EUROPEAN CHEMICALS AGENCY

Helsinki, 27 September 2017

Addressee: [redacted]

Decision number: CCH-D-2114370487-40-01/F
Substance name: dodecyl acrylate
EC number: 218-463-4
CAS number: 2156-97-0
Registration number: [redacted]
Submission number: [redacted]
Submission date: 17/09/2015
Registered tonnage band: 100-1000

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. **Growth inhibition study aquatic plants (Annex VII, Section 9.1.2.; test method: Alga, growth inhibition test, EU C.3./OECD TG 201) with the registered substance;**

2. **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;**

3. **Long-term toxicity testing on fish (Annex IX, Section 9.1.6.1.; test method: Fish, early-life stage (FELS) toxicity test, OECD TG 210) 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 to the REACH Regulation. 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 adequate and reliable documentation.

You have to submit the requested information in an updated registration dossier by **4 October 2018**. You also have to update the chemical safety report, where relevant.

The reasons of this decision are set out in Appendix 1. The procedural history is described in Appendix 2 and 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, has to 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 Ofelia Bercaru, Head of Unit, Evaluation E3

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

Appendix 1: Reasons

0. Grouping of substances and read-across approach

ECHA based its decision on the evaluation of your registration dossier that contains adaptation arguments in form of a grouping and read-across approach under Annex XI, 1.5. of the REACH Regulation for the endpoints *Growth inhibition study aquatic plants (Annex VII, Section 9.1.2.)* and *Long-term toxicity testing on aquatic invertebrates (Annex IX, Section 9.1.5.*). ECHA has assessed first the scientific and regulatory validity of your read-across approach in general (sections 0.1, 0.2, 0.3) before assessing the individual endpoints (sections 1 and 2).

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 similar substances (grouping of substances and read-across), "provided that the conditions set out in Annex XI are met". According to Annex XI, section 1.5. there needs to be structural similarity among the substances within a group or category and furthermore, it is required that the relevant properties of a substance within the group can be predicted from the data for the reference substance(s), and the data should be adequate for the purpose of classification and labelling and/or risk assessment. The REACH Regulation aims at promoting wherever possible the use of alternative means, where equivalent results to the prescribed test are provided on health and environmental hazards. In accordance with these objectives and the objectives of the Compliance Check process, ECHA shall assess whether a prediction of the relevant properties of the substance subject to this decision by using the results of the proposed read-across is acceptable based on the information currently available.

0.1 Description of the grouping and read-across approach proposed by the Registrant

You seek to adapt the following ecotoxicology information requirements, subject to the current decision:

- Growth inhibition study aquatic plants (Annex VII, 9.1.2.);
- Long-term toxicity testing on aquatic invertebrates (Annex IX, 9.1.5.);

by applying a read-across approach according to Annex XI, Section 1.5.

You propose read-across between the substance subject to this decision, dodecyl acrylate (EC No. 218-463-4, CAS No. 2156-97-0) as target substance and the structurally similar substance, Laurylacrylat 1214 (*"mixture of laurylacrylate (CAS No.: 2156-97-0) and tetradecylacrylate (CAS No.: 21643-42-5)"*) as source substance.

Your technical dossier contains read-across documentation as a separate record in IUCLID Section 13 ("*Read Across Statement*").

You use the following arguments to support the prediction of properties of the registered substance from data for the source substance: "*The test item is comprised of a long-chain hydrocarbon linked to an acrylate group. (..) The chosen read-across substances share the same functional groups with the test item and thus provide important physicochemical and (eco-) toxicological information (..)*"

Furthermore, to justify the prediction of aquatic toxicity you indicate that "*Since these acute aquatic toxicity tests were conducted with a mixture of* [redacted] *these toxicity values can be used for the read across approach with the test item due to the fact that testing with the mixture represents a worst case assumption with respect to the* [redacted]*.*"

You propose that the source and registered substances have similar properties for the above-mentioned information and that using information on the source substance would constitute a worst-case approach in the prediction of aquatic toxicity of the target substance.

ECHA considers that this information is your read-across hypothesis, which provides the basis whereby you predict the properties of the registered substance from the source substance.

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

Based on the information provided in your registration dossier, ECHA concludes that there is not a reliable basis whereby the properties of the registered substance may be predicted from data for the source substance, as outlined below.

Substance characterisation of source and target substances

The substance characterisation of the source substance(s) needs 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 2.1, May 2017) 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.

ECHA acknowledges that you have provided information on the substance identity for the target substance in the technical dossier, with a typical concentration of [redacted]% w/w (99.9-100% w/w) and no impurities reported.

ECHA notes that in the read-across documentation the source substance is described only as "*mixture of* [redacted]" and no further information on its composition is provided. Regarding the test material in the study for Long-term toxicity testing on aquatic invertebrates, the Robust Study Summary (RSS; IUCLID section 6.1.4) refers to the analytical report "[redacted]", which is attached to IUCLID Section 1.4 of the technical dossier. According to the information in the analytical report, ECHA understands that the material tested in this study, described as Laurylacrylate 1214, CAS No. 84238-60-8 (Test substance No. 11/0545-1), has a purity of 93.6% and contains [redacted]% of the [redacted] component and [redacted]% of the [redacted] component (area %). However, regarding the test material in the study for Growth inhibition study aquatic plants (IUCLID section 6.1.5) described as Laurylacrylat 12/14 (Test Substance No. 0668/88), no information is given on the ratio of the [redacted] and [redacted] components.

In the absence of this information, ECHA concludes that it is not possible to compare the source substance with the registered substance as a basis for the read-across for the Growth inhibition study aquatic plants.
Furthermore, ECHA notes that you have not discussed the impact of impurities of the source substance on the predictions.

Structural similarity

According to the provisions of Annex XI, section 1.5 of the REACH Regulation, structural similarity is a prerequisite for applying grouping and read-across approaches. However, structurally similar substances still exhibit differences in their chemical structures. The impact of these structural differences on the properties of the substances needs to be accounted for in the read-across hypothesis in order to establish that the properties of the target substance can be predicted from data on the source substance.

You state that "*The test item is comprised of a long-chain hydrocarbon linked to an acrylate group. (..) The chosen read-across substances share the same functional groups with the test item and thus provide important physicochemical and (eco-) toxicological information (..)*" and that "*Since these acute aquatic toxicity tests were conducted with a mixture of [redacted]), these toxicity values can be used for the read across approach with the test item due to the fact that testing with the mixture represents a worst case assumption with respect to the* [redacted] ECHA observes that the source substance is a mixture of dodecyl acrylate ([redacted]), i.e. the target substance, and tetradecyl acrylate ([redacted]). ECHA notes that these two components are similar in structure as they share the same acrylate group and that the target substance ([redacted]) differs from the [redacted] component of the source substance by having a shorter aliphatic chain. You acknowledge that "*basic physicochemical properties such as water solubility and the partition coefficient (logPow) depend strongly on the hydrophobic hydrocarbon chain. The longer the aliphatic tail the lower the water solubility.*" However, while you discuss the impact of chain length on the physicochemical properties of the substances, ECHA notes that you have not discussed how the difference in chain length may impact the prediction of ecotoxicity.

ECHA concludes that in absence of such discussion it has not been demonstrated that the source substance could be used to predict the ecotoxicological properties of the target substance.

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 structural 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.

You have not submitted a data matrix. Furthermore, the key studies available in the technical dossier of the target substance for the physico-chemical properties of most relevance for prediction of ecotoxicological properties (in particular partition coefficient and water solubility) are only on the source substance (mixture of [redacted]). While it is not possible to compare directly the physico-chemical properties of target and source substances, based on the structural difference between the target substance and the [redacted] component of the source substance, the latter is expected to have lower water solubility and higher partitioning coefficient (Log Kow). Such differences may lead to differences in environmental fate and ecotoxicological properties. For instance, differences in water solubility and partition coefficient may have an impact on the bioavailability of substances during ecotoxicity tests, as well as on the prediction of ecotoxicological properties.

Furthermore, ECHA notes that in the technical dossier you have included two studies for short-term toxicity on fish (IUCLID Section 6.1.1):

- a key study with the source substance Laurylacrylat 1214 (mixture of [redacted]) (key study, reliability 2, 1988, report no. 10F0155/885145; LC50 (96h) = 460.0 mg/L, nominal, non GLP, test method: German industrial standard test guideline DIN 38 412, part L 15, JUNE 1982);
- a supporting study with the registered substance (supporting study, reliability 2, 1986, 2 publications: Geiger et al. 1986, Russom et al. 1988; LC50 (96h) > 4.34 mg/L measured initial, non GLP, test method: no guideline followed).

However, the ECHA Guidance on information requirements and chemical safety assessment (version 4.0, June 2017), Chapter R7b, indicates that absence of toxicity in short-term studies cannot be used to conclude on the toxicity potential of low water solubility substances since the time taken for an equilibrium to be reached and toxic effects to be shown for a low water solubility substance is too long for an effect to be revealed in an acute study. Therefore, as both substances have low water solubilities and in particular as no effects were observed in the study on the target substance, it is not possible to use acute data to compare their toxicities. Furthermore, the study on the source substance cannot be considered valid as it is not possible to know the exposure concentrations since the test has been conducted without analytical monitoring and at test concentrations above the water solubility of the tested material.

Therefore, there is currently no data to allow comparison of the ecotoxicities of the target and the source substance. As a consequence, you have not demonstrated nor discussed that studies with the source substance would not underestimate the effects that would be observed in studies with only the [redacted] component.

ECHA concludes that you have not demonstrated that the source substance provides the worst case estimation of the toxic potential of the registered substance. Accordingly, your read-across hypothesis is not a reliable basis whereby the properties of the registered substance may be predicted from data of the source substance. ECHA notes that in your comments on the draft decision (DD) you agree with the requests for Growth inhibition study aquatic plants (Annex VII, section 9.1.2.) and Long-term toxicity testing on fish (Annex IX, section 9.1.6.1.). However, in addition based on your comments on the DD, ECHA understands you still wish to pursue a read-across adaptation according to Annex XI, Section 1.5 for the endpoint of Long-term toxicity testing on aquatic invertebrates (Annex IX, section 9.1.5.) using the same study already addressed by ECHA under request 2. below.

In your comments on the DD you provide an updated "[redacted]" document where you have included 11 "[redacted] *with differing aliphatic tail lengths, with or without terminal branching*". However, in the data matrix therein you have data on the physico-chemical, ecotoxicological and toxicological properties for the target and the following six substances, only: 2-Ethylhexyl acrylate (CAS No 103-11-7, [redacted]); 2-Propylheptyl acrylate (CAS No 149021-58-9, [redacted]); Tetradecyl acrylate (CAS No 21643-42-5, [redacted]); Laurylacrylat 1214 (CAS No 84238-60-8, mixture of [redacted]); Stearyl acrylate (CAS No 90530-21-5, mixture of [redacted]); Behenyl acrylate (CAS No not provided, mixture of [redacted])

You state that the "*length of the aliphatic tails influences the physicochemical and (eco) toxicological properties*" making it possible to "*extrapolate information for the addressed endpoints by using a range of read-across substances with differing tail lengths (weight-of-evidence approach*)". Hence, ECHA considers that you have included these six substances to support your hypothesis that physicochemical and toxicity properties are influenced by the length of the aliphatic chain.

ECHA notes that while you have indicated that a read-across / weight of evidence approach has been submitted, you have not provided any explanation or justification on how the sources of information/studies that you have provided enable to conclude on an endpoint based on a weight of evidence approach. ECHA notes that a weight of evidence adaptation pursuant to Annex XI, Section 1.2. requires sufficient weight of evidence from several independent sources of information leading to the conclusion that a substance has or has not a particular dangerous property with respect to the information requirement in question including an adequate and reliable documentation while the information from each single source alone is regarded insufficient to support this notion. Hence, based on the above, ECHA considers that the information provided in the "[redacted]" document, currently, cannot be interpreted as a *Weight -of-Evidence* justification. However, in addressing the decision requests, you can further revise this document and provide a revised adaptation of the information requirement according to Annex XI, Section 1.2., which therein will be evaluated by ECHA at the follow up stage.

ECHA has assessed the information provided in the "[redacted]" document. ECHA considers your revision of this documents as a revison of your adaptation of the information requirement according to Annex XI, Section 1.5., only. Therefore, ECHA has assessed the information presented in your comments according to Annex XI, Section 1.5. grouping of substances and read-across approach, only.

Furthermore, ECHA notes that in parts of your read-across document you also refer to a category and attempt to justify that there is "*a constant pattern in the changign of the potency of the properties across the category*". ECHA notes that while you list the category members, you do not define unambiguously the applicability domain of the proposed category. You also identify 11 members, while in the data matrix include only six. Information on applicability domain is necessary to outline possible differences among the category members and constitutes a set of inclusion and exclusion rules establishing the molecular structure(s) that a substance must have to be part of the category and describing the accepted structural differences within the category. You have not defined these inclusion and exclusion criteria.

According to ECHA *Guidance on information requirements and chemical safety assessment* (version 1, May 2008), Chapter R.6, such criteria should be described in order to identify the range of values within which reliable estimations can be made for the members of the category and to define the borders of the category. ECHA considers that the general statement of "*differing aliphatic tail lengths, with or without terminal branching were found to be suitable candidates for this approach"* does not sufficiently or adequately characterise the category nor its boundaries.

Given that the category definition is not clear, ECHA is unable to verify that the substances in the category can be used so that environmental effects may be predicted from data for reference substance(s) within the group by interpolation to other substances in the group (read-across approach). Nevertheless, the determination that the grouping is insufficiently defined, and thereby fails to provide a basis for prediction in accordance with Annex XI, 1.5. does not affect the possibility for you to invoke a read-across approach in order to predict environmental effects of these substances individually on the basis of a one-to-one analogue approach.

In addition, ECHA notes that while you attempt to use a category approach to identify a trend, for the endpoint of Long-term toxicity testing on aquatic invertebrates you still propose only a one-to-one read-across approach with Laurylacrylat 1214 (mixture of [redacted]) as the proposed source substance. While in the following ECHA has assessed the validity of this one-to-one analogue approach in light of the udpated read-across information and your comments on the DD, ECHA has also addressed whether indeed a change in the potency of the properties of the category would support this one-to-one read-across approach.
ECHA notes that in your updated read-across justification you provide further arguments to support your read-across. Firstly, you indicate that read-across between acrylic esters is possible due to a common metabolic pathway, that of metabolic hydrolysis to acrylic acid (common breakdown product) and to the corresponding alcohol. ECHA notes that the discussion on biotransformation to common compounds provided in your comments on the DD is used to justify the read-across on human health endpoints only and no discussion on its relevance for ecotoxicity is provided. Therefore, ECHA considers that your updated read-across justification does not support the read-across proposed for the ecotoxicity endpoints addressed in the current decision.

Secondly, you maintain that the target substance and the source substance, Laurylacrylat 1214 are structurally similar and that the chain length influences the physicochemical properties. While this was acknowledged by ECHA in the initial DD, ECHA considered that you did not justify how the differences in chemical structure and physicochemical properties may impact ecotoxicity. In your comments on the DD you now claim that there is "*a constant pattern in the changing of the potency of the properties across the category.(with increasing chain length the reactivity (toxicity) decreases*".

ECHA considers that the information above is your updated read-across hypothesis. ECHA has assessed the information presented in your comments on the DD and your updated read-across justification and concludes that there is not a reliable basis whereby the properties of the registered substance may be predicted from data for the source substance, as outlined below.

As indicated above, in your comments on the DD and your updated read-across justification, you propose that there is a pattern of decreasing toxicity with increasing chain length and have provided a data matrix with ecotoxicity values for six acrylates. However, ECHA observes that a regular pattern in the changing of the potency is not observed due to the following:

ECHA notes that in the data matrix you have included acute aquatic data as an evidence of a trend. However, as indicated in the initial DD, for low water solubility substances absence of effects in acute data cannot be used to conclude on toxic potential. Therefore, it is not possible to use acute aquatic data to accurately demonstrate a changing potency in toxicity for these substances with such different water solubility values.

Therefore, ECHA considers that based on the properties of the target and source substances, chronic data is preferred to be used to support your hypothesis. In the data matrix you have presented experimental chronic algae data for five substances and experimental chronic daphnia data for one substance only. ECHA notes that you have not provided any Robust Study Summaries (RSSs) as part of your comments on the DD. ECHA acknowledges that for the proposed source substance, Laurylacrylat 1214, the RSS for the algae and *daphnia* studies have been submitted as part of the registration dossier of the target substance. However, as indicated in requests 1. and 2. below, based on the available information in the registration dossier, ECHA considers these studies as not reliable. While in your comments on the DD, you do not directly agree with ECHA's assessment on the non validity of the algae study, you agree to carry out a new study on the registered substance for this endpoint. Concerning the *daphnia* data, ECHA notes that as discussed in request 2. below, the data reliablity remains unknown. Also, ECHA notes that for a trend to be established and confirmed, valid aquatic data on more than one substance needs to be available. Similarly with one chronic daphnia data on one substance only, there are no bridging studies available to support a one-to-one read-across approach.

Regarding aquatic testing of aliphatic acrylates in general, in your comments on the DD you identify that "*The problem testing long-chain aliphatic acrylates is the measurement of test concentrations, which is a test guideline validity criterion. Since these substances are so poorly soluble, the available analytical methods are not capable of measuring test concentrations, so the properties of the substance do not allow for a valid test*". Furthermore, you indicate that "*For long-chain aliphatic acrylates based on the poor water solubility only ecotoxicology tests are available given nominal effect concentrations. However, especially in the more current tests all reasonable efforts were taken to produce a saturated solution of the test substance in test media, following the guidance in OECD Guidance 23.*" In light of these difficulties in testing higher chain aliphatic esters and in absence of Robust Study Summaries (RSSs), ECHA cannot assess the validity of the other data in the data matrix and considers that they cannot be currently used as evidence of changing of potency of ecotoxicity, to support your one-to-one read-across.

In conclusion, due to the limitations described above, the data provided in the data matrix cannot be used to justify your hypothesis that the ecotoxicity decrease with increasing chain length.

In your comments on the DD, you also provide QSAR predictions for the target substance ([redacted]) and for the [redacted], the other constituent of the proposed source substance Laurylacrylat 1214, for the following ecotoxicity endpoints: acute toxicity to fish, acute toxicity to aquatic invertebrates, chronic toxicity to aquatic invertebrates, acute toxicity to aquatic plants and chronic toxicity to aquatic plants. You indicate that "*This estimation approach is based on the structure activity relationship of the substances' Log Pow value with the chosen endpoint. Using this approach endpoints such as LC50 (fish, 96 h, mortality), LC50 (daphnia, 48 h), LC50 (green algae, 96 h, growth), and chronic values (survival/growth) (fish, 96 h) can be predicted. Consequently, read across of similar substances for aquatic toxicity endpoints are acceptable. (..) In this regard read across approaches for aquatic toxicity endpoints can be made for substances showing similar molecular weights or Log Pow values and thus similar molecular structures. This is the case for the reference substances chosen here.*" However, you do not discuss how this information supports your read-across adaptation.

Furthermore, ECHA notes that these predictions do not meet the general rule for adaptation of Annex XI, Section 1.3. set for acceptance of QSAR models in Annex XI, section 1.3. due to the following reasons. ECHA notes that these predictions are not correctly documented, since (Q)SAR prediction reporting format (QPRF) and (Q)SAR model reporting format (QMRF) have not been submitted, and the specific model used is not explicity mentioned. However, ECHA understands that these predictions have been calculated with the publicly available "Acrylate" SAR models in ECOSAR (US EPA). Thus, even in absence of adequate documentation, ECHA was able to assess the predictions provided, and considers them not valid due to the following:

- The following ECOSAR models for acrylates are built only on few data points and/or have very low correlation coefficients (R^2), leading to unreliable predictions: acute toxicity to aquatic plants (n=6+1, R^2 = 0.1463), chronic toxicity to aquatic invertebrates (n=0+2, R^2 = N/A) and chronic toxicity to aquatic plants (n=4+1, R^2 = 0.4209). Therefore the results for the endpoints above are not derived from a (Q)SAR model whose scientific validity has been established.
- The target [redacted] with Log Kow of 6.13 and the [redacted] with Log Kow of 7.11 do not fall within the applicability domain (AD) of the following models, whose AD is described by an upper limit of log Kow: for acute toxicity to fish and to aquatic invertebrates the maximum Log Kow is 5, and for acute toxicity to aquatic plants the maximum Log Kow is 6.4.

In conclusion, the (Q)SAR information submitted is not sufficient to fulfil the requirements of Annex XI, section 1.3. Consequently, this data cannot be used to support your read-across hypothesis that the ecotoxicity decrease with increasing chain length.

While for the purpose of this decision making, ECHA does not take into account any dossier updates after the notification of this draft decision under Article 50(1) of the REACH Regulation, ECHA notes that dossier updates and any adaptations therein will be evaluated by ECHA at the follow up stage.

0.3 Conclusion on the grouping and read-across approach

In summary, based on the submitted information, in the technical dossier and considering your comments on the draft decision and your updated read-across justification, ECHA considers you have not currently demonstrated that the substances would have similar properties or they would follow a regular pattern in their properties regarding the specific endpoints requests in the draft decision. As a consequence, for the reasons as set out above, and taking into account all of your arguments, ECHA considers that this grouping and read-across approach there is not an adequate basis for predicting the properties of the target substance from the data obtained with the source substances and read-across approach does not comply with the general rules of adaptation as set out in Annex XI, 1.5. of the REACH Regulation. Therefore, ECHA concludes that you have not demonstrated the aquatic toxicities of the target and source substances are similar.

Therefore, this adaptation cannot be accepted and there is a data gap for the endpoints covered by this read-across approach.

1. Growth inhibition study aquatic plants (Annex VII, Section 9.1.2.)

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

"Growth inhibition study aquatic plants" is a standard information requirement as laid down in Annex VII, Section 9.1.2. 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 1.5. of the REACH Regulation by providing a study record for an Alga, Growth Inhibition Test (key study, reliability 2, 1989, report no. 01/88/0668; non GLP, test method: German national standard DIN 38412, Part 9) with the analogue substance Laurylacrylat 1214 (mixture of [redacted]). However, as explained above in Appendix 1, section 0 of this decision, your adaptation of the information requirement cannot be accepted.

Therefore, Annex XI 1.5 adaptation requirements are not fulfilled and there is a data-gap.

Furthermore, the read-across study submitted does not provide the information required by Annex VII, Section 9.1.2., because it is not valid due to the following. The study has been conducted without analytical monitoring and the test concentrations (1.00, 2.50, 5.00, 10.00, 25.00, and 50.00 mg/L nominal) are above the water solubility of the test material. ECHA understands that you have taken into account the low water solubility of the source substance in the preparation of the test solutions. You indicate that "*The stock solution was prepared by dissolving 1000 mg test substance and 100 mg of the solubilizer Cremophor in dilution water. The test concentrations were then prepared by dilution with test water.*" You further report that the nominal concentrations of the solubiliser in the test solutions were 0.10, 0.25, 0.50, 1.0, 2.5, 5.0 mg/L.

ECHA notes that, as a deficiency to the study, in the robust study summary (RSS; IUCLID section 6.1.5) you have indicated that "*The use of Tween 80 as solubilizer could have lead to generation of artifacts and thus generated lower effect concentrations.*" However, you have neither discussed the change in bioavailability of the test substance in the presence of high concentrations of solubiliser, nor assessed the impact of the use of the solubiliser on the aquatic toxicity of the test material, as recommended in OECD Guidance Document on Aquatic Toxicity Testing of Difficult Substances and Mixtures, ENV/JM/MONO (2000)6. In addition, ECHA notes that you have not indicated in the relevant IUCLID field whether the validity criteria of OECD TG 201 have been fulfilled. Since the RSS does not report details on the study results nor observations made during the test, it is not possible to verify whether the validity criteria have been fulfilled for the submitted key study.

In conclusion, in the absence of analytical monitoring and of a discussion on the bioavailability of the source substance, it has not been demonstrated that the substance, which is poorly water soluble, has been kept in solution. Since it is not possible to know the exposure concentrations, ECHA concludes that the key study is not valid. It thus cannot be used to fulfil the standard information requirement for the present endpoint nor does it meet the requirements of Annex XI, Section 1.5 of REACH (be adequate for the purpose of classification and labelling and/or risk assessment).

In your comments on the DD, you agree to conduct the requested study with the registered substance. You also indicate that you will follow the OECD Guidance Document on Aquatic Toxicity Testing of Difficult Substances and Mixtures (OECD 23) as also advised by ECHA below. You nevertheless indicate that it may not be possible to measure test substance concentrations in the test systems. ECHA notes that if you should encounter technical difficulties to perform the test, for example related to sensitivity of the analytical method used for the determination of test concentration, such difficulties and attempted solutions should be clearly documented. In your comments on the DD, you also indicate that water solubility measurements of the registered substance according to OECD TG 105 are initiated, in order to further clarify the water solubility. ECHA considers that this information should be taken into account when choosing the appropriate methods for test substance preparation and for determination of the test substance concentrations.

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.7b* (version 4.0, June 2017) Algae growth inhibition test (test method EU C.3. / OECD TG 201) is the preferred test to cover the standard information requirement of Annex VII, Section 9.1.2.

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: Algae growth inhibition test, EU C.3./OECD TG 201).

Notes for your consideration

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

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

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

You have sought to adapt this information requirement according to Annex XI, Section 1.5. of the REACH Regulation by providing a study record for a Long-term toxicity testing on aquatic invertebrates (key study, reliability 1, 2012, report no. 51E0545/11E136; GLP, test method: OECD TG 211 (*Daphnia magna* Reproduction Test)) with the analogue substance Laurylacrylat 1214 (mixture of [redacted]). However, as explained above in Appendix 1, section 0 of this decision, your adaptation of the information requirement cannot be accepted. Therefore, Annex XI 1.5 adaptation requirements are not fulfilled and there is a data-gap.

Furthermore, the read-across study submitted does not provide the information required by Annex IX, Section 9.1.5., because the results cannot be considered reliable due to the following. The study has been conducted without analytical monitoring and the test concentration (100 mg/L nominal) is above the water solubility of the test material. "You indicate that "*all reasonable efforts were taken to produce a saturated solution of the test substance in test media, following the guidance in OECD 23*" but also state that "*the analytical detection limit was above the water solubility of the test substance.*" ECHA notes that in absence of analytical monitoring, it has not been demonstrated that the substance, which is poorly water soluble, has been kept in solution. It is therefore not possible to know the exposure concentrations. Therefore ECHA concludes that the key study is not reliable. It thus cannot be used to fulfil the standard information requirement for the present endpoint nor does it meet the requirements of Annex XI, Section 1.5 of REACH (be adequate for the purpose of classification and labelling and/or risk assessment).

In your comments on the DD, you maintain that this standard information requirement can be fulfilled with the data on the analogue substance, Laurylacrylat 1214 (mixture of [redacted]), and that you consider the current study in the technical dossier to accurately reflect the (absence of) chronic toxicity of the source substance to daphnia. As indicated by ECHA above, ECHA considered that the study is not reliable due to absence of anaytical monitoring. In your comments on the DD, you quote ECHA Guidance on information requirements and chemical safety assessment, Chapter R.7b (version 4.0, June 2017) Table R.7.8-3.

ECHA guidance states that in cases where toxicity is observed at concentrations above water solubility the results may be expressed in terms of nominal concentration. However, ECHA notes that in this case no effects were observed at the nominal (limit) test concentration of 100 mg/L and as indicated above due to no analytical monitoring taking place it is not possible to be certain whether the test organisms were indeed exposed to the test substance as substances like the registered substance have low water solubility which are difficult to test.

Furthermore, ECHA observes that in the RSS, you indicate that the limit of quantification (LoQ) for the anlytical method used was 5 mg/L, at the same time you have indicated that the water solubility of the substance is < 0.2 mg/L. According to the OECD 211 guideline "*a reliable analytical method for the quantification of the substance in the test solutions with reported recovery efficiency and limit of determination should be available*". ECHA considers that the difference in the LoQ and the sensitivity of the method used in the water solubiliy study (ECHA notes that no method defined in the RSS for the water solubility study) that an analytical method with greater sensitivity than the one available at the OECD TG 211, could have been considered. While in your read-across document you identify that "*the available analytical methods are not capable of measring test concentrations",* ECHA considers the LoQ of 5 mg/L for a recent study, considering the advances in analytical method development, as high.

Due to the uncertainties identified above, ECHA still considers that with currently available submitted information, the reliability due to the analytical method of the OECD 211 study on the source substance, Laurylacrylat 1214 is unknown.
Furthermore, ECHA has addressed your comments on the read-across approach in section 'Grouping of substances and read-across approach' above and notes that the read-across adaptation is not currently supported by the information provided in the comments on the DD nor in the technical dossier.
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.

Furthermore, ECHA notes that Column 2 of Annex VII, Section 9.1.1 specifies that long-term aquatic toxicity study on *Daphnia* (Annex IX, section 9.1.5) shall be considered if the substance is poorly water soluble. ECHA notes that, based on the information provided in the technical dossier, the registered substance has low water solubility. Therefore, ECHA considers that long-term testing is indicated for the registered substance.

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). Once results of the proposed test on long-term toxicity to aquatic invertebrates are available, you shall revise the chemical safety assessment as necessary according to Annex I of the REACH Regulation.

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

In accordance with Articles 10(a) and 12(1) of the REACH Regulation, a technical dossier registered at 100 to 1000 tonnes per year must contain, as a minimum, the information specified in Annexes VII to IX to 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 not provided any study record of a long-term toxicity on fish in the dossier that would meet the information requirement of Annex IX, Section 9.1.6.1 / 9.1.6.2 / 9.1.6.3.

You have sought to adapt this information requirement according to Annex IX, Section 9.1.6., column 2. You provided the following justification for the adaptation: "*According to column 2 of REACH Regulation (EC) No 1907/2006, Annex IX, section 9.1 a long term toxicity testing shall be proposed by the registrant if the chemical safety assessment according to Annex 1 indicates the need to investigates further the effects on aquatic organisms. From the available acute data for this substance for all 3 trophic levels there is no indication that fish are more sensitive than aquatic invertebrates and algae to this substance. Therefore, performing a chronic fish study falling under the animal protection legislation of the EU (86/609/EEC), is unjustified. The available chronic daphnia study is thus sufficient for the risk assessment.*"

However, ECHA notes that currently your adaptation does not meet the specific rules for adaptation of Annex IX, Section 9.1.6., column 2. First, ECHA considers that the results of short-term studies cannot be used to conclude on the hazard of the registered substance in the aquatic environment since long-term toxicity testing must be considered due to the low water solubility of the substances. Second, ECHA notes that the results for Growth inhibition study aquatic plants (Annex VII, Section 9.1.2.) and Long-term toxicity testing on aquatic invertebrates (Annex IX, Section 9.1.5) used in your in your Chemical safety Assessment (CSA) are not valid, as discussed in sections 1. and 2. above. As a result, also the PNEC derivation and consequent risk characterisation are currently not reliable. Therefore, the CSA cannot currently be used to adapt the current information requirement.

In your comments on the DD, you agree to conduct the requested study with the registered substance. You also indicate that you will follow the OECD Guidance Document on Aquatic Toxicity Testing of Difficult Substances and Mixtures (OECD 23) as also advised by ECHA below. You nevertheless indicate that it may not be possible to measure test substance concentrations in the test systems. ECHA notes that if you should encounter technical difficulties to perform the test, for example related to sensitivity of the analytical method used for the determination of test concentration, such difficulties and attempted solutions should be clearly documented. In your comments on the DD, you also indicate that water solubility measurements of the registered substance according to OECD TG 105 are initiated to further clarify the water solubility. ECHA considers that this information should be taken into account when choosing the appropriate methods for test substance preparation and for determination of the test substance concentrations.

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.

Furthermore, ECHA notes that Column 2 of Annex VIII, Section 9.1.3 specifies that long-term aquatic toxicity study on fish (Annex IX, Section 9.1.6) shall be considered if the substance is poorly water soluble. ECHA notes that, based on the information provided in the technical dossier, the registered substance has low water solubility. Therefore, ECHA considers that long-term testing is indicated for the registered substance.

According to ECHA *Guidance on information requirements and chemical safety assessment, Chapter R.7b* (version 4.0, June 2017) fish early-life stage (FELS) 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.

However, the FELS toxicity test according to OECD TG 210 is more sensitive than the fish, short-term toxicity test on embryo and sac-fry stages (test method EU C.15 / OECD TG 212), or the fish, juvenile growth test (test method EU C.14. / OECD TG 215), as it covers several life stages of the fish from the newly fertilized egg, through hatch to early stages of growth (see ECHA *Guidance on information requirements and chemical safety assessment* (version 4.0, June 2017), *Chapter R7b, Figure R.7.8-4).*

Moreover, the FELS toxicity test is preferable for examining the potential toxic effects of substances which are expected to cause effects over a longer exposure period, or which require a longer exposure period of time to reach steady state (ECHA *Guidance Chapter R7b,* version 4.0, June 2017).

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).

Once results of the proposed test on long-term toxicity to fish are available, you shall revise the chemical safety assessment as necessary according to Annex I of the REACH Regulation.

Note for your consideration for requests 2-3

Due to the low water solubility of the substance and in the absence of valid short-term aquatic toxicity data, the Integrated testing strategy (ITS) outlined in ECHA *Guidance on information requirements and chemical safety assessment* (version 4.0, June 2017), Chapter R7b (Section R.7.8.5 including Figure R.7.8-4), is not applicable in this case and the long-term studies on both invertebrates and fish are requested to be conducted.

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

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 28 February 2017.

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.

As no amendments were proposed, ECHA took the decision according to Article 51(3) 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 requests in this decision, or to otherwise fulfil the information requirements 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 tests 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 tests 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 tests must be suitable to assess these grades. Finally there must be adequate information on substance identity for the sample tested and the grades registered to enable the relevance of the tests to be assessed.