of concern.

ECHA acknowledges your discussion on environmental relevance, testing vertebrate species and potential analytical limitations. Nevertheless ECHA considers that as the data on bioaccumulation is needed for the PBT/vPvB assessment the data produced needs to be usable for that purpose. As discussed above, there are limitations in using the results obtained from the OECD TG 315 study as it is not possible to give any threshold values for using the sediment BSAF values in the PBT/vPvB assessment. Nevertheless, ECHA notes that according to ECHA *Guidance on information requirements and chemical safety assessment* (version 3.0, June 2017), Chapter R.11.4. bioaccumulation studies on sediment dwelling organisms can be used both for the screening and as part of the Weight-of-Evidence (WoE) assessment of bioaccumulation properties. A case-by-case assessment based on expert judgement of the reliability and relevance of the available information is required in order to be able to give BSAF values an appropriate weight in the B and vB assessment (ECHA *Guidance on information requirements and chemical safety assessment* (version 3.0, June 2017), Chapter R.11.4). ECHA notes also that any WoE approaches need to fulfil the requirements of Annex XI section 1.2. As already indicated any adaptations included in the updated technical dossier will be assessed by ECHA at the follow-up stage. 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.

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".

Deadline to submit the requested information in this decision

In the draft decision communicated to you the time indicated to provide the requested information was 24 months from the date of adoption of the decision. In order to perform both simulation tests and the bioaccumulation test in a sequential manner (*i.e.* following the ITS), this time frame should be extended to 33 months. Therefore, ECHA has set the deadline to 33 months from the date of adoption of this decision.

In your comments on the MSCAs PfAs you requested an extension of the deadline to 36 months to alow time for intelligent testign strategy for the environment fate related endpoints. ECHA notes that as indicated above the timeline was already extended following the MSCAs PfAs to 33 months to allow time to conduct the simulation tests and the bioaccumulation test in a sequential manner (*i.e.* following the ITS). Therefore, ECHA has not modified the deadline of the decision.

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 16 June 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 amended the request(s) and the deadline.

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.