EUROPEAN CHEMICALS AGENCY

Helsinki, 31 August 2016

Addressee: [redacted]

Decision number: CCH-D-2114340992-45-01/F
Substance name: Alcohols, C6-24 and C6-24-unsatd., distn. residues
EC number: 310-079-6
CAS number: 102242-48-8
Registration number: [redacted]
Submission number: [redacted]
Submission date: 19.03.2013
Registered tonnage band: 1000 tonnes or more per year

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(s) in the IUPAC nomenclature or other international chemical name(s) (Annex VI, Section 2.1.1.) of the registered substance;**

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

3. **In vivo mammalian erythrocyte micronucleus test (Annex IX/X, Section 8.4, column 2; test method: OECD TG 474) in mice or rats, oral route with the registered substance or**

   In vivo mammalian bone marrow chromosomal aberration test (Annex IX/X, Section 8.4, column 2; test method: OECD TG 475) in mice or rats, oral route with the registered substance;

4. **Sub-chronic toxicity study (90-day), oral route (Annex IX, Section 8.6.2; test method: EU B.26/OECD TG 408) in rats with the registered substance;**

5. **Pre-natal developmental toxicity study (Annex IX, Section 8.7.2; test method: EU B.31/OECD TG 414) in a first species (rats or rabbits), oral route with the registered substance;**

6. **Pre-natal developmental toxicity study (Annex X, Section 8.7.2; test method: EU B.31/OECD TG 414) in a second species (rats or rabbits), oral route with the registered substance;**

7. **Extended one-generation reproductive toxicity study (Annex X, Section 8.7.3; test method: OECD TG 443) in rats, oral route with the registered substance;**

- **Ten weeks premating exposure duration for the parental (P0) generation;**
- **Dose level setting shall aim to induce some toxicity at the highest dose level;**
- **Cohort 1A (Reproductive toxicity);**
- **Cohort 1B (Reproductive toxicity) without extension to mate the Cohort 1B animals to produce the F2 generation;**[1]

8. **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;**

9. **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 with the registered substance;**

10. **Short-term toxicity testing on fish (Annex VIII, Section 9.1.3; test method: Fish, acute toxicity test, OECD TG 203) with the registered substance;**

11. **Activated sludge respiration inhibition testing (Annex VIII, Section 9.1.4, test method: activated sludge respiration inhibition test, OECD TG 209) with the registered substance;**

12. **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;**

13. **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;**

14. **Ready biodegradability (Annex VII, Section 9.2.1.1; test method: CO2 evolution test, OECD TG 301B) or**

    Ready biodegradability (Annex VII, Section 9.2.1.1; test method: MITI test (I), OECD TG 301C) or

    Ready biodegradability (Annex VII, Section 9.2.1.1; test method: Closed bottle test, OECD TG 301D) or

    Ready biodegradability (Annex VII, Section 9.2.1.1; test method: Manometric respirometry test, OECD TG 301F) or

    Ready biodegradability (Annex VII, Section 9.2.1.1; test method: Ready biodegradability – CO2 in sealed vessels (headspace test), OECD TG 310) with the registered substance;

15. **Hydrolysis as a function of pH (Annex VIII, Section 9.2.2.1; test method: EU C.7/OECD TG 111) with the registered substance;**

[1] No testing for an extended one-generation reproductive toxicity study may be started or performed at this moment: You may start performing the extended one-generation reproductive toxicity study only after **07 December 2017** unless ECHA has communicated to you to do otherwise.

16. **Adsorption/desorption screening (Annex VIII, Section 9.3.1.; test method: Adsorption/desorption using an appropriate test method, with the registered substance;**

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

With respect to the request for extended one-generation reproductive toxicity study as set out in Annex X, section 8.7.3, columns 1 and 2 (request 7), based on the currently available information, the conditions to extend Cohort 1B are currently not met and no triggers for the inclusion of Cohorts 2A and 2B (developmental neurotoxicity) and Cohort 3 (developmental immunotoxicity) have been identified. However, the sub-chronic toxicity study (90-day) requested in this decision (request 4) may provide information that requires these changes of the design of the extended one-generation reproductive toxicity study. Therefore, you shall first conduct the sub-chronic toxicity study (90-day) and submit the study results to ECHA in a dossier update by **07 September 2017**.

If based on these results and any other relevant available information the above mentioned changes in study design may be needed, ECHA will inform you that it intends to initiate a new decision-making process for these changes of the extended one-generation reproductive toxicity study under Articles 41, 50 and 51 of the REACH Regulation at the earliest by **07 December 2017**, i.e. within three months after expiry of the 12-month deadline to provide the 90-day study, or within three months of the date of submission of the study summary of the sub-chronic toxicity study (90-day). This may result in a decision changing the requested extended one-generation reproductive toxicity study and, if necessary, setting a new deadline.

If you do not receive a communication from ECHA by **07 December 2017**, the request of the present decision for the extended one-generation reproductive toxicity study remains effective and the results of this study have to be provided in a dossier update by **09 March 2020** (i.e. the deadline defined in this decision).

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

You are required to submit the requested information in an updated registration dossier by **09 March 2020** except for the information requested under point 4 for a repeated dose toxicity study (90-day) which shall be submitted in an updated registration dossier by **07 September 2017**. You shall also update the chemical safety report, where relevant. The timeline has been set to allow for sequential testing.

The reasons of this decision are set out in Appendix 1. The procedural history is described in Appendix 2. Advice and further observations are provided in Appendix 3.

Appeal

This decision can be appealed to the Board of Appeal of ECHA within three months of its notification. An appeal, together with the grounds thereof, shall be submitted to ECHA in writing. An appeal has suspensive effect and is subject to a fee. Further details are described under http://echa.europa.eu/regulations/appeals.]

Authorised[2] by Ofelia Bercaru, Head of Unit, Evaluation E3

[2] 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

IDENTIFICATION OF THE SUBSTANCE

In order to ensure that potential hazardous properties of the substance are not underestimated, the above substance identification deficiencies must be resolved before identifying the test sample to be used for the testing requested in the present decision.

1. **Name(s) in the IUPAC nomenclature or other international chemical name(s) (Annex VI, Section 2.1.1.)**

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

You have identified the registered substance as a substance of Unkown or Variable composition, Complex reaction products or Biological materials (UVCB). As indicated in chapter 4.3 of the "Guidance for identification and naming of substances under REACH and CLP", referred to hereinafter as "the Guidance", the naming of UVCB substances shall consist of two parts: (1) the chemical name and (2) a detailed description of the manufacturing process.

ECHA observes that you did not provide sufficient information for correctly identifying the registered substance. You have identified the registered substance with IUPAC name "Alcohols, C6-24 and C6-24-unsatd. even numbered, distn. residues". The description of the substance in the description field of section 1.1 of the IUCLID technical dossier is: "[redacted]."

In addition, under technological process, in section 3.1 of the IUCLID technical dossier, you have included the following information "[redacted]"

The composition of the starting materials is not described specifically enough. The concentration of the individual carbon numbers and the ratio of saturated to unsaturated constituents in the starting material is not specified.

Further, you have not included an adequate description for the manufacture of the registered substance. An adequate description of the manufacturing process is necessary because variation in the process parameters or process steps may lead to a change in the identity of the registered substance. An adequate description should include the following:

a. Identity of and ratio of starting materials as described above.
b. Description of each processing step in the order that they happen.
c. Description of the process parameters such as distillation temperature and pressure

The information on the manufacturing process shall be reported in the Description field in section 1.1 of IUCLID.

ECHA acknowledges your agreement and comment on the draft decision and your intention to update the registration dossier.

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

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

The substance composition corresponds to the chemical representation of what the substance consists of and is therefore an essential part of substance identification and a cornerstone of all REACH obligations.

Annex VI 2.3 of the REACH Regulation requires that each registration dossier contains sufficient information for establishing the composition of the registered substance and therefore its identity.

In that respect, according to chapter 4.3.1.1 of the Guidance, you shall note that for UVCB substances presenting a large number of constituents, such as the registered substance, the following applies:

- All constituents present in the substance with a concentration of ≥ 10% shall be identified and reported individually;
- All known constituents and constituents relevant for the classification and/or PBT assessment of the registered substance shall be identified and reported individually;
- Unknown constituents shall be identified as far as possible by a generic description of their chemical nature; and
- For each constituent or group of constituents, the typical, minimum and maximum concentrations shall be specified

ECHA notes that in section 1.2 of the IUCLID technical dossier, you did not provide any information on the identity and concentration of the constituents or groups of constituents present in the composition of the registered substance. You have instead reported the composition as consisting of [redacted]% of the substance itself, i.e., *Alcohols, C6-24 and C6-24-unsatd., distn. Residues*.

In contrast to this, in the report from the gas chromatograph-mass spectoscopy (GC-MS) and gas chromatograph-flame ionization detection (GC-FID) analysis attached in section 1.4 of the IUCLID technical dossier a total of 12 different peaks have been identified with chemical names and concentration values associated to them. Therefore, the information provided on composition in section 1.2 of the IUCLID technical dossier does not correspond to the analytical information.

ECHA acknowledges your agreement and comment on the draft decision and your intention to update the registration dossier.

You are therefore requested to report in section 1.2 of IUCLID the chemical identity and typical, upper and lower concentration values for each of the constituents identified in the analytical report attached in section 1.4 of the IUCLID technical dossier. The reporting shall meet the criteria specified in chapter 4.3.1.1 of the Guidance, as summarised above.

PROPERTIES OF THE SUBSTANCE

Grouping of substances and read-across approach

You have proposed to cover the standard information requirements for the registered substance Alcohols, C6-24 and C6-24-unsatd., distn. Residues for the following endpoints:

- *In vivo mammalian erythrocyte micronucleus test (Annexes IX and X, Section 8.4., column 2)*
- *Pre-natal developmental toxicity study (Annexes IX and X, Section 8.7.2;*
- *Extended one-generation reproductive toxicity study (Annex X, Section 8.7.3;*
- *Short-term toxicity testing on aquatic invertebrates (Annex VII, Section 9.1.1.);*
- *Short-term toxicity testing on fish (Annex VIII, Section 9.1.3.);*
- *Growth inhibition study aquatic plants (Annex VII, Section 9.1.2.),*
- *Activated Sludge respiration inhibition testing (Annex VIII, Section 9.1.4)* and
- *Ready biodegradability (Annex VII, Section 9.2.1.1.)*

by adapting the information requirements according to Annex XI, Section 1.5. of the REACH Regulation i.e. grouping of substances and read-across approach by providing studies with the analogue substances C-SAT 100018 or Alcohols C6-24, distn. residues (CAS 102242-49-9), Alcohols, C8- 22, distn. Residues (CAS 90622-25-6), Octadecan-1 -ol (CAS 112-92-5, EC 204-017-6) and the long chain alcohols included in the OECD SIDS assessment report (2006) (further referred as source substances).

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

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

A. Introduction of the grouping and read-across approach proposed by the Registrant

In order to describe your read across approach you have provided a generic statement under each endpoint, such as:
"No data on the biodegradation potential of the test substance itself are currently available. However, a ready biodegradation study on the structurally similar CAS 102242-49-9 according to OECD 301B is available ([redacted]*)".*
Or

"No data are available for "alcohols C6-C24 and C6-C24 unsat., distn residues" (CAS 102242-48-8). Nevertheless repeated dose data are available ([redacted]), and further data of an OECD TG 422 screening test performed with octadecan-1-ol (CAS 112-92-5), which is considered as a conservative representative regarding the toxicological effects of all alcohol-based constituents, were considered suitable data within read across approach."

On ground of the above presented information, ECHA understands that the grouping approach is based on the similarity in the chemical structure of the above mentioned substances i.e. all substances contain a hydroxyl moiety, as a functional group i.e. are alcohols.

However ECHA notes that you have not described in your dossier a hypothesis of the proposed read-across approach for any of the above listed endpoints.

B. Information submitted by the Registrant to support the grouping and read-across approach

You have provided study records on the endpoints, as listed above, conducted with source substances and the above mentioned generic statements to support the grouping and read-across approach.
However, you have provided no read-across justification in your technical dossier or in your CSR for any of the above listed endpoints.
In addition no data on the physico-chemical characteristics and environmental fate and behaviour similarities with the registered substance were reported.

ECHA notes that the provided information solely identifies the source substances on which studies are available and are proposed to be used to predict toxicological properties of the registered substance (the target substance).

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

ECHA understands that the grouping approach is based on the similarity in the chemical structure of the above mentioned substances i.e. all substances contain a hydroxyl moiety as a functional group.

Substance characterisation of source and target substances

ECHA notes that you have submitted information on the composition and impurities for the target substance according to Annex VI of the REACH regulation. You also provided information on the numerical identifiers and the name of the source substances. However, you have not provided detailed information on the composition and impurities of any of the source substances.

ECHA concludes that given the lack of information on the composition and impurities of the proposed source substances, the suitability of the source substances for read-across purposes cannot be verified and there is not an adequate basis for predicting the properties of the registered substance from the data of the source substances.

Structural similarity and dissimilarity

You have provided the statement that the studies proposed to be read across are generated on *"structurally similar substances"*. ECHA notes that structural similarity alone is not sufficient for predicting toxicological properties. Furthermore, you have not provided the structure of the source substances and/or not explained the structural similarities and dissimilarities of the substances (e.g. chain length, branching, saturation of the chain, position and number of the hydroxyl functional group etc.).

ECHA concludes that you have not addressed the structural similarities and dissimilarities between the source substances and the target substance and did not explain why the probable differences would not indicate differences in the toxicity profile of target and sources.

Given the lack of information on the structural similarities and dissimilarities between target and sources, ECHA considers that there is not an adequate basis for predicting the properties of the registered substance from the data of the source substances.

D. Conclusion on the read-across approach

ECHA considers that the read-across in its current form cannot be accepted due to

- lack of hypothesis and justification of your read across approach, establishing a basis whereby relevant human health and environmental properties of the registered substance may be predicted from data on the source substances;
- lack of information on the composition and impurities of the proposed source substances and
- the fact that the structural similarities between the registered and analogue substances have not been established and the impact of the structural dissimilarities on toxicity profile have not been addressed.

Therefore, there is not an adequate basis for predicting the properties of Alcohols, C6-24 and C6-24-unsatd., distn. Residues from the source substances. The adaptation of the standard information requirements for the endpoints:

- *In vivo mammalian erythrocyte micronucleus test (Annexes IX and X, Section 8.4., column 2)*
- *Pre-natal developmental toxicity study (Annexes IX and X, Section 8.7.2);*
- *Extended one-generation reproductive toxicity study (Annex X, Section 8.7.3;*
- *Short-term toxicity testing on aquatic invertebrates (Annex VII, Section 9.1.1.);*
- *Short-term toxicity testing on fish (Annex VIII, Section 9.1.3.);*
- *Growth inhibition study aquatic plants (Annex VII, Section 9.1.2.);*
- *Activated Sludge respiration inhibition testing (Annex VIII, Section 9.1.4)* and
- *Ready biodegradability (Annex VII, Section 9.2.1.1.)*

in the technical dossier is based on the proposed read-across approach examined above. ECHA does not consider the read-across justification to be a reliable basis to predict the properties of the registered substance for the reasons set out above. Thus, the adaptation does not comply with the general rules of adaptation as set out in Annex XI, 1.5. Therefore, ECHA rejects all adaptations in the technical dossier that are based on Annex XI, 1.5.

Accordingly, there is a data gap for all endpoints mentioned above and therefore it is necessary to perform testing on the registered substance.

ECHA acknowledges your comment with the intention to update the registration dossier with an analogue justification by end of October 2016. ECHA therefore reminds you of the update policy for compliance check draft decisions. The draft decision does not take into account any updates after 4 December 2015 when the draft decision was notified to the Registrant. Any such update submitted will be examined by ECHA only after the deadline established in the present decision has passed. Independent of this draft decision and under Article 22 of the REACH Regulation, you can submit updates to the registration dossier.

3. In vivo mammalian erythrocyte micronucleus test (Annex IX/X, Section 8.4., column 2) or In vivo mammalian bone marrow chromosomal aberration test (Annex IX/X, Section 8.4, column 2)

Pursuant to Articles 10(a)(vi) and/or (vii), 12(1)(e) and 13(4) of the REACH Regulation, your technical dossier registered at more than 1000 tonnes per year shall contain as a minimum the information specified in Annexes VII to X.

"Mutagenicity" is an information requirement as laid down in Annex VIII, Section 8.4. of the REACH Regulation. Column 2 of Annex IX, Section 8.4. provides that "If there is a positive result in any of the *in vitro* genotoxicity studies in Annex VII or VIII and there are no results available from an *in vivo* study already, an appropriate *in vivo* somatic cell genotoxicity study shall be proposed by the Registrant."

The technical dossier contains one *in vitro micronucleus test (2012,* key, reliability 1) performed according to *OECD 487* with the registered substance that shows a positive result without metabolic activation. The positive result indicates that the substance is inducing chromosomal aberrations under the conditions of the test.

Hence, you have self classified the substance as Muta 2. with the following justification: *"Based on the available data classification of "alcohols, C6-C24 and C6-C24 unsat., distn residues" (CAS 102242-48-8) for mutageniciy is warranted as "R 68" according to the EU Directive 67/548/EEC and as "category 2" according to the CLP regulation (EC) No. 1272/2008".*

ECHA notes that self-classification as Muta 2. is not an appropriate adaptation for an *in vivo* somatic genotoxicity study.
A second *in vitro* micronucleus test (Key, reliability 1, 2010, OECD 487) with a read-across substance (C-SAT 100018) with negative result (with and without metabolic activation) is also included in the dossier. As explained above in the Section *'Grouping of substances and read-across approach'*, your adaptation of the information requirement according to Annex XI, Section 1.5 cannot be accepted.

In addition, the technical dossier contains an adaptation for an *in vivo* study with the following justification: *"As there is a positive result in one of the in vitro genetic toxicity tests (Micronucleus test without metabolic activation; [redacted]), conduction of a test to evaluate the mutagenic potential in vivo is mandatory according to REACH Annex IX. As the test substance is only handled under strictly controlled conditions and there is only one use (combustion), exposure is considered negligible and no hazard is expected.*

Furthermore, considering all available in vitro data including those from the read across substance "alcohols, C6 -C24, distn residues" (CAS 102242 -49 -9), the positive result found in the micronucleus test without metabolic activation was not confirmed in any other test. Based on the fact that exposure to the test substance is not possible due to the strictly controlled conditions as well as on the 3R principle and animal welfare, further in vivo testing is not considered necessary".

However, ECHA notes that your adaptation does not meet the general rule for adaptation of Annex XI, Section 3. because no information on strictly controlled conditions and no exposure assessment is provided in the technical dossier and no exposure scenario(s) are developed in the Chemical Safety Report. Therefore, it is not demonstrated that strictly controlled conditions apply and that exposure is negligible during combustion.

Hence, ECHA concludes that the test provided was not appropriate to follow-up a concern for chromosomal aberrations.

An appropriate *in vivo* genotoxicity study to follow up the concern on chromosomal aberrations is not provided for the registered substance. Consequently there is an information gap and it is necessary to provide information for this endpoint.

According to the ECHA *Guidance on information requirements and chemical safety assessment* (version 4.0, July 2015) Chapter R.7a, section R.7.7.6.3, the mammalian erythrocyte micronucleus test ("MN test", OECD TG 474), the mammalian bone marrow chromosomal aberration test ("CA test", OECD TG 475) or the *in vivo* mammalian alkaline comet assay ("comet assay", OECD TG 489) are suitable to follow-up a positive *in vitro* result on chromosomal aberration if the test substance or its metabolite(s) will reach the target tissue.

The MN test and the CA test are able to detect chromosomal aberrations, whereas the comet assay is an indicator assay detecting putative DNA lesions. Hence, ECHA considers that the most appropriate test to follow-up *in vivo* a concern for chromosomal aberration is either the MN or the CA test.

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:

In vivo mammalian erythrocyte micronucleus test (test method: OECD TG 474) in mice or rats, oral route

Or

In vivo mammalian bone marrow chromosomal aberration test (test method: OECD TG 475) in mice or rats, oral route.

Notes for your consideration

According to paragraph 10 of the OECD TG 474 (Mammalian Erythrocyte Micronucleus Test, updated on 26 Sept 2014) and paragraph 6 of the OECD TG 475 (Mammalian Bone Marrow Chromosomal Aberration Test, updated on 26 Sept 2014) *"If there is evidence that the test substance(s), or its metabolite(s), will not reach the target tissue, it may not be appropriate to use this test".*

Additionally, according to paragraph 48 (d) of the OECD TG 474 and paragraph 44 (d) of the OECD TG 475, a test chemical is considered clearly negative if "*Bone marrow exposure to the test substance(s) occurred*". Accordingly, if a substance is negative in this test, and if it is not possible to demonstrate that bone marrow exposure to the substance occurred, then ECHA will consider any remaining uncertainty concerning the mutagenic potential of the substance and whether to request any further information.

You are reminded that according to Annex X, Section 8.4., column 2 of the REACH Regulation, if positive results from an *in vivo* somatic cell study are available, *"the potential for germ cell mutagenicity should be considered on the basis of all available data, including toxicokinetic evidence. If no clear conclusions about germ cell mutagenicity can be made, additional investigations shall be considered".*

In case the results of the somatic *in vivo* genotoxicity tests indicate that chromosomal aberrations occurred you shall consider the need to make a testing proposal to conduct the mammalian spermatogonial chromosome aberration test (OECD TG 483).

4. Sub-chronic toxicity study (90-day), oral route (Annex IX, Section 8.6.2.)

Pursuant to Articles 10(a)(vi) and/or (vii), 12(1)(e) and 13(4) of the REACH Regulation, your technical dossier registered at more than 1000 tonnes per year shall contain as a minimum the information specified in Annexes VII to X.

A "sub-chronic toxicity study (90 day)" is a standard information requirement as laid down in Annex IX, Section 8.6.2. 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 a repeated dose toxicity study with the following justification: *"Orientating repeated dose toxicity study, conducted prior to the implementation of currently acknowledged testing guidelines such as the OECD TG 408, and according to an in-house protocol. Even if the study conduct does not fulfil current requirements, suitable basic data were given"*. You further state in the technical dossier *"Since the study was conducted prior to the implementation of currently acknowledged testing guidelines (OECD TG 408), current testing requirements are not fulfilled; nevertheless the study provides suitable basic data, acceptable for assessment of the toxic potential of the compound following repeated dosing"*.

While you have not explicitly claimed an adaptation, you have provided information that could be interpreted as an attempt to adapt the information requirement according to Annex XI, Section 1.1.2.

However, ECHA notes that your adaptation does not meet the general rule for adaptation of Annex XI, Section 1.1.2. because the study you have provided does not provide equivalent information to the information requirement of Annex IX, Section 8.6.2., in particular the key elements such as exposure duration, number of doses of the OECD TG 408 guideline were not adequately and reliably covered. 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 has evaluated the most appropriate route of administration for the study and considers that, in the absence of any indications to the contrary in the technical dossier or in the chemical safety report, the oral route which is the preferred one as indicated in ECHA *Guidance on information requirements and chemical safety assessment* (version 4.1, October 2015) Chapter R.7a, section R.7.5.4.3) is the most appropriate route of administration. More specifically, the substance is a liquid of very low vapour pressure and no uses with spray application are reported that could potentially lead to aerosols of inhalable size.
Hence, the test shall be performed by the oral route using the test method OECD TG 408/EU B.26.

According to the test method EU B.26/OECD TG 408 the rat is the preferred species. ECHA considers this species as being appropriate and testing should be performed with the rat.

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: Repeated dose 90-day oral toxicity study (test method: EU B.26./OECD TG 408) in rats.

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

Pursuant to Articles 10(a)(vi) and/or (vii), 12(1)(e) and 13(4) of the REACH Regulation, your technical dossier registered at more than 1000 tonnes per year shall contain as a minimum the information specified in Annexes VII to X.

A "pre-natal developmental toxicity study" for a first species is a standard information requirement as laid down in Annex IX, Section 8.7.2. of the REACH Regulation. Adequate information on this endpoint needs to be present in the technical dossier for the registered substance to meet this information requirement.

The technical dossier does not contain information on a pre-natal developmental toxicity study with the registered substance.

You have sought to adapt this information requirement according to Annex XI, Section 3. You provided the following justification for the adaptation *"As the test substance is only handled under strictly controlled conditions and there is only one use (combustion), exposure is considered negligible and no hazard is expected. Based on the fact that exposure to the test substance is not possible due to the strictly controlled conditions, testing on developmental toxicity may be omitted according to Annex XI (3). This is also in line with the 3R principle and animal welfare".*

However, ECHA notes that your adaptation does not meet the general rule for adaptation of Annex XI, Section 3. because no information on strictly controlled conditions and no exposure assessment is provided in the technical dossier and no exposure scenario(s) are developed in the Chemical Safety Report. Therefore, it is not demonstrated that strictly controlled conditions apply and that exposure is negligible during combustion. In addition, ECHA notes that no DNEL is derived and the legal text (footnote) also states "for the purpose of subparagraph 3.2(a)(ii), without prejudice to column 2 of Section 8.7 of Annexes IX and X, a DNEL derived from a screening test for reproductive/developmental toxicity shall not be considered appropriate to omit a prenatal developmental toxicity study or a two-generation reproductive toxicity study".

Finally, the substance is not incorporated in an article and, therefore, Annex XI, Section 3.2(c) does not apply.

Therefore, your adaptation of the information requirement according to Annex XI, Section, 3 cannot be accepted.

You have also sought to adapt this information requirement according to Annex XI, Section 1.5. of the REACH Regulation by providing a study record for a Combined Repeated Dose Toxicity Study with the Reproduction / Developmental Toxicity Screening Test, OECD TG 422 (Hansen 1992), with the source substance octadecan-1-ol (CAS no 102242-48-8, EC no 204-017-6).

However, the submitted study does not provide the information required by Annex IX, Section 8.7.2., because an OECD TG 422 study does not cover the key parameters of a pre-natal developmental toxicity study like examinations of foetuses for skeletal and visceral alterations. Hence, an OECD TG 422 study does not provide the information required by Annex IX, 8.7.2.

Furthermore, as explained above in the section '*Grouping of substances and read-across approach*' of this decision, your adaptation of the information requirement according to Annex XI, Section 1.5 cannot be accepted.

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

ECHA considers that the oral route is the most appropriate route of administration for substances except gases to focus on the detection of hazardous properties on reproduction as indicated in ECHA *Guidance on information requirements and chemical safety assessment* (version 4.0, July 2015) R.7a, chapter R.7.6.2.3.2. Since the substance to be tested is a liquid, ECHA concludes that testing should be performed by the oral route.

In your comments on the draft decision, you reiterated the very restricted use of the substance ("used only as biofuel or biofuel component in block heat and power plants under strictly controlled, industrial conditions"). ECHA acknowledges the comment and information provided. However, the current dossier submission does not meet the requirements to fulfil an exposure based adaptation since the information requirements set out in REACH Annexes VII to X cannot be deviated from based on lack of wide dispersive use unless an Exposure Based Adaptation is successfully demonstrated throughout the life-cycle of the substance (REACH Annex XI 3.2(b)) as described in REACH Article 18(4)(a)-(f). Consequently the draft decision was not amended.

ECHA reminds you of the update policy for compliance check draft decisions. The draft decision does not take into account any updates after 4 December 2015 when the draft decision was notified to the Registrant. Any such update submitted will be examined by ECHA only after the deadline established in the present decision has passed. Independent of this draft decision and under Article 22 of the REACH Regulation, you can submit updates to the registration dossier.

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

6. Pre-natal developmental toxicity study (Annex X, Section 8.7.2.) in a second species

Pursuant to Articles 10(a)(vi) and/or (vii), 12(1)(e) and 13(4) of the REACH Regulation, your technical dossier registered at more than 1000 tonnes per year shall contain as a minimum the information specified in Annexes VII to X.

Pre-natal developmental toxicity studies (test method EU B.31./OECD TG 414) on two species are part of the standard information requirements for a substance registered for 1000 tonnes or more per year (Annex IX, Section 8.7.2., column 1, Annex X, Section 8.7.2., column 1, and sentence 2 of introductory paragraph 2 of Annex X of the REACH Regulation).

The technical dossier does not contain information on a pre-natal developmental toxicity study with the registered substance in a first or a second species.

You have sought to adapt this information requirement according to Annex XI, Section 3 and ECHA notes that your adaptation does not meet general rule for adaptation of Annex XI, section 3 and cannot be accepted as explained above in Section 5.
In addition, 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 Combined Repeated Dose Toxicity Study with the Reproduction / Developmental Toxicity Screening Test, OECD TG 422 (Hansen 1992), with the analogue substance octadecan-1-ol (CAS no 102242 -48 -8, EC no 204-017-6). As explained above in Section 5, the study is not adequate to provide equivalent information on prenatal developmental toxicity to a prenatal developmental toxicity study (OECD TG 414). In addition it does not provide information on a second species.

Furthermore, as explained above in the section *'Grouping of substances and read-across approach'* of this decision, your adaptation of the information requirement according to Annex XI, Section 1.5 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 the test method EU B.31/OECD TG 414, the rat is the preferred rodent species and the rabbit the preferred non-rodent species. On the basis of this default consideration, ECHA considers testing should be performed with rabbits or rats as a second species, depending on the species tested in the first pre-natal developmental toxicity study.

ECHA considers that the oral route is the most appropriate route of administration for substances except gases to focus on the detection of hazardous properties on reproduction as indicated in ECHA *Guidance on information requirements and chemical safety assessment* (version 4.1, October 2015) R.7a, chapter R.7.6.2.3.2. Since the substance to be tested is a liquid, ECHA concludes that testing should be performed by the oral route.

In your comments on the draft decision, you reiterated the very restricted use of the substance ("used only as biofuel or biofuel component in block heat and power plants under strictly controlled, industrial conditions"). ECHA acknowledges the comment and information provided. However, the current dossier submission does not meet the requirements to fulfil an exposure based adaptation since the information requirements set out in REACH Annexes VII to X cannot be deviated from based on lack of wide dispersive use unless an Exposure Based Adaptation is successfully demonstrated throughout the life-cycle of the substance (REACH Annex XI 3.2(b)) as described in REACH Article 18(4)(a)-(f). Consequently the draft decision was not amended.

ECHA reminds you of the update policy for compliance check draft decisions. The draft decision does not take into account any updates after 4 December 2015 when the draft decision was notified to the Registrant. Any such update submitted will be examined by ECHA only after the deadline established in the present decision has passed. Independent of this draft decision and under Article 22 of the REACH Regulation, you can submit updates to the registration dossier.

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

Notes for your consideration

You are reminded that before performing a pre-natal developmental toxicity study in a second species you must consider the specific adaptation possibilities of Annex X, Section 8.7.2., column 2 and general adaptation possibilities of Annex XI. If the results of the test in the first species enable such adaptation, testing in the second species should be omitted and the registration dossier should be updated containing the corresponding adaptation statement.

7. Extended one-generation reproductive toxicity study (Annex X, Section 8.7.3)

Pursuant to Articles 10(a)(vi) and/or (vii), 12(1)(e) and 13(4) of the REACH Regulation, your technical dossier registered at more than 1000 tonnes per year shall contain as a minimum the information specified in Annexes VII to X.

The basic test design of an extended one-generation reproductive toxicity study (Cohorts 1A and 1B, without extension of Cohort 1B to include a F2 generation, and without Cohorts 2A, 2B and 3) is a standard information requirement as laid down in column 1 of 8.7.3., Annex X. If the conditions described in column 2 of Annex X are met, the study design needs to be expanded to include the extension of Cohort 1B, Cohorts 2A/2B, and/or Cohort 3. Adequate information on this endpoint needs to be present in the technical dossier for the registered substance to meet this information requirement.

a) *The information requirement*

You have not provided any study record of an extended one-generation reproductive toxicity study in the dossier that would meet the information requirement of Annex X, Section 8.7.3.

You have sought to adapt this information requirement according to Annex XI, Section 1 of the REACH Regulation. While you have not explicitly mentioned a particular subsection under Annex XI, Section 1, you have provided information that could be interpreted as an attempt to adapt the information requirement according to Annex XI, Section 1.2 and Section 1.5. You provided the following justification for the adaptation:
"In accordance with Section 1 of Annex XI, the two generation reproductive toxicity study (as required in Section 8.7.3) is scientifically unjustified, since data from a subchronic toxicity study give no indication on a toxic effect affecting fertility and reproduction; in this study, the NOAEL for systemic toxicity was 250 mg/kg bw/day.
On the other hand, octadecan-1-ol (CAS 112-92-5), which is considered as a conservative representative regarding the toxicological effects of all alcohol-based constituents,has been tested according to OECD TG 422; no treatment-related effects were seen and thus, the NOAEL was set at 2000 mg/kg bw, which was the highest dose tested. Moreover, according to an OECD SIDS report on long-chain alcohols (2006), no evidence of adverse findings in the reproductive organs in repeated dose toxicity studies and in screening studies for reproductive effects for long-chain alcohols is given. Thus, it can be concluded that no toxic effect on reproduction and fertility is to be expected from "alcohols, C6-C24 and C6-C24 unsat., distn residues" (CAS 102242-48-8) and thus, with respect to animals welfare, no testing is scheduled".

In your adaptation justification you refer to study records you have provided in your technical dossier: a sub chronic toxicity study with the registered substance and a reproduction/developmental toxicity screening test (OECD TG 422) with an analogue substance octadecan-1-ol (CAS 112-92-5). In addition, you refer to results from repeated dose toxicity studies and screening studies with long-chain alcohols reported in an OECD SIDS report.

With regard to the information obtained form the reproduction/developmental toxicity screening test (OECD TG 422) with a source substance octadecan-1-ol (CAS 112-92-5), as well as long-chain alcohols in OECD SIDS report, as explained above in the section '*Grouping of substances and read-across approach*' of this decision, your adaptation of the information requirement according to Annex XI, Section 1.5 cannot be accepted.

As for your adaptation according to Annex XI section 1.2. of the REACH regulation ECHA notes that repeated dose toxicity studies (OECD TG 408) and screening studies (OECD TG 422) may be relevant to provide elements for weighing evidence on reproductive toxicity.

ECHA further notes that information on the following elements, critical for reproductive toxicity (in particular for hazard class sexual function and fertility), has to be covered when applying weight of evidence for the endpoint:

- effects on the histopathologically observable changes in reproductive organs in the parental and F1 generation;
- functional fertility and reproductive performance of the parental generation;
- postnatal development and sexual maturation and endocrine mode of action;
- information on potency and on potential relationship between reproductive toxicity and systemic toxicity;

- availability of the additional information relevant for the requirements of column 2, Section 8.7.3.

However, the provided studies lack information on major relevant aspects of reproduction required for this tonnage level: they provide only limited information on the effects on functional fertility, histopathology of the reproductive organs and postnatal development (including sexual developement). Thus they do not allow a conclusion/decision on the lack of effects on the reproductive toxicity for hazard class sexual function and fertility.

In particular, ECHA observes that in the repeated dose toxicity oral study the substance has been tested at only one dose level (250 mg/kg bw/day) and did not show histopathologically observable changes in the reproductive organs in parental animals. Lack of reproductive toxicity cannot be concluded solely based on this information. Furthermore, the study lacks information on F1 animals, the full coverage of the spermatogenesis and folliculogenesis, statistical power and the examinations were performed not up to the limit doses and only on a limited number of animals.

Male and reproductive performance has been evaluated in the screening study (OECD TG 422) with the analogue substance to some extent. However, lack of reproductive toxicity cannot be concluded based on this limited information caused by short premating exposure duration, limited statistical power and limited parameters.

The studies provided no information on hazardous properties to the postnatal development including sexual maturation for F1 generation. Furthermore, information on oestrous cycle, sperm parameters and endocrine modes of action is missing.

In summary, the available information considered separately or together is not sufficient to conclude based on Annex XI, 1.2 (weight of evidence) that the substance has or has not a particular dangerous property, in this case reproductive toxicity (for hazard class sexual function and fertility).
Therefore, your adaptation based on Annex XI, section 1.2 of the REACH regulation cannot be accepted.

Additionally, you have sought to adapt this information requirement according to Annex XI, Section 3. However, ECHA notes that your adaptation does not meet the general rule for adaptation of Annex XI, Section 3. as explained in detail in section 5 of the present decision. Therefore, your adaptation of the information requirements according to Annex XI, Section 3. cannot be accepted.

In conclusion, 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. Thus, an extended one-generation reproductive toxicity study according Annex X, Section 8.7.3. is required. The following refers to the specifications of this required study.

a) *The specifications for the study design*

Premating exposure duration and dose-level setting

To ensure that the study design adequately addresses the fertility endpoint, the duration of the premating exposure period and the selection of the highest dose level are key aspects to be considered. According to ECHA Guidance, the starting point for deciding on the length of premating exposure period should be ten weeks to cover the full spermatogenesis and folliculogenesis before the mating, allowing meaningful assessment of the effects on fertility.

Ten weeks premating exposure duration is required because there is no substance specific information in the dossier supporting shorter premating exposure duration as advised in the ECHA Guidance on information requirements and chemical safety assessment R.7a, chapter R.7.6 (version 4.1, October 2015). Ten weeks exposure duration is supported also by the lipophilicity (log Kow >5.7) of the substance to ensure that the steady state in parental animals has been reached before mating.

The highest dose level shall aim to induce some toxicity to allow comparison of effect levels and effects of reproductive toxicity with those of systemic toxicity. The dose level selection should be based upon the fertility effects with the other cohorts being tested at the same dose levels.

It is recommended that results from a range-finding study (or range finding studies) for the extended one-generation reproductive toxicity study are reported with the main study. This will support the justifications of the dose level selections and interpretation of the results.

Species and route selection

According to the test method EU B.56/ OECD TG 443, the rat is the preferred species. On the basis of this default assumption, ECHA considers that testing should be performed in rats.

ECHA considers that the oral route is the most appropriate route of administration for substances except gases to focus on the detection of hazardous properties on reproduction as indicated in ECHA *Guidance on information requirements and chemical safety assessment* (version 4.1, October 2015) R.7a, chapter R.7.6.2.3.2. Since the substance to be tested is a liquid, ECHA concludes that testing should be performed by the oral route.

In your comments on the draft decision, you reiterated the very restricted use of the substance ("used only as biofuel or biofuel component in block heat and power plants under strictly controlled, industrial conditions"). ECHA acknowledges the comment and information provided. However, the current dossier submission does not meet the requirements to fulfil an exposure based adaptation since the information requirements set out in REACH Annexes VII to X cannot be deviated from based on lack of wide dispersive use unless an Exposure Based Adaptation is successfully demonstrated throughout the life-cycle of the substance (REACH Annex XI 3.2(b)) as described in REACH Article 18(4)(a)-(f). Consequently the draft decision was not amended.

ECHA reminds you of the update policy for compliance check draft decisions. The draft decision does not take into account any updates after 4 December 2015 when the draft decision was notified to the Registrant. Any such update submitted will be examined by ECHA only after the deadline established in the present decision has passed. Independent of this draft decision and under Article 22 of the REACH Regulation, you can submit updates to the registration dossier.

b) Outcome

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: Extended one-generation reproductive toxicity study (test method EU B.56/ OECD TG 443), in rats, oral route, according to the following study-design specifications:

- Ten weeks premating exposure duration for the parental (P0) generation;
- Dose level setting shall aim to induce some toxicity at the highest dose level;
- Cohort 1A (Reproductive toxicity);
- Cohort 1B (Reproductive toxicity) without extension to mate the Cohort 1B animals to produce the F2 generation;

As stated in the decision (request 7), no triggers for the extension of Cohort 1B and the inclusion of Cohorts 2A and 2B (developmental neurotoxicity) and Cohort 3 (developmental immunotoxicity) have been identified based on the available information. However, the sub-chronic toxicity study (90-day) requested in this decision (request 4) and any other relevant available information may provide information that could trigger these changes in study design. Therefore the 90-day study is to be conducted first and the study results submitted to ECHA in a dossier update by the given deadline. If ECHA identifies a need for the above mentioned changes in study design, it will initiate by **07 December 2017** (i.e. within three months after expiry of the 12-month deadline to provide the 90-day study, or within three months of the date of submission of the study summary of the sub-chronic toxicity study) a new decision making procedure changing this request and setting a new deadline for the expanded request. If ECHA does not identify a need for additional changes in study design the request for an extended one-generation reproductive toxicity study of the present decision remains effective including the time by when the requested information has to be provided as specified above.

Notes for your consideration

Notwithstanding what is requested by ECHA in this or a subsequent decision referred to above, you may expand the study by extending Cohort 1B and including Cohorts 2A and 2B and Cohort 3 if new information becomes available after this decision is issued to justify such an inclusion. Inclusion is justified if the new information shows triggers which are described in column 2 of Section 8.7.3., Annex X and further elaborated in ECHA Guidance on information requirements and chemical safety assessment R.7a, chapter R.7.6 (version 4.1, October 2015). You may also expand the study to address a concern identified during the conduct of the extended one-generation reproduction toxicity study and also due to other scientific reasons in order to avoid a conduct of a new study. The justification for the changes in the study design must be documented. The study design must be justified in the dossier and, thus, the existence/non-existence of the conditions/ triggers must be documented.

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

Pursuant to Articles 10(a)(vi) and/or (vii), 12(1)(e) and 13(4) of the REACH Regulation, your technical dossier registered at more than 1000 tonnes per year shall contain as a minimum the information specified in Annexes VII to X of the REACH 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.

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.

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 acute toxicity test on Daphnids (Key, reliability 1, 1995) made with Daphnid ToxRTool (EU C.2 study) with the source substance(s) (CAS 102242-49-9), called Alcohols, C6-C24, desti. residues.
However, as explained above in the section '*Grouping of substances and read-across approach*' of this decision, your adaptation of the information requirement cannot be accepted.

In addition, there are the following endpoint specific reasons for rejecting the proposed read-across for short-term toxicity testing on aquatic invertebrates. The above mentioned study is not adequate because the robust study summary indicates that the concentrations tested were 1000, 3000 and 10000 mg/l with no specific method applied for the test substance preparation whereas the substance was mentioned to have low water solubility. This low water solubility was not taken into account in the study design nor in the reporting of observations and test results and hence the results are assessed as unreliable as they are reported: LC 0= 10000 mg/L 48hr. LC50 > 10000 mg/L for nominal concentration, with no toxicity effects reported.

Furthermore the following deficiencies can be observed from the robust study summary of the source substance study results: no details on the study results nor observations made during the testing were reported.
Finally, these study results are not adequate for the purpose of C&L and/or risk assessment purposes due to these deficiencies.
Therefore, Annex XI 1.5 adaptation requirements are not fulfilled and there is a data-gap.

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 2.0, November 2014) 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).

Notes for your consideration

Pursuant to column 2 of Annex VIII, Section 9.1.1 and 9.1.3. the short-term toxicity testing on aquatic invertebrates and on fish need not be conducted if a long-term study on fish and /or Daphnia is available. Thus the Registrant may choose to perform the long-term toxicity on fish (Annex IX, 9.1.6.1.; test method: Fish, early-life stage toxicity test, OECD 210) and long-term toxicity testing on aquatic invertebrates (Annex IX, 9.1.5.; test method: Daphnia magna reproduction test, EU C.20/OECD 211) and waive the short-term toxicity on fish and on aquatic invertebrates.

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 2.0, November 2014), 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).

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

Pursuant to Articles 10(a)(vi) and/or (vii), 12(1)(e) and 13(4) of the REACH Regulation, your technical dossier registered at more than 1000 tonnes per year shall contain as a minimum the information specified in Annexes VII to X of the REACH Regulation.

"Growth inhibition study aquatic" 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 a growth inhibition test on Algae (Key, reliability 1, GLP, 2010) (OECD 201), with the source substance (CAS 102242-49-9) called C-SAT 100018.

However, as explained above in the section '*Grouping of substances and read-across approach*' of this decision, your adaptation of the information requirement cannot be accepted.

In addition, there are the following endpoint specific reasons for rejecting the proposed read-across for short-term toxicity testing on Algae. The above mentioned study is not adequate because the robust study summary indicated that the concentrations tested were 6.25, 12.5, 25, 50 and 100 mg/L nominal, following OECD GD 23 with stirring for 24h to dissolve the substance then filtration afterwards to test only the eluent. The following results were reported: NOEC for biomass and growth rate >= 100 mg/L nominal and EC 50 > 100 mg/L. So no toxic effects were reported when only the eluent and nominal concentrations reported.

Finally, these study results are not adequate for the purpose of C&L and/or risk assessment purposes due to these deficiencies.

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

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 2.0, November 2014) 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).

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

Pursuant to Articles 10(a)(vi) and/or (vii), 12(1)(e) and 13(4) of the REACH Regulation, your technical dossier registered at more than 1000 tonnes per year shall contain as a minimum the information specified in Annexes VII to X of the REACH Regulation.

"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.
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.

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 non-GLP fish acute toxicity test (Key, reliability 2, 1988) performed on Golden orfe fish (Leuscidus idus) (OECD TG 203) with the source substance (CAS 90622-25-6) called Alcohols, C8- 22, distn. residues.

However, as explained above in the section '*Grouping of substances and read-across approach*' of this decision, your adaptation of the information requirement cannot be accepted.

In addition, there are following endpoint specific reasons for rejecting the proposed read-across for short-term toxicity testing on Fish. The above mentioned study is not adequate because the robust study summary indicated that the concentrations tested were 0, 100, 300 and 1000 mg/L nominal with no specific guidance applied for the test substance preparation said to be sparingly soluble. Furthermore the following deficiencies can be observed from the robust study summary of the source substance study results: no details on the study results, no analysis monitoring, no replicate indicated and the exposure duration of the test was shortened to 48h instead of 96h. Therefore, the test does not adequately and reliably cover the key parameters of the guidelines and it cannot be considered as providing equivalent data according to the criteria in Annex XI, 1.1.2. of the REACH Regulation.

Nor can it be considered as providing equivalent data according to the criteria in Annex XI, 1.1.2. of the REACH Regulation.

Finally, these study results are not adequate for the purpose of C&L and/or risk assessment purposes due to these deficiencies.

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

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 2.0, November 2014) fish acute toxicity test (test method EU C.1. / OECD TG 203) is the preferred test to cover the standard information requirement of Annex VIII, Section 9.1.3.

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, acute toxicity test (test method: EU C.1./OECD TG 203).

11. Activated sludge respiration inhibition testing (Annex VIII, Section 9.1.4)

Pursuant to Articles 10(a)(vi) and/or (vii), 12(1)(e) and 13(4) of the REACH Regulation, your technical dossier registered at more than 1000 tonnes per year shall contain as a minimum the information specified in Annexes VII to X of the REACH Regulation.

"Activated sludge respiration inhibition testing" is a standard information requirement as laid down in Annex VIII, Section 9.1.4. 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 VIII, Section 9.1.4 specifies that the study does not need to be conducted if there is no emission to a sewage treatment plant, or there are mitigating factors indicating that microbial toxicity is unlikely to occur, for instance the substance is highly insoluble in water, or the substance is found to be readily biodegradable and the applied test concentrations are in the range of concentrations that can be expected in the influent of a sewage treatment plant.

You have sought to adapt this information requirement according to Annex XI, Section 1.5. of the REACH Regulation by providing a study record of a non GLP study test method DIN 384 12, Part 27 (Key, reliability 2, 1988), with the source substance CAS 90622-25-6 called Alcohols. C8-22, distn.residues.

However, as explained above in the section '*Grouping of substances and read-across approach*' of this decision, your adaptation of the information requirement cannot be accepted.

In addition, there are the following endpoint specific reasons for rejecting the proposed read-across for short-term toxicity testing on sludge microbial organisms.

The above mentioned study is not adequate because the robust study summary indicated that the test is performed on P. putida as a limit test with 0 and 10000 mg/L tested, for 30 min. The result given is EC0 = 10000mg/L nominal concentration in respiration rate on only one species of micro-organisms with a non GLP test. Therefore, the test does not adequately and reliably cover the key parameters of the guidelines and it cannot be considered as providing equivalent data according to the criteria in Annex XI, 1.1.2. of the REACH Regulation.

Finally, these study results are not adequate for the purpose of C&L and/or risk assessment purposes due to their deficiencies.

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

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 2.0, November 2014) activated sludge respiration inhibition test (carbon and ammonium oxidation) (test method OECD TG 209) is the preferred test to cover the standard information requirement of Annex VIII, Section 9.1.4.

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: Activated sludge, respiration inhibition test (carbon and ammonium oxidation) (test method: OECD TG 209).

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

Pursuant to Articles 10(a)(vi) and/or (vii), 12(1)(e) and 13(4) of the REACH Regulation, your technical dossier registered at more than 1000 tonnes per year shall contain as a minimum the information specified in Annexes VII to X of the REACH 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 using the following justification: *"In Annex IX of Regulation (EC) No 1907/2006, it is laid down that chronic 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 1272/2008 or is assessed to be a PBT or vPvB. The hazard assessment of the substance 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 on aquatic invertebrates is not provided."*

Your justification for adaptation does not meet the criteria of the specific adaptation rules of Column 2 of Annex IX, section 9.1.5. because none of the tests used in the acute aquatic toxicity tests supporting the chemical safety report is acceptable under Annex XI, Sections 1.1.2 and 1.5 of the REACH Regulation (see sections 8 and 9 above). Therefore, the chemical safety report, which is based on such inadequate data results, cannot be considered as a valid justification for an information adaption.

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 2.0, November 2014) 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).

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

Pursuant to Articles 10(a)(vi) and/or (vii), 12(1)(e) and 13(4) of the REACH Regulation, your technical dossier registered at more than 1000 tonnes per year shall contain as a minimum the information specified in Annexes VII to X of the REACH 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 using the following justification:
Long term fish test was waived based on the following justification:
"In Annex IX of Regulation (EC) No 1907/2006, it is laid down that chronic 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 1272/2008 or is assessed to be a PBT or vPvB. The hazard assessment of the substance 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 on aquatic invertebrates is not provided."

Your justification for adaptation does not meet the criteria of the specific adaptation rules of Column 2 of Annex IX, section 9.1.6. because none of the tests used in the acute aquatic toxicity tests supporting the chemical safety report is acceptable under Annex XI, Sections 1.1.2 and 1.5 of the REACH Regulation (see sections 8 and 10 above). Therefore, the chemical safety report, which is based on such inadequate data results, cannot be considered as a valid justification for an information adaption.

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 2.0, November 2014) fish early-life stage toxicity test (test method OECD TG 210), fish short-term toxicity test on embryo and sac-fry stages (test method EU C.15. / OECD TG 212) and fish juvenile growth test (test method EU C.14. / OECD TG 215) are the preferred tests to cover the standard information requirement of Annex IX, Section 9.1.6.

Regarding the long-term toxicity testing on fish pursuant to Annex IX, section 9.1.6.1, ECHA considers that the FELS toxicity test according to OECD TG 210 is the most sensitive of the standard fish tests available as it covers several life stages of the fish from the newly fertilised egg, through hatch to early stages of growth and should therefore be used (see ECHA Guidance on information requirements and chemical safety assessment (version 2.0, November 2014), Chapter R7b, Figure R.7.8-4). The test method OECD TG 210 is also the only suitable test currently available for examining the potential toxic effects of bioaccumulation (ECHA Guidance Chapter R7b, version 2.0, November 2014). For these reasons, ECHA considers the FELS toxicity test using the test method OECD TG 210 as most appropriate and suitable.
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 sections 8-10, 12 and 13 you shall consult the ECHA Guidance on information requirements and chemical safety assessment (version 2.0, November 2014), 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 2.0, November 2014), 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.

14. Ready biodegradability (Annex VII, Section 9.2.1.1.)

Pursuant to Articles 10(a)(vi) and/or (vii), 12(1)(e) and 13(4) of the REACH Regulation, your technical dossier registered at more than 1000 tonnes per year shall contain as a minimum the information specified in Annexes VII to X of the REACH Regulation.

"Ready biodegradability" is a standard information requirement as laid down in Annex VII, Section 9.2.1.1. 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.

You have sought to adapt this information requirement according to Annex XI, Section 1.5. of the REACH Regulation. The justification of the adaptation given by you is:
"No data on the biodegradation potential of the test substance itself are currently available. However, a ready biodegradation study on the structurally similar CAS 102242-49-9 according to OECD 301B is available ([redacted]). In this GLP study the CO2 evolution was determined over 28 days. On day 13 approx. 66% biodegradation were observed while after 28 days 81% of the test substance were degraded.
These results are supported by a second biodegradation study on another structurally related substance (CAS 90622-25-6). In this study, the BOD for insoluble substance was measured to be 72% after a test duration of 28 days."

However, as explained above in the section '*Grouping of substances and read-across approach*' of this decision, 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.

In the present case, depending on the substance profile, the Registrant may conclude on ready biodegradability, by applying the most appropriate and suitable Test Guideline among those listed in the ECHA Guidance on information requirements and chemical safety assessment, Volume 5 Chapter R7b (February 2016) and in the paragraph below. The test guidelines include the description of their respective applicability domains. The substance properties, high adsorption (log Kow <5.7) and low water solubility (<0.15 mg/L) as well as applicability domain of the Test Guideline needs to be taken into account when selecting the most appropriate test method for the registered substance. You shall therefore provide rationale to justify the selection of the most appropriate test method for the ready biodegradability assessment.

Therefore, pursuant to Article 41(1) and (3) of the REACH Regulation, you are requested to submit the following information using one of the indicated test methods and the registered substance subject to the present decision:

Ready biodegradability (test method: CO_2 evolution test, OECD TG 301B).
or
Ready biodegradability (test method: Ready biodegradability – CO_2 in sealed vessels (headspace test), OECD TG 310).
or
Ready biodegradability (test method: MITI test (I), OECD TG 301C).
or
Ready biodegradability (test method: Closed bottle test, OECD TG 301D).
or
Ready biodegradability (test method: Manometric respirometry test, OECD TG 301F).

Notes for your consideration:

Once the re-evaluation of the biodegradation test(s), as required by this decision, has been done, the Registrant shall revise the chemical safety assessment as necessary according to Annex I of the REACH Regulation. If the revised chemical safety assessment indicates the need to submit further information in order to fulfil the REACH information requirements depending on the interpretation of biodegradability he should do so, and if necessary, submit a testing proposal for additional test. If the Registrant concludes that no further tests are required, he should update his technical dossier specifically for those information requirements that dependent on biodegradability.

15. Hydrolysis as a function of pH (Annex VIII, 9.2.2.1)

Pursuant to Articles 10(a)(vi) and/or (vii), 12(1)(e) and 13(4) of the REACH Regulation, your technical dossier registered at more than 1000 tonnes per year shall contain as a minimum the information specified in Annexes VII to X of the REACH Regulation.

"Hydrolysis as a function of pH" is a standard information requirement as laid down in Annex VIII, Section 9.2.2.1 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.

You sought to adapt the information requirement, using an adaptation as per column 2 Annex VIII :"*In accordance with column 2 of REACH Annex VIII, the hydrolysis test does not need to be conducted as the test substance is considered to be readily biodegradable.*"

However, no biodegradation or ecotoxicological tests were performed on the registered substance, but the results from ready biodegradation test on source substances, were used to waive the hydrolysis test study. As the information on these endpoints is not available for the registered substance as explained above in the section '*Grouping of substances and read-across approach*' of this decision, your adaptation of the hydrolysis testing information requirement cannot be accepted.

The technical dossier does not contain relevant data to fulfil this standard information requirement. Therefore, you are requested to submit the information for this endpoint using an appropriate test method on the registered substance.
As explained above, the information provided on this endpoint for the registered substance in the technical dossier does not meet the information requirement. Consequently there is an information gap and it is necessary to provide information for this endpoint.

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: Hydrolysis as a function of pH (test method: EU C.7/OECD TG 111).

16. Adsorption/desorption screening (Annex VIII, Section 9.3.1.)

Pursuant to Articles 10(a)(vi) and/or (vii), 12(1)(e) and 13(4) of the REACH Regulation, your technical dossier registered at more than 1000 tonnes per year shall contain as a minimum the information specified in Annexes VII to X of the REACH Regulation.

"Adsorption/desorption screening" is a standard information requirement as laid down in Annex VIII, Section 9.3.1. 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.

You sought to adapt the information requirement using a column 2 adaptation as justification: *"According to REACH Annex VIII of Regulation (EC) No 1907/2006, an adsorption study does not need to be conducted if the test substance decomposes rapidly. Since the test substance is considered to be readily biodegradable, the conduction of an study on the adsorption behavior of the test substance is not deemed necessary".*

However, no biodegradation or ecotoxicological tests were performed on the registered substance, but the results from ready biodegradation test on source substances, were used to waive the adsorption/desorption screening. The information on these endpoints is not available for the registered substance as explained above in Appendix 1, '*Grouping of substances and read-across approach*' of this decision, so your adaptation of the adsorption/desorption testing information requirement cannot be accepted.

Furthermore, based on log Kow > 5.7 for the registered substance there are concerns with adsorption on soil or bioaccumulation to organisms strengthening the need to perform the adsorption/desorption test.

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.

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: Adsorption/desorption screening. Guidance for determining appropriate test methods for the adsorption/desorption screening is available in the ECHA Guidance on information requirements and chemical safety assessment (version 4.1, October 2015), Chapter R.7a, Section R.7.1.15.3.

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

Pursuant to Articles 10(a)(vi) and/or (vii), 12(1)(e) and 13(4) of the REACH Regulation, your technical dossier registered at more than 1000 tonnes per year shall contain as a minimum the information specified in Annexes VII to X of the REACH Regulation.

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

You have sought to adapt this information requirement using the following justification: *"As the substance is a complex UVCB of long-chain (C-chain-length >=18) organic components, such as fatty alcohols, diols and wax ester, neither an appropriate analytical method is available, nor could it be developed for conducting a bioconcentration study, e.g. according to OECD guideline 305.*

As an indication, for the main constituent [redacted], a BCF of 163.6 L/kg wet weight has been calculated using the BCFBAF-module (version 3.01) of EpiSuite4.1, while the module calculates lower BCF for molecules with longer C-chains, e.g. tetracosanol (CAS 506-51-4: BCF = 54.03 L/kg wet weight) or Lanolin wax (CAS 68200-49-0: BCF= 7.48 L/kg wet weight)."

However, your justification for adaptation does not meet the criteria of the specific adaptation rules of Column 2 of Annex IX, section 9.3.2., as you did not show that:
- The substance has no potential for bioaccumulation as the Log Kow is greater than 5.7,
- No evidence were provided on the inability to cross the biological membranes,
- There is no evidence that aquatic compartment is unlikely to be exposed and
- The substance cannot be used, mixing of the substance with water may cause danger of fire or explosion or the radio-labelling of the substance required in certain studies may not be possible.

Instead you sought to adapt the information requirement based on the technical unfeasibility to perform the OECD 305 test. According to Annex XI, Section 2. of the REACH Regulation:

"Testing for a specific endpoint may be omitted, if it is technically not possible to conduct the study as a consequence of the properties of the substance: e.g. very volatile, highly reactive, or unstable, or the radio-labelling of the substance required in certain studies may not be possible". However, such bioaccumulation studies have been performed on UVCBs. It should be possible to follow the concentration of some of the individual constituents of the UVCB with analytical techniques. Furthermore, according to the test guideline OECD 305 it is possible to test UVCBs as indicated in its paragraph 81: "For multi-constituent substances and UVCB (chemical substances of Unknown or Variable composition, Complex reaction products and Biological materials) description, as far as possible, of the chemical identity of the individual constituents and, for each, of its percentage of the total mass of the substance. How the analytical method used in the test reflects a measure of the concentration of the substance should be summarised; all analytical procedures should be described including the accuracy of the method, method detection limit, and limit of quantification."

Therefore, your adaptation of the information requirement as per Annex XI, Section 2 is not acceptable.

You also provided in this adaptation QSAR values which cannot be assessed either under Annex XI, Section 1.3 or Section 1.5: "[redacted], a BCF of 163.6 L/kg wet weight has been calculated using the BCFBAF-module (version 3.01) of EpiSuite4.1, while the module calculates lower BCF for molecules with longer C-chains, e.g. tetracosanol (CAS 506-51-4: BCF = 54.03 L/kg wet weight) or Lanolin wax (CAS 68200-49-0: BCF = 7.48 L/kg wet weight)."
Your QSAR cannot be considered as reliable as no QPRF nor QMRF were provided and no justifications were provided to prove how the CAS 506-51-4 and CAS 68200-49-0 could be related to the registered substance or fulfil this bioaccumulation information requirement.

Finally, the measured Log Kow of >5.7 indicates a potential concern for bioaccumulation. Therefore, your justification for adaptation does not meet the criteria of either the specific adaptation rules of Column 2 of Annex IX, section 9.3.2 or the general adaptation rules of Annex XI. Therefore, the adaptations cannot be accepted.

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

According to ECHA *Guidance on information requirements and chemical safety assessment, Chapter R.7c* (version 2.0, November 2014) bioaccumulation in fish: aqueous and dietary exposure (test method EU C.13. / OECD TG 305) is the preferred test to cover the standard information requirement of Annex IX, Section 9.3.2.

Therefore, pursuant to Article 41(1) and (3) of the REACH Regulation, you are requested to submit the following information derived with the registered substance subject to the present decision :Bioaccumulation in fish: aqueous or dietary bioaccumulation fish test (test method: OECD TG 305).

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 6 November 2015.

The decision making followed the procedure of Articles 50 and 51 of the REACH Regulation:

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 proposal(s) for amendment.

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

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

ECHA referred the draft decision to the Member State Committee.

You did not provide any comments on the proposed amendment(s).

The Member State Committee reached a unanimous agreement on the draft decision during its MSC-48 meeting and ECHA took the decision according to Article 51(6) of the REACH Regulation.

Appendix 3: Further information, observations and technical guidance

1. This compliance check decision does not prevent ECHA from initiating further compliance checks on the present registration at a later stage.

2. Failure to comply with the request(s) in this decision, or to fulfil otherwise the information requirement(s) with a valid and documented adaptation, will result in a notification to the enforcement authorities of your Member State.

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