EUROPEAN CHEMICALS AGENCY

Helsinki, 27 September 2017

Addressee: [redacted]

Decision number: CCH-D-2114370486-42-01/F
Substance name: LINALYL ACETATE
EC number: 204-116-4
CAS number: 115-95-7
Registration number: [redacted]
Submission number: [redacted]
Submission date: 17/03/2017
Registered tonnage band: 100 to 1000 t

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. **Short-term toxicity testing on aquatic invertebrates (Annex VII, Section 9.1.1.; test method: Daphnia sp. Acute immobilisation test, EU C.2./OECD TG 202) with the registered substance;**

2. **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;**

3. **Robust study summary (RSS) for key study, "*key F.Hoffmann-La Roche AG 1998.Short-term toxicity to fish*", Short-term toxicity testing on fish (Annex VIII, Section 9.1.3. in conjunction with Annex I, Section 3.1.5);**

4. **Long-term toxicity testing on aquatic invertebrates (Annex IX, Section 9.1.5.; test method: Daphnia magna reproduction test, EU C.20./OECD TG 211) with the registered substance;**

5. **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;**

6. **Exposure assessment and risk characterisation (Annex I, Sections 5. and 6.) for environment: generate an exposure assessment for all relevant exposure scenarios and revise the risk characterisation accordingly.**

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 **3 January 2020**. You also have to 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 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

1. **Short-term toxicity testing on aquatic invertebrates (Annex VII, Section 9.1.1.)**

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

"Short-term toxicity testing on aquatic invertebrates" is a standard information requirement as laid down in Annex VII, Section 9.1.1. 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.

In the technical dossier you have provided a study record for an OECD Guideline 202 (Daphnia sp. Acute Immobilisation Test) (*"key F.Hoffmann-La Roche AG 1994.Short-term toxicity to aquatic invertebrates"*). However, this study does not provide the information required by Annex VII, Section 9.1.1., because it is not valid due to the following deficiencies.

The OECD 202 guideline defines that *"It is recommended that results be based on measured concentrations. However, if evidence is available to demonstrate that the concentration of the test substance has been satisfactorily maintained within* [redacted] *per cent of the nominal or measured initial concentration throughout the test, then the results can be based on nominal or measured initial values".* In the endpoint study record (ESR) submitted under IUCLID section 6.1.3. Short-term toxicity to aquatic invertebrates, you have provided nominal concentrations together with measured concentrations of the test substance at the start and at the end of the study. The initial nominal concentrations of the substance are reported to be 0, 10, 18, 32, 58 and 100 mg/L. While the measured concentrations at the start were <0.2, 8.2, 15.5, 26.3, 48.7 and 87.9 mg/L, by the end of the study they were less than 0.2 mg/L (not detected) in all but the highest exposure concentration where the measured concentration was 3.5 mg/L. Even while it is clear that the test substance concentrations did not remain within the required [redacted] %, you have provided as the effect value of the study an EC50 of 15 mg/l based on nominal concentration.

Based on the above, ECHA notes further that at the end of the test it was not possible to detect the test substance in the lowest four test concentrations. It is therefore not possible to know the level of substance the test organisms were exposed to. If the results were expressed in relation to a measured concentration, based on the data provided the EC50 would be < 0.20 mg/L. However, according to ECHA *Guidance on information requirements and chemical safety assessment, Chapter R.7b* (version 4.0, June 2017) a test result reported as a *less than* (<) value cannot be used. For the reasons outlined above, ECHA considers the study not valid.

ECHA notes that based on substance properties the substance has high potential to be lost from solution due to volatilisation making the substance concentration unstable in test solutions. ECHA notes further that the study was conducted using a static study design, with watch glasses used to cover the test beakers.

The OECD 202 guideline however defines that "*The test may be carried out using semi-static renewal or flow-through system when the concentration of the test substance is not stable*". Furthermore, 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, July 2017), Chapter R7b, Table R.7.8-3 gives advice on testing difficult substances. Therefore, you should consult these sources for choosing the design of the requested ecotoxicity test and for calculation and expression of the result of the test(s).

Furthermore, in the ESR for the OECD 202 study you have not given any information on control mortality. Therefore it is not possible for ECHA to verify whether the validity criteria of not more than 10 % of daphnids in the control being immobilised, as defined in paragraph 6 of the OECD TG 202, was fulfilled in the study submitted.

In your comments on the draft decision (DD) you note that due to substance properties, the registered substance is difficult to test, even in a closed system. You indicate that according to a hydrolysis study only 3 % of the registered substance was detected after 2.4 h at pH 7, and that the main hydrolysis products are acetic acid and linalool (CAS No 78070-6). You consider that especially due to rapid hydrolysis, the registered substance is lost from solution during exposure making hazard assessment based on measured concentrations, as per the guideline and as outlined by ECHA, not feasible.

You propose that the information requirements for short-term aquatic toxicity testing of the registered target substance, can be fulfilled with data on its proposed hydrolysis product linalool (CAS No 78070-6), the source substance. ECHA has assessed the information presented in your comments according to Annex XI, section 1.5. grouping of substances and read-across approach.

You use the following arguments to support the prediction of properties of the registered substance: "*In a GLP study on hydrolysis according to EEC Directive 92/69 EEC, part C, only 3 % of the parent substance could be detected after 2.5 hours at pH 7*". "*The hydrolyzation of carboxylic esters like linalyl acetate occurs by cleavage at the ester oxygen leading to acetic acid and the corresponding alcohola s product–in this case linalool (CAS 78-70-6)*" and "*Even in closed test systems, the parent compound will disappear very rapidly to form linalool and acetic acid*". You consider testing linalool is feasible since Linalool "*is hydrolytically stable and there already are acute test reports available for all trophic levels*" and that "*The measured test concentrations reveal, that a significant amount of linalool was available during exposure and that it was stable at least for the test duration*".

ECHA notes that no further justification for the read-across is submitted in your comments. However, ECHA notes that in IUCLID section 13 you have attached a read-across justification document "[redacted]". ECHA observes that the document is intended to support the read-across submitted in human health endpoints, only, and does not cover the proposed read-across for environmental endpoints. Nevertheless, ECHA notes that in the documentation you discuss that

"*The key hypothesis for this read-across refers to biotransformation of the target substance (linalyl acetate, i.e. an ester of linalool) leading to the source substance (linalool) as the toxicological relevant metabolite*" and that "T*he target substance linalyl acetate shares structural similarities with the source substance linalool besides the fact, that the target is an ester of the source substance and therefore differs in the presence of acetate*". ECHA notes that in the read-across justification submitted to support read-across in human health endpoints, you have also included a second source substance. The justifications and the hypothesis provided in the technical dossier and documents therein cannot as such be used to justify the read-across proposed for environmental endpoints in your comments on the DD.

ECHA hence considers that there is no specific documentation for the read-across for environmental endpoints proposed in your comments on the DD. Therefore, your dossier is lacking a basis for predicting relevant environmental properties of the registered substance from data for the source substance.

Nevertheless ECHA notes the following. ECHA considers that your read-across hypothesis for environmental endpoints is based upon rapid hydrolysis of the target to the source substance. ECHA acknowledges that the hydrolysis study you refer to in your comments on the DD is submitted as part of the technical dossier as an Endpoint Study Record in section 5.1.2. Hydrolysis. ECHA considers the study reliable, however notes that no hydrolysis products were identified in the study submitted. ECHA notes that identification and quantification of the hydrolysis products would support the proposed read-across approach. Furthermore, in addition to considering the effects caused by the proposed analogue substance, linalool, to further support the predicted property under consideration, it would be beneficial to consider the impact of exposure to the parent compound and to any other hydrolysis products, also taking into account the rate at which they are formed.

ECHA notes further that while you have indicated that aquatic toxicity data on linalool is available, no data and/or results on aquatic toxicity of linalool is included in your comments on the DD nor in the technical dossier of the registered substance. ECHA hence considers that you have not established why a prediction for environmental properties can be applied and considered reliable. ECHA notes that you have indicated that you will update the RSS of the short-term fish study as requested by ECHA in this decision (request 3. below). Having a valid short-term fish study on the registered substance may enable you to compare the aquatic toxicities of the target and the source substance. In the OECD 203 study on registered substance flow-through setup was used making it possible to quantify the effects of the registered substance.

Concerning your proposal to use data on the degradation product to fulfil the information requirements of aquatic toxicity testing of the parent (the registered substance) ECHA notes the following. As given in ECHA Guidance on information requirements and chemical safety assessment, Chapter R.7b (version 4.0, July 2017; Table R.7.8—2 Critical parameters for aquatic toxicity testing) "*OECD recommends testing parent compound for Disappearance Time 50 (DT50 >3) days, breakdown products for DT50 <1h and case-by-case basis for anything in between*", while "*ECETOC (2003) and the TGD recommend to test parent substance with a DT50 as low as 12 h*". ECHA acknowledges that based on the hydrolysis data provided the registered substance has a hydrolysis half life of less than 12 hours.

In conclusion, ECHA notes that lack of documentation and other supporting evidence to support the read-across predictions proposed is preventing ECHA from fully assessing whether the properties of the registered substance can be predicted from data for the source substance. Nevertheless, as outlined above, ECHA agrees that in this case testing the hydrolysis product may be justified. However, as outlined above further evidence is needed for the approach proposed to be acceptable. At the follow up stage ECHA will assess the updated dossier including any adaptations submitted therein.

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, July 2017) Daphnia sp. acute immobilisation test (test method EU C.2. / OECD TG 202) is the preferred test to cover the standard information requirement of Annex VII, Section 9.1.1.

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* sp. Acute immobilisation test, EU C.2./OECD TG 202).

2. 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 more than 1000 tonnes per year must contain, as a minimum, the information specified in Annexes VII to X 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 in 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.

In the technical dossier you have provided a study record for an OECD Guideline 201 (Alga, Growth Inhibition Test) ("*key F.Hoffmann-La Roche AG 1994.Toxicity to aquatic algae and cyanobacteria*"). However, this study does not provide the information required by Annex VII, Section 9.1.2., because it is not valid due to the following deficiencies.

In the endpoint study record (ESR) submitted under IUCLID section 6.1.5. Toxicity to aquatic algae and cyanobacteria, you have provided nominal concentrations together with measured concentrations of the test substance at the start and at the end of the study. The initial nominal concentrations of the substance are reported to be 0, 4.4, 9.6, 21, 46, and 100 mg/L.

While the measured concentrations at the start were <0.2, 2.3, 4.7, 11.6, 15.9, and 75.5 mg/l, by the end of the study they were less than 0.2 mg/L (not detected) in all exposure concentrations. The OECD 201 guideline defines that *"If the deviation from the nominal or measured initial concentration is not within the range of ± [redacted] %, analysis of the results should be based on geometric mean concentration during exposure or on models describing the decline of the concentration of the test substance".* Even while it is clear that the test substance concentrations did not remain within the required [redacted] %, you have provided as the effect values of the study an EC50 of 62 mg/l and a NOEC of 9.6 mg/l based on nominal concentrations.

Furthermore, you have provided measured concentrations only at the start and at the end of study, when the OECD 201 Guideline defines that *"For volatile, unstable or strongly adsorbing test substances, additional samplings for analysis at 24 hour intervals during the exposure period are recommended in order to better define loss of the test substance."*

Based on the above, ECHA notes further that at the end of the test it was not possible to detect the test substance in any of the test concentrations. It is therefore not possible to know the level of substance the test organisms were exposed to. If the results were expressed in relation to a measured concentration, based on the data provided the EC50/NOEC values would be < 0.20 mg/L. However, according to ECHA *Guidance on information requirements and chemical safety assessment, Chapter R.7b* (version 4.0, July 2017) a test result reported as a *less than* (<) value cannot be used. For the reasons outlined above, ECHA considers the study not valid.

The OECD 201 guideline defines that *"For testing of substances that are volatile, strongly adsorbing, coloured, having a low solubility in water or substances that may affect the availability of nutrients or minerals in the test medium, certain modifications of the described procedure may be required (e.g., closed system, conditioning of the test vessels)".* The guideline provides reference for further guidance on how studies for substances difficult to test may be designed. ECHA notes that based on substance properties the substance has high potential to be lost from solution due to volatilisation" making the substance concentration unstable in test solutions.

ECHA notes further that the algae study submitted was conducted using a static study design, with cotton stoppers to cover the test beakers. ECHA acknowledges that some measures were taken to prevent losses of substance, however, as no substance was detected at the end of the test, such measures were not successful. ECHA notes further that in 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, July 2017), Chapter R7b, Table R.7.8-3 further advice on testing difficult substances in algae studies is provided. Therefore, you should consult these sources for choosing the design of the requested ecotoxicity test and for calculation and expression of the result of the test(s).

Furthermore, in the ESR for the OECD 201 study you have not given any information on controls. Therefore, it is not possible for ECHA to verify whether the validity criteria relating to growth of control cultures, as defined in paragraph 11 of the OECD TG 201, were fulfilled in the study submitted.

ECHA notes that the read-across approach proposed in your comments to fulfil the standard information requirements of short-term aquatic toxicity testing is fully addressed in ECHA's reply in section 1. above. In short, ECHA considers that further information is required to fulfil the requirements set in Annex XI, section 1.5. grouping of substances and read-across approach.

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, July 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).

3. Short-term toxicity testing on fish (Annex VIII, Section 9.1.3.)

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

Pursuant to Articles 10(a)(vii) of the REACH Regulation, the information set out in Annex VII to XI must be provided in the form of robust study summary, if required under Annex I. Article 3(28) defines a robust study summary (RSS) as a detailed summary of the objectives, methods, results and conclusions of a full study report providing sufficient information to make an independent assessment of the study minimising the need to consult the full study report. Guidance on the preparation of the robust study summaries is provided in the ECHA Practical Guide 3: 'How to report robust study summaries'.

"Short-term toxicity testing on fish" is a standard information requirement as laid down in Annex VIII, Section 9.1.3. 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. Furthermore, pursuant to Article 10 (a)(vii) and Annex I, Section 3.1.5. if there are several studies addressing the same effect, the study or studies giving rise to the highest concern shall be used to draw the conclusion and a robust study summary shall be prepared for that study or studies and included as part of the technical dossier. Robust study summaries will be required of all key data used in the hazard assessment.

In the technical dossier, under IUCLID section 6.1.1. "Short-term toxicity to fish", you have provided the following study record to fulfil the standard information requirement of Annex VIII, Section 9.1.3.:

- Key study, reliability 2, GLP, test method OECD Guideline 203 (Fish, Acute Toxicity Test) with the registered substance. Data source: "96-hour Acute Toxicity Study in Carp with Linalyacetate", F.Hoffmann-La Roche AG, 1998, [redacted].

The OECD TG 203 (1992), according to which the key study has been conducted, lists four validity criteria that need to be fulfilled in order for a study to be considered valid. One of these, given in paragraph 6 of the guideline, defines that the mortality in the control(s) should not exceed 10 per cent at the end of the test.

ECHA notes that you have not provided any information on control mortality, nor have you in the RSS indicated whether the validity criteria set in OECD 203 have been fulfilled. In absence of any information on control mortality, it is not possible for ECHA to verify the validity of the study submitted.

Therefore, ECHA notes that, contrary to Article 3(28) of the REACH Regulation, the documentation of this study is insufficient and does not allow an independent assessment of the adequacy of this study, its results and its use for hazard/risk assessment.

In your comments on the draft decision you agreed to provide the information missing from the RSS as requested.

Furthermore, you propose to submit data on the hydrolysis product linalool. ECHA notes that the proposed read-across approach is fully addressed in ECHA's reply in section 1. above. In short, ECHA considers that further information is required to fulfil the requirements set in Annex XI, section 1.5. grouping of substances and read-across approach.

In order to allow an independent assessment of the study submitted, pursuant to Article 41(1) and (3) of the REACH Regulation you are requested to provide a complete robust study summary with the above missing elements for the key study.

4. 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 more than 1000 tonnes per year must contain, as a minimum, the information specified in Annexes VII to X 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 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 9.1.5., column 2. You provided the following justification for the adaptation: "*In Annex IX of Regulation (EC) No 1907/2006, it is laid down that chronic toxicity tests shall be proposed by the registrant if the chemical safety assessment indicates the need to investigate further the effects on aquatic invertebrates. According to Annex I of this regulation, the chemical safety assessment triggers further action when the substance or the preparation meets the criteria for classification as dangerous according to Directive 67/548/EEC or Directive 1999/45/EC or is assessed to be a PBT or vPvB.*

The hazard assessment of linalyl acetate reveals neither a need to classify the substance as dangerous to the environment, nor is it a PBT or vPvB substance, nor are there any further indications that the substance may be hazardous to the environment. Therefore, a chronic test in aquatic invertebrates is not provided".

However, ECHA notes that your adaptation does not meet the specific rules for adaptation of Annex IX, Section 9.1.5., column 2 because of the following. You consider that the Chemical Safety Assessment (CSA) has not indicated the need to conduct chronic aquatic testing since the substance is not classified for environment nor is it considered a PBT/vPvB substance. ECHA notes that you consider the need for further aquatic testing to arise from the need to conduct an exposure assessment (EA) and risk characterisation (RC) for environment as per Annex I. As further discussed under section 6 of this decision, the need for carrying out EA/RC for environment is not dependant on a substance being classified for environment, nor does the substance need to be considered a PBT/vPvB.

On the contrary, as you have not submitted the environmental EA/RC sections in your CSA, the CSA cannot be used to show that there are no risks to the environment and that further aquatic testing would not be necessary.

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.

ECHA acknowledges that in your comments on the DD you agree to consider the need for long-term aquatic testing following on from completing the information requirements for short-term aquatic toxicity testing and the subsequent update of the CSA, also requested in this decision. ECHA notes that your proposal to use data on a hydrolysis product to fulfil the information requirements for short-term aquatic testing has been addressed in request 1. above.

According to ECHA *Guidance on information requirements and chemical safety assessment, Chapter R.7b* (version 4.0, July 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).

5. 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 more than 1000 tonnes per year must contain, as a minimum, the information specified in Annexes VII to X 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 sought to adapt this information requirement [according to Annex IX, Section 9.1.6., column 2. You provided the following justification for the adaptation: *"In Annex IX of Regulation (EC) No 1907/2006, it is laid down that chronic toxicity tests shall be proposed by the registrant if the chemical safety assessment indicates the need to investigate further the effects on fish. According to Annex I of this regulation, the chemical safety assessment triggers further action when the substance or the preparation meets the criteria for classification as dangerous according to Directive 67/548/EEC or Directive 1999/45/EC or is assessed to be a PBT or vPvB. The hazard assessment of linalyl acetate reveals neither a need to classify the substance as dangerous to the environment, nor is it a PBT or vPvB substance, nor are there any further indications that the substance may be hazardous to the environment. Therefore, and for reasons of animal welfare a chronic test in fish is not provided".*

However, ECHA notes that your adaptation does not meet the specific rules for adaptation of Annex IX, Section 9.1.6., column 2 because as discussed under section 4 above the CSA cannot currently be used to adapt the standard information requirement for long-term aquatic testing.

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.

ECHA acknowledges that in your comments on the DD you agree to consider the need for long-term aquatic testing following on from completing the information requirements for short-term aquatic toxicity testing and the subsequent update of the CSA, also requested in this decision. ECHA notes that your proposal to use data on a hydrolysis product to fulfil the information requirements for short-term aquatic testing has been addressed in request 1. above.

According to ECHA *Guidance on information requirements and chemical safety assessment, Chapter R.7b* (version 4.0, July 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, July 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, July 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).

Notes for your consideration for aquatic toxicity testing (sections 1 to 5 above)

Before conducting the tests requested above under points 4. and 5., you shall consult the ECHA Guidance on information requirements and chemical safety assessment (version 4.0, July 2017Chapter R7b, Section R.7.8.5 to determine the necessity to conduct the long-term toxicity testing on aquatic invertebrates and on fish.

Concerning the order of studies to be conducted, you may first fulfil the information requests made for short-term aquatic studies under points 1., 2., and 3. above and subsequently update the CSA according to Annex I of the REACH Regulation, as also requested under section 6. below.

If you come to the conclusion that no further investigation of chronic effects on aquatic organisms is required, you shall update your technical dossier by clearly stating the reasons for adapting the standard information requirement of Annex IX, 9.1.5 and 9.1.6. taking into account the new information submitted for the short-term aquatic studies as requested by the present decision and the exposure assessment and risk characterisation.

On the other hand, if after the update of the CSA you come to the conclusion that the long-term toxicity tests are still required to refine the risk assessment, you should consider the Integrated Testing Strategy (ITS) for aquatic toxicity as described in ECHA Guidance on information requirements and chemical safety assessment (version 4.0, July 2017), Chapter R7b (Section R.7.8.5., including Figure R.7.8-4).

According to the ITS, if based on acute aquatic toxicity data neither fish nor invertebrates are shown to be substantially less sensitive than other trophic levels (i.e. fish, invertebrates, algae), long-term studies may be required on both fish and invertebrates. In such case, according to the ITS, the long-term *Daphnia* study is to be conducted first. If based on the results of the long-term *Daphnia* study and the application of a relevant assessment factor, no risks are observed (PEC/PNEC<1), no long-term fish testing may need to be conducted. However, if a risk is indicated, the long-term fish study needs to be conducted.

Due to the high volatility of the registered substance and the problems encountered in the acute aquatic tests in keeping the substance in solution, you should 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, July 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).

6. Exposure assessment and risk characterisation (Annex I, Sections 5. and 6.) for environment

In accordance with Articles 10(b) and 14(1) of the REACH Regulation, the registration must contain a chemical safety report (CSR) which documents the chemical safety assessment (CSA) conducted in accordance with Article 14(2) to (7) and with Annex I to the REACH Regulation.

Pursuant to Article 14(4), if the substance fulfils the criteria for any of the hazard classes listed in that provision or is assessed to be a PBT (persistent, bioaccumulative and toxic) or vPvB (very persistent and very bioaccumulative), the CSA shall include exposure assessment and risk characterisation.

Annex I, Section 5 of the REACH Regulation requires the Registrant to generate exposure scenarios and exposure estimations for the registered substance. The exposure assessment shall consider all stages of the life-cycle of the substance resulting from the manufacture and identified uses and shall cover any exposures that may relate to the identified hazards.

Annex I, Section 6 of the REACH Regulation requires you to characterise the risk for each exposure scenario and to consider the human population (exposed as workers, consumer or indirectly via the environment and if relevant a combination thereof) and the environmental spheres for which exposure to the substance is known or reasonable foreseeable, under the assumption that the risk management measures described under exposure scenario in Section 5 of the same Annex have been implemented. In addition, the overall environmental risk caused by the substance shall be reviewed by integrating the results for the overall releases, emissions and losses from all sources to all environmental compartments.

ECHA's Guidance on information requirements and chemical safety assessment, Part B: Hazard Assessment, Section B.8.4. (pages 47 to 48) (version 2.1, December 2011) states that "*if no adverse effects have been observed in studies at the highest recommended concentration/doses tested, this would normally indicate that no hazard has been identified and no DNEL or PNEC can be derived and hence exposure assessment for that route of exposure, type of effect or protection target would not be needed*".

In the CSR you provided, the exposure assessment for the environment is missing. You claimed that no exposure assessment is necessary for the environment by stating that " *In the chemical safety assessment performed according to Article 14(3) in connection with Annex I section 3 (Environmental Hazard Assessment) and section 4 (PBT/ vPvB Assessment) no hazard was identified. Therefore according to REACH Annex I (5.0) an exposure estimation is not necessary. Consequently all identified uses of the substance are assessed as safe for the environment.*"

ECHA notes that you have classified the substance as Skin Irrit. 2 (H315) and Eye Irrit. 2 (H 319) thus, fulfilling the criteria set out in Article 14(4) of the REACH Regulation to require an exposure assessment and a risk characterisation in the chemical safety assessment.

With regard to the scope of the required exposure assessment, as stated above and in accordance with Annex I, section 5.0., it has to cover all hazards that have been identified according to sections 1 to 4 of Annex I of REACH Regulation.

ECHA notes that adverse effects were observed in some environmental toxicity studies. In particular, in the short-term toxicity study on fish an LC50 of 11 mg/l was obtained. You have used the short-term fish result for the derivation of the aquatic PNEC. While ECHA has requested further information to fulfil the RSS requirements for this study (request 3 above), ECHA considers that the result shows that hazards to the environment are demonstrated. Furthermore, ECHA notes that while the short-term data on daphnids and algae cannot be accepted due to the deficiencies identified in the respective sections 2. and 3. above, those results indicate even a higher potential hazard for environment. Therefore, exposure assessment and risk characterisation for environment are needed to address the hazards identified for the environment. As further outlined in Guidance *on information requirements and chemical safety assessment*, Part B: Hazard Assessment, Section B.8.1. (version 2.1, December 2011), such identified hazards (among others) necessitating exposure assessment are the *"hazards for which there are classification criteria and there is information on these properties of the substance showing that it does have these properties, but the severity of the effects is lower than the criteria for classification and so the substance is not classified".*

Moreover, the above mentioned guidance specifies further (in Section 8.4.2.2.) that *"If there are ecotoxicity data showing effects in aquatic organisms, but the substance is not classified as dangerous for the aquatic environment, an aquatic PNEC can nevertheless be derived thus indicating a hazard to the aquatic environment.(...) Hence. quantitative exposure assessment, i.e. derivation of PECs, is mandatory for the water, sediment and soil environmental compartments."*

In your comments on the DD you agreed to provide the information requested.

Therefore, pursuant to Article 41(1) and (3) of the REACH Regulation, you are requested to generate an environmental exposure assessment for all relevant exposure scenarios and subsequently perform the risk characterisation for each exposure scenario to demonstrate the safe use of the substance, and update the dossier accordingly.

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 01 December 2016.

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

ECHA notified you of the draft decision and invited you to provide comments.

ECHA took into account your comments and did not amend the request(s).

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

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.