EUROPEAN CHEMICALS AGENCY

Helsinki, 17 November 2017

Addressee: [redacted]

Decision number: CCH-D-2114375722-45-01/F
Substance name: OLAFLUR
EC number: 911-915-8
CAS number:
Registration number: [redacted]
Submission number: [redacted]
Submission date: 19/01/2017
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. **Name or other identifier of the substance (Annex VI, Section 2.1.) of the registered substance;**

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

3. **Description of the analytical methods (Annex VI, Section 2.3.7.);**

4. **In vitro gene mutation study in mammalian cells (Annex VIII, Section 8.4.3.; test method: OECD TG 476 or TG 490) with the registered substance;**

5. **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;**

6. **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;**

7. **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 **26 November 2018**. 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 Kevin Pollard, Head of Unit, Evaluation E1.

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

Appendix 1: Reasons

A. Identity of the Substance

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

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

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

According to chapter 4.2.2 of the Guidance for identification and naming of substances under REACH and CLP (Version: 2.1, May 2017) – referred to as "the SID Guidance" hereafter, a multi-constituent substance is a substance defined by its composition, for which more than one main constituent is present at a concentration ≥ 10% (w/w) and < 80% (w/w). A multi-constituent substance is named as a reaction mass of the main constituents of the substance as such i.e. not the starting materials needed to produce the substance. The generic format is: "Reaction mass of [names of the main constituents]".

According to chapter 4.3 of the SID Guidance, Substances of Unknown or Variable composition, Complex reaction products or Biological Materials (UVCB substances), cannot be sufficiently identified by their chemical composition, because:

- The number of constituents is relatively large and/or
- The composition is, to a significant part, unknown and/or
- The variability of composition is relatively large or poorly predictable.

As a consequence, UVCB substances require other types of information for their identification, in addition to what is known about their chemical composition.

You have defined the substance as multi-constituent and have provided the following IUPAC name for the substance:

"[redacted]"

The substance has been registered with the List number 911-915-8; the List name associated with this List number is:

"[redacted]"

In IUCLID section 1.2 you have reported in the composition block "[redacted]" three well-defined main constituents:

[redacted]

The structural information given in section 1.1 also refers to these constituents.

Both the IUPAC name and the List name refer to the substance only with the generic terms "[redacted]" and "[redacted]" which do not specify the degree of ethoxylation or the content of [redacted] in the constituents, and would therefore refer rather to a UVCB substance (substance of Unknown or Variable composition, Complex reaction products or Biological materials). On the contrary, in the structural formula and in section 1.1 the substance is described more specifically with [redacted], which are not indicated as repeating units of EO, and two [redacted].

Therefore, although the substance has been identified as a well-defined multi-constituent substance, with the structural formula and composition including three well-defined main constituents, the IUPAC name and List name are not in line with this information. Therefore, you have not used consistent substance identifiers in the naming and identification of your substance.

You are requested to update the substance identifiers such that all identifiers are consistent.

If the substance is a well-defined multi-constituent substance, the IUPAC name should be derived from the names of the main constituents reported in section 1.2.

If the substance is a UVCB substance where the degree of ethoxylation and the content of hydrofluorides in the constituents is variable, you should provide information in the different IUCLID sections (1.1, 1.2, 1.4) that is specific for the UVCB substance and is reported in line with the guidelines as explained in SID Guidance, chapter 4.3 for UVCB substances.

Should the substance be identified as a UVCB substance, further information is required to appropriately identify the registered substance in accordance with section 4.3 of the SID Guidance. Information required to be provided on the naming of UVCB substances consists of two parts: (1) the chemical name and (2) a more detailed description of the manufacturing process. The description of the manufacturing process shall at least include the following:

- the ratio of used starting materials and other reactants used (i.e. catalysts, etc.);
- description of relevant steps of the manufacturing process;
- for each step, all relevant process parameters, such as temperature and pressure, that affect the composition and therefore the identity of the substance;
- Isolation steps and related parameters.

If the current identifiers are not appropriate to describe the registered substance, you should not remove or modify at this stage this List entry for technical reasons, the registration being linked to that List entry in REACH-IT. To ensure unambiguous identification of the registered substance, you should however indicate, in the "Remarks" field of the reference substance in IUCLID section 1.1, the following: "The List number 911-915-8 currently assigned does not specifically correspond to the registered substance. This identifier cannot be modified or deleted at this stage in the present registration update for technical reasons". You should also specify, in the same "Remarks" field, any available and appropriate EC number for the substance. Any available CAS entry for the registered substance should be reported under the "CAS information" header of the reference substance in IUCLID section 1.1.

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

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

Regarding how to report the identifiers of the substance, the information shall be included in the reference substance assigned in IUCLID section 1.1. In case the substance is a UVCB substance, the chemical name shall be reported in IUCLID section 1.1 in the IUPAC name field, and the description of the manufacturing process shall be included in IUCLID section 1.2 in the "Description of composition" field. You shall ensure that the information in sections 1.1, 1.2 and 1.4 refers consistently to the same substance.

Further information on how to report the identifiers is available on the ECHA manual on "How to prepare registration and PPORD dossiers" published on the ECHA website at http://www.echa.europa.eu/manuals.

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

According to Annex VI , section 2.3. of the REACH Regulation, sufficient compositional information is required to be reported in a registration dossier such that the substance identity can be verified.

According to chapter 4.2 of the "SID Guidance", the following applies for well-defined substances:

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

As a general rule, the compositional information should be completed up to 100%.

In the case the substance is considered a UVCB substance, the following applies according to chapter 4.3 of the SID Guidance for UVCB substances:

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

Furthermore for each constituent required to be reported individually, the IUPAC name, CAS name and CAS number (if available), molecular and structural formula, as well as the minimum, maximum and typical concentration, should be reported in the appropriate fields in IUCLID. For the other constituents to be reported under a generic description, a generic chemical name describing the group of constituents, generic molecular and structural information (if applicable), as well as the minimum, maximum and typical concentration, should be reported in the appropriate fields in IUCLID.

You reported in IUCLID section 1.2 for the composition block [redacted] three main constituents and two impurities, corresponding to constituents [redacted].

It is noted that the identifiers provided for these constituents and impurities are not consistent, since the structural formulas in section 1.2 do not include the [redacted] reported in the constituent names.

Furthermore, as is descibed below in the context of "Description of the analytical methods", the MALDI-TOF-MS and H-NMR results included in section 1.4 were showing signals which were not identified in detail or quantified. Also, no explanation was provided which would verify if the signals are due to constituents/impurities that are required to be reported in section 1.2.

Therefore, the composition is potentially not reported to the degree required for well-defined substances or for UVCB substances.

In the case that the substance is well-defined, you are requested to revise for the composition block [redacted] the compositional information regarding the main constituents and the impurities, such that the composition is in accordance with the analytical information in section 1.4, and is fully accounted for, in line with the requirements for well-defined substances. You shall ensure that for the main constituents and impurities required to be reported individually, the provided identifiers are consistent.

In the case that the substance is a UVCB substance, you are requested to revise for the composition block [redacted] the compositional information according to what is required for UVCB substances. You shall ensure that the composition is in accordance with the analytical information in section 1.4, and for the reported (groups of) constituents the provided identifiers are consistent.

The information shall be included in section 1.2 of the registration dossier. Further technical details on how to report the composition of a substance in IUCLID are available in the ECHA manual "How to prepare registration and PPORD dossiers" (https://echa.europa.eu/manuals).

3. Description of the analytical methods (Annex VI, Section 2.3.7.)

According to Annex VI, section 2.3.7 of the REACH Regulation, a registration dossier shall report a description of the analytical methods or the appropriate bibliographic references for the identification of the substance and where appropriate for the identification of impurities and additives. The reporting shall be given in sufficient detail that the methods can be reproduced.

You provided in IUCLID section 1.4 analytical data including UV, IR, NMR (H-, F- and C-) spectra, XRD, and results from MALDI-TOF-MS analysis.

The MALDI-TOF-MS analysis was sufficient to confirm the [redacted] reported for the substance in sections 1.1 and 1.2 of the IUCLID dossier. However, the results were also showing in addition to the constituents reported in section 1.2, also additional signals which were assigned to "[redacted]" and "[redacted]" species (referring to "[redacted]") with [redacted]. No quantification was provided for these additional signals, also no information was provided to clarify whether the signals would be due to constituents/impurities present in the substance, which would need to be reported in the composition in section 1.2.

The H-NMR results reported in Table 3 of the analytical report attached in section 1.4 of the IUCLID dossier ([redacted]") include assignments for "[redacted]" and for "[redacted]" for which no quantification was provided. For these assignments you also did not provide any clarification whether these signals are referring to constituents or impurities. Furthermore, for well-defined substances constituents (impurities) present in a concentration ≥1% are required to be specified at least by their chemical name and reported in section 1.2, while constituents (impurities) that are relevant for classification and/or PBT assessment shall always be specified. The latter is also required for UVCB substances.

Also, you did not provide any high-pressure liquid chromatographic (HPLC) or gas chromatographic (GC) analysis results in section 1.4 for the quantification of the substance composition to verify the composition as it is currently reported in IUCLID section 1.2.

In addition, you did not provide the quantification of the [redacted] counter-ion, which is necessary to confirm that the substance is "....[redacted]

Therefore, you are requested to provide a detailed description of the analytical method(s) used for identification and quantification of the constituents and impurities present in the substance and which are required to be reported in section 1.2, including as well the quantification of [redacted].

The description shall be sufficient for the methods to be reproduced and shall therefore include details of the experimental protocol followed, any calculation made and the results obtained.

For quantification methods based on chromatography, the information shall include a legible print-out of the chromatogram as well as the report from the chromatographic analysis including the table of peak assignments that report the peak areas and corresponding amounts of each relevant constituent/impurity with respective identity (i.e. name and/or structural formula) as far as possible.

In addition, as explained above in the context of the composition of the substance, you shall ensure that the composition reported in IUCLID section 1.2 is in line with the information provided in section 1.4, which shall be sufficient to identify and quantify the substance.

The information shall be included in section 1.4 of the registration dossier.

B. [Eco]Toxicological Information

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.

Your registration dossier contains for the endpoints *in vitro* gene mutation study in mammalian cells (Annex VIII, 8.4.3) and long-term toxicity testing on aquatic invertebrates (Annex IX, 9.1.5) adaptation arguments in form of a grouping and read-across approach under Annex XI, Section 1.5. of the REACH Regulation. ECHA has considered first the scientific and regulatory validity of your read-across approach in general before assessing the individual endpoints (sections section 4 and 6).

Grouping of substances and read-across approach

You have sought to adapt the information requirements for *in vitro* gene mutation study in mammalian cells (Annex VIII, 8.4.3.), and long-term toxicity testing on aquatic invertebrates (Annex IX, 9.1.5) by applying a read-across approach in accordance with Annex XI, Section 1.5. According to Annex XI, Section 1.5., two conditions shall be necessarily fulfilled. Firstly, there needs to be structural similarity between substances which results in a likelihood that the substances have similar physicochemical, toxicological and ecotoxicological properties so that the substances may be considered as a group or category. Secondly, it is required that the relevant properties of a substance within the group may be predicted from data for reference substance(s) within the group (read-across approach). ECHA considers that the generation of information by such alternative means should offer equivalence to prescribed tests or test methods.

Based on the above, a read-across hypothesis needs to be provided. This hypothesis establishes why a prediction for a toxicological or ecotoxicological property is reliable and should be based on recognition of the structural similarities and differences between the source and registered substances[2]. This hypothesis explains why the differences in the chemical structures should not influence the toxicological/ ecotoxicological properties or should do so in a regular pattern. The read-across approach must be justified scientifically and documented thoroughly, also taking into account the differences in the chemical structures. There may be several lines of supporting evidence used to justify the read-across hypothesis, with the aim of strengthening the case.

Due to the different nature of each endpoint and consequent difference in scientific considerations (e.g. key parameters, biological targets), a read-across must be specific to the endpoint or property under consideration. Key physicochemical properties may determine the fate of a compound, its partitioning into a specific phase or compartment and largely influence the availability of compounds to organisms, e.g. in bioaccumulation and toxicity tests. Similarly, biotic and abiotic degradation may alter the fate and bioavailability of compounds as well as be themselves hazardous, bioaccumulative and/or persistent. Thus, physicochemical and degradation properties influence the human health and environmental properties of a substance and should be considered in read-across assessments. However, the information on physicochemical and degradation properties is only a part of the read-across hypothesis, and it is necessary to provide additional justification which is specific to the endpoint or property under consideration.

[2] Please see for further information ECHA *Guidance on information requirements and chemical safety assessment* (version 1, May 2008), Chapter R.6: QSARs and grouping of chemicals.

The ECHA Read-across assessment framework foresees that there are two options which may form the basis of the read-across hypothesis[3]- (1) (Bio)transformation to common compound(s)- the read-across hypothesis is that different substances give rise to (the same) common compounds to which the organism is exposed and (2) Different compounds have the same type of effect(s)- the read-across hypothesis is that the organism is exposed to different compounds which have similar (eco)toxicological and fate properties as a result of structural similarity (and not as a result of exposure to common compounds).

Finally, Annex XI, Section 1.5. lists several additional requirements, which deal with the quality of the studies which are to be read-across.

You consider to achieve compliance with the REACH information requirements for the registered substance "[redacted]" using data of structurally similar substances "[redacted]" and "[redacted]" (hereafter the 'source substance'), with respect to the endpoints *in vitro* gene mutation study in mammalian cells (Annex VIII, 8.4.3.), and long-term toxicity testing on aquatic invertebrates (Annex IX, 9.1.5), respectively.

You have provided a read-across documentation as a separate attachment in section 13 of IUCLID.

You use the following arguments to support the prediction of properties of the registered substance from data for source substances within the group: "*The read across hypothesis is supported by comparable structural characteristics and functional groups as well as a similar toxicological and ecotoxicological behaviour of the target and source substances. Adequate, reliable and available scientific information indicates that the source and target substances have similar toxicological and ecotoxicological profiles and that data for the source substance are reliable to predict the toxicity of the target substance.*
Since modification of the target or source substances before entering the body is unlikely, it can be assumed that the organism is exposed to the substances themselves. The toxicokinetic profiles of the target and source substances can be assumed as very similar due to the structural similarities. Therefore systemic toxicity is not affected by potentially different kinetics. No bioaccumulation is expected as the substances are biotransformed and their hydrophilic metabolites are excreted predominately through the kidneys.
This can be supported by the results of the toxicity and ecotoxicological studies indicating comparable effects of target and source substances which lead to same classification pattern with regards to systemic effects. This comparable environmental and toxicity behaviour can be attributed to the similarity of structure and functional groups of the substances and therefore read across is justified.
In conclusion, the proposed read across approach is applied as an appropriate adaptation to the standard information requirements of the REACH Regulation, in accordance with the provisions of Annex XI, 1.5."

Hence, ECHA considers that you have defined structural similarity as basis for your read-across hypothesis for the prediction for the above-mentioned information requirements.

[3] Please see ECHA's Read-Across Assessment Framework (https://echa.europa.eu/support/registration/how-to-avoid-unnecessary-testing-on-animals/grouping-of-substances-and-read-across).

ECHA's evaluation and conclusion

Your proposed adaptation argument is that the structural similarity between the source and registered substance is a sufficient basis for predicting the properties of the registered substance. Structural similarity is a prerequisite for applying the grouping and read-across approach. However structural similarity does not necessarily lead to predictable or similar human health/ environmental properties. You have not established why a prediction for a human health/ environmental property is reliable on the basis of structural similarities and differences between the source and registered substances. Thus structural similarity per se is not sufficient to enable the prediction of human health/ environmental properties of a substance.

On that basis, the requirement of Annex XI, Section 1.5., that human health/ environmental effects may be predicted from data for reference substance(s) within the group, has not been met. ECHA notes that there are specific considerations for the individual endpoints which also result in a failure to meet the requirement of Annex XI, Section 1.5., and these are set out under the endpoint concerned.

As described above, further elements are needed to establish a reliable prediction for a toxicological or ecotoxicological property, based on recognition of the structural similarities and differences between the source and registered substances. This could be achieved (if it is possible) by a well-founded hypothesis of (bio)transformation to a common compound(s), or that the registered and source substance(s) have the same type of effect(s), together with sufficient supporting information to allow a prediction of human health/ environmental properties.

4. In vitro gene mutation study in mammalian cells (Annex VIII, Section 8.4.3.)

An "*In vitro* gene mutation study in mammalian cells" is an information requirement as laid down in Annex VIII, Section 8.4.3., of the REACH Regulation, "if a negative result in Annex VII, Section 8.4.1., and Annex VIII, Section 8.4.2." is obtained.

You have sought to adapt this information requirement according to Annex XI, Section 1.5. of the REACH Regulation by providing a study record(s) for a "*in Vitro Mammalian Cell Gene Mutation Test*" (OECD TG 476) with the analogue substance "[redacted]".

You have stated in the read across documentation, attached to section 13 of IUCLID, that "[redacted] *is even present in* [redacted]*, since it is a derivative of* [redacted]". ECHA notes that, contrary to that statement, the source substance [redacted] is not present in the target substance [redacted] considering the composition provided in section 1.2 of IUCLID and present significant structural differences. Thus, [redacted] while the target substance is a [redacted] and the [redacted] distribution is different for the source and target substances. However, you have not discussed the impact of such structural differences on the prediction of the toxicological properties with respect to genotoxicity.

In addition, you have concluded in the read across documentation that due to structural similarity, the information for the target substance can be predicted from the source substance. However, as explained above in Appendix 1 under "*Grouping of substances and read-across approach*", your adaptation of the information requirement according to Annex XI, Section 1.5., is rejected.

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

ECHA considers that the *in vitro* mammalian cell gene mutation tests using the*Hprt* and *xprt* genes (OECD TG 476) and the *in vitro* mammalian cell gene mutation tests using the thymidine kinase gene (OECD TG 490) are appropriate to address the standard information requirement of Annex VIII, Section 8.4.3.

5. 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.

Column 2 of Annex VII, Section 9.1.2 specifies that the study does not need to be conducted if there are mitigating factors indicating that aquatic toxicity is unlikely to occur, for instance if the substance is highly insoluble in water or the substance is unlikely to cross biological membranes.

In the technical dossier you have provided a study record for a Toxicity to aquatic algae and cyanobacteria ([redacted] 2010). However, this study does not provide the information required by Annex VII, Section 9.1.2., because the nominal concentrations were used for the calculation of the effect concentrations, even if the measured concentrations were only 43-60% from the nominal concentrations. You claim in the dossier that the test organisms were fully exposure to the bulk concentrations of the test substance, however, failed to give a valid justification to prove it.

Moreover, if the NOEC would have been derived based on measured concentrations, it would have been 0.0078 mg/l (based on 60% of recovery, instead of 0.013 mg/l based on nominal concentration), leading to change of classification from Aquatic chronic 2 to Aquatic chronic 1 and also to the conclusion that the substance meets the T criteria.

Alternatively, you can base the effect concentrations on measured values and change the C&L accordingly.

Therefore, the submitted test 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 3.0, February 2016) 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 surface activity you should consult OECD Guidance Document on Aquatic Toxicity Testing of Difficult Substances and Mixtures, ENV/JM/MONO (2000)6 and ECHA *Guidance on information requirements and chemical safety assessment* (version 3.0, February 2016), Chapter R7b, Table R.7.8-3 summarising aquatic toxicity testing of difficult substances for choosing the design of the requested ecotoxicity test(s) and for calculation and expression of the result of the test(s).

6. 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.

"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 XI, Section 1.5. of the REACH Regulation by providing a study records for a "Daphnia magna freshwater long-term toxicity to aquatic invertebrates according to OECD Guideline 211 (Daphnia magna Reproduction test) with the analogue substance [redacted]).
ECHA notes, that physco-chemical properties from the source and target substance are different (e.g. water solubility), therefore also the information requirements for these substances are different regarding long-term aquatic toxicity. ECHA also notes that you have not discussed the impact of missing the fluoride ion from the source substance on the prediction of the ecotoxicological properties with respect to the long-term toxicity to aquatic invertebrates on the target substance.

Moreover, the submitted test for long-term toxicity on aquatic invertebrates is not considered compliant as the test substance was disappeasring from the test media (adsorption to glassware) and the measured concentrations of the substance were below 80% of the nominal concentrations or even below detection limit. Also, no reference substance has been used to confirm the validity of the performed test.

ECHA also notes that information provided for the other endpoints on long-term toxicity for aquatic organisms is also not compliant (toxicity to algae and long-term toxicity to fish, see sections 5 and 7). Therefore, it is not possible predict this property for daphnia as well.

In addition, you have concluded in the read across documentation that due to structural similarity, the information for the target substance can be predicted from the source substance. However, as already explained above in Appendix 1 under "*Grouping of substances and read-across approach*", your adaptation of the information requirement according to Annex XI, Section 1.5., is rejected.

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 3.0, February 2016) *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).

Notes for your consideration

Once results of the 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.

According to ECHA *Guidance on information requirements and chemical safety assessment* (version 3.0, February 2016), Chapter R7b (Section R.7.8.5., including Figure R.7.8-4) if based on acute aquatic toxicity data neither fish nor invertebrates are shown to be substantially more sensitive, long-term studies may be required on both. In such case, according to the integrated testing strategy, the *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 surface activiity you should consult OECD Guidance Document on Aquatic Toxicity Testing of Difficult Substances and Mixtures, ENV/JM/MONO (2000)6 and ECHA *Guidance on information requirements and chemical safety assessment* (version 3.0, February 2016), Chapter R7b, Table R.7.8-3 summarising aquatic toxicity testing of difficult substances for choosing the design of the requested ecotoxicity test(s) and for calculation and expression of the result of the test(s).

7. 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 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 accordance with column 2 of REACH Annex IX, the test on long-term toxicity to fish (required in section 9.1.6) does not need to be conducted as the chemical safety assessment according to Annex I indicates no need to investigate further the effects on aquatic organisms. The following aspects need to be considered: In general, the results obtained for the effect and no-effect concentrations based on the acute aquatic toxicity studies are low but significantly higher than for the most sensitive species (Algae) also triggering the PNEC. However, the log Pow of 1,94 does not indicate a potential for bioaccumulation, the water solubility of* [redacted] *was determined to be 164 g/l and thus very good. In addition, the calculated BCF by EPIWIN (BCFBAF v.3.00) revealed a figure of 8.851 L/kg, also supporting the conclusion that* [redacted] *will not bioaccumulate. Furthermore, the substance can be classified as ready biodegradable. Taking these findings together, a long-term exposure of aquatic organisms to ecotoxicological relevant concentrations of* [redacted] *can be excluded. Hence, further information concerning long-term effects on aquatic organisms is dispensable.*"

ECHA notes that no adequate information is available for assessing the long-term toxicity of the registered substance to aquatic invertebrates (see section 6 of the present decision) and that no long-term toxicity study on fish is available. This implies that the Predicted No Effect Concentration (PNEC) proposed in the dossier is not adequate. If the PNEC is recalculated based on the results of the short-term studies and with an assessment factor of 1000 as recommended by *ECHA Guidance on information requirements and chemical safety assessment, Chapter R.10*, then some risk characterisation ratios will exceed 1 (PEC/PNEC<1) indicating that risk to the environment is not controlled. Therefore, ECHA considers that the information currently available does not rule out risk to the environment and indicates the need to investigate further the effects on aquatic organisms.

ECHA further notes that no valid information is available for assessing the toxicity of the registered substance to algae (see section 5 of the present decision) and that the results from short-term studies indicate that fish and *Daphnia* are equally sensitive to the registered substance. Therefore, it is not possible to conclude that fish is less sensitive than algae or than *Daphnia*. A long-term study on fish may therefore be required if the PNEC needs to be refined.

Consequently, ECHA concludes that your adaptation does not meet the specific rules for adaptation of Annex IX, Section 9.1.6., column 2 and cannot be accepted.

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 3.0, February 2016) 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 3.0, February 2016), *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 3.0, February 2016).

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

Before conducting any of the tests mentioned above in points 7-8 you shall consult the ECHA *Guidance on information requirements and chemical safety assessment (version 3.0, February 2016)*, Chapter R7b, Section R.7.8.5 to determine the sequence in which the aquatic long-term toxicity tests are to be conducted and the necessity to conduct long-term toxicity testing on fish.

According to ECHA *Guidance on information requirements and chemical safety assessment* (version 3.0, February 2016), Chapter R7b (Section R.7.8.5., including Figure R.7.8-4), if based on acute aquatic toxicity data neither fish nor invertebrates are shown to be substantially more sensitive, long-term studies may be required on both. In such case, according to the integrated testing strategy, the *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.

Once results of the 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.

Due to the surface activity you should consult OECD Guidance Document on Aquatic Toxicity Testing of Difficult Substances and Mixtures, ENV/JM/MONO (2000)6 and ECHA *Guidance on information requirements and chemical safety assessment* (version 3.0, February 2016), Chapter R7b, Table R.7.8-3 summarising aquatic toxicity testing of difficult substances for choosing the design of the requested ecotoxicity test(s) and for calculation and expression of the result of the test(s).

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 15 March 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 did not receive any comments by the end of the commenting period.

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 carrying out the tests required by the present decision, it is important to ensure that the particular sample of substance tested is appropriate to assess the properties of the registered substance, taking into account any variation in the composition of the technical grade of the substance as actually manufactured or imported. If the registration of the substance covers different grades, the sample used for the new tests must be suitable to assess these.

   Furthermore, 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.