EUROPEAN CHEMICALS AGENCY

~~Confidential~~

Helsinki, 02 June 2021

Addressees
Registrant(s) of JS_FENE 18794-84-8 as listed in the last Appendix of this decision

Date of submission of the dossier subject to this decision
16/02/2018

Registered substance subject to this decision ("the Substance")
Substance name: (E)-7,11-dimethyl-3-methylenedodeca-1,6,10-triene
EC number: 242-582-0
CAS number: 18794-84-8

Decision number: Please refer to the REACH-IT message which delivered this communication (in format CCH-D-XXXXXXXXXX-XX-XX/F)

DECISION ON A COMPLIANCE CHECK

Under Article 41 of Regulation (EC) No 1907/2006 (REACH), you must submit the information listed below, by the deadline of ***8 March 2024***.

Requested information must be generated using the Substance unless otherwise specified.

A. Information required from all the Registrants subject to Annex VII of REACH

1. Long-term toxicity testing on aquatic invertebrates (triggered by Annex VII, Section 9.1.1., column 2; test method: EU C.20./OECD TG 211)

2. Growth inhibition study aquatic plants (Annex VII, Section 9.1.2.; test method: EU C.3./OECD TG 201)

3. Ready biodegradability (Annex VII, Section 9.2.1.1.; test method: OECD TG 301C/D/F or OECD TG 310)

B. Information required from all the Registrants subject to Annex VIII of REACH

1. Screening for reproductive/developmental toxicity (Annex VIII, Section 8.7.1.; test method: EU B.63/OECD TG 421 or EU B.64/OECD TG 422) by oral route, in rats

C. Information required from all the Registrants subject to Annex IX of REACH

1. Pre-natal developmental toxicity study (Annex IX, Section 8.7.2.; test method: OECD TG 414) by oral route, in one species (rat)

2. Long-term toxicity testing on aquatic invertebrates (Annex IX, Section 9.1.5.; test method: EU C.20./OECD TG 211)

3. Long-term toxicity testing on fish (Annex IX, Section 9.1.6.; test method: OECD TG 210)

4. Soil simulation testing (Annex IX, Section 9.2.1.3.; test method: EU C.23./OECD TG 307) at a temperature of 12 °C

5. Identification of degradation products (Annex IX, 9.2.3.; test method: using test method EU C.23./OECD TG 307)

6. Bioaccumulation in aquatic species (Annex IX, Section 9.3.2; test method: OECD TG 305)

Reasons for the request(s) are explained in the following appendices:

- Appendix entitled "Reasons common to several requests";
- Appendices entitled "Reasons to request information required under Annexes VII to IX of REACH", respectively.

Information required depends on your tonnage band

You must provide the information listed above for all REACH Annexes applicable to you, and in accordance with Articles 10(a) and 12(1) of REACH:

- the information specified in Annex VII to REACH, as a transported isolated intermediate in quantity above 1000 tpa;
- the information specified in Annexes VII, VIII and IX to REACH, for registration at 100-1000 tpa;

You are only required to share the costs of information that you must submit to fulfil your information requirements.

For certain endpoints, ECHA requests the same study from registrants at different tonnages. In such cases, only the reasoning why the information is required at lower tonnages is provided in the corresponding Appendices. For the tonnage where the study is a standard information requirement, the full reasoning for the request including study design is given. Only one study is to be conducted; the registrants concerned must make every effort to reach an agreement as to who is to carry out the study on behalf of the other registrants under Article 53 of REACH.

How to comply with your information requirements

To comply with your information requirements you must submit the information requested by this decision in an updated registration dossier by the deadline indicated above. You must also update the chemical safety report, where relevant, including any changes to classification and labelling, based on the newly generated information.

You must follow the general testing and reporting requirements provided under the Appendix entitled "Requirements to fulfil when conducting and reporting new tests for REACH purposes". In addition, you should follow the general recommendations provided under the Appendix entitled "General recommendations when conducting and reporting new tests for REACH purposes". For references used in this decision, please consult the Appendix entitled "List of references".

The studies relating to biodegradation and bioaccumulation are necessary for the PBT assessment. However, to determine the testing needed to reach the conclusion on the persistency and bioaccumulation of the Substance you should consider the sequence in which these tests are performed and other conditions described in Appendix entitled "Requirements

to fulfil when conducting and reporting new tests for REACH purposes".

Appeal

This decision, when adopted under Article 51 of REACH, may be appealed to the Board of Appeal of ECHA within three months of its notification to you. Please refer to http://echa.europa.eu/regulations/appeals for further information.

Failure to comply

If you do not comply with the information required by this decision by the deadline indicated above, ECHA will notify the enforcement authorities of your Member State.

Authorised[1] under the authority of Christel Schilliger-Musset, Director of Hazard Assessment

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

Appendix on Reasons common to several requests

1. Assessment of your read-across approach under Annex XI, Section 1.5.

You seek to adapt the following standard information requirements by applying (a) read-across approach(es) in accordance with Annex XI, Section 1.5:

- Screening for reproductive/developmental toxicity (Annex VIII, Section 8.7.1.)
- Pre-natal developmental toxicity study (Annex IX, Section 8.7.2.)
- Long-term toxicity testing on aquatic invertebrates (Annex VII, Section 9.1.1., column 2 and Annex IX, Section 9.1.5.);
- Long-term toxicity testing on fish (Annex IX, Section 9.1.6.).

ECHA has considered the scientific and regulatory validity of your read-across approach(es) in general before assessing the specific standard information requirements in the following appendices.

Grouping of substances and read-across approach

Annex XI, Section 1.5. specifies two conditions which must be fulfilled whenever a read-across approach is used. Firstly, there needs to be structural similarity between substances which results in a likelihood that the substances have similar physicochemical, toxicological and ecotoxicological properties so that the substances may be considered as a group or category. Secondly, it is required that the relevant properties of a substance within the group may be predicted from data for reference substance(s) within the group (addressed under 'Assessment of prediction(s)').

A. Predictions for toxicological properties

You have provided a read-across justification document in IUCLID Section 13 and you provided comments on the draft decision on this matter

You read-across between the structurally similar substances, *beta*-Myrcene EC 204-622-5 (CAS 125-35-3), Squalene (EC 203-826-1), and Farnesane (EC 622-542-2) as source substance-1, -2 and -3, and the Substance as target substance.

You have provided the following reasoning for the prediction of toxicological properties in your dossier: *"The proposed read-across hypothesis for the reproductive-developmental toxicity endpoints is based on the analogue approach, scenario 1, ECHA RAAF. The basis of the analogue approach is similarity in structure, physical chemical properties and toxicokinetics between target and proposed structural analogue. For phys-chem and most toxicological endpoints, experimental data are available for Farnesene, the target molecule. Comparison of these endpoints with data available for beta-Myrcene, proposed structural analogue gives comparable results"* and in your comments on the draft decision: *"there is potential for increased toxicity in alkenes as a class than alkanes, a search for further structural analogues* [...] *was subsequently performed. Therefore, Beta-Myrcene* [...] *and Squalene* [...] *have been selected as structural analogue source substances* [...]".

In your read-across approach you refer to scenario 1 from ECHA RAAF in order to predict the properties of the Substance using a read-across hypothesis which is based on the formation of common (bio)transformation products. In your comments on the draft decision, and based on ECHAs understanding of your arguments and provided information, you intend to predict the properties of the Substance using a read-across hypothesis which assumes that different compounds have the same type of effects (RAAF scenario 2). The properties of your Substance

are predicted to be quantitatively equal to those of the source substances. ECHA has assessed your intended read across according to both scenarios.

ECHA has evaluated the available information and notes the following shortcomings for both scenarios with regards to predictions of toxicological properties:

Supporting information

Annex XI, Section 1.5 of the REACH Regulation states that "*physicochemical properties, human health effects and environmental effects or environmental fate may be predicted from data for reference substance(s)*". For this purpose "*it is important to provide supporting information to strengthen the rationale for the read-across*"[2]. The set of supporting information should allow to verify the crucial aspects of the read-across hypothesis and establish that the properties of the Substance can be predicted from the data on the source substance(s).

Supporting information must include toxicokinetic information on the formation of the common compound.

1. *Missing information on the formation of common compound*

As indicated above, your read-across hypothesis is based on the (bio)transformation of the Substance and of the source substance(s) to a common compound(s). In this context, information characterising the rate and extent of the hydrolysis of the Substance and of the source substance(s) is necessary to confirm the formation of the proposed common hydrolysis product and to assess the impact of the exposure to the parent compounds.

In your read-across justification you state that toxicity decreases with increasing carbon chain length due to an inverse correlation between carbon chain length and oral absorption, with little absorption of compounds with carbon chain lengths > C14. You support this claim with an *in vitro* gut sac absorption study with the Substance ([redacted], 2014) and similar studies with a series of alpha olefins ([redacted] 2014). You have not provided any experimental data or other information, neither about the (bio)transformation of your Substance nor about the (bio)transformation of the source substances to common compounds.

The existing information gives indications about the bioavailability of the Substance and the source substance(s). However, in the absence of data demonstrating the rapid and quantitative (bio)transformation of the Substance to a common compound through e.g. a toxicokinetic study, it is not possible to predict properties of the Substance from the source substance(s) via this hypothesis. In the absence of this information, you have not provided supporting evidence establishing that the proposed common compound is formed from (bio)transformation as assumed in your read-across hypothesis. Therefore, you have not provided sufficient supporting information to strengthen the rationale for the read-across.

Additionally ECHA considers, based on the information available in the dossier, that there is no metabolism likely by which compounds are formed from the Substance which are the same as for those formed from the source substance(s). Therefore, RAAF[3] scenario 1 is unlikely to be applicable.

[2] Guidance on information requirements and chemical safety assessment Chapter R.6: QSARs and grouping of Chemicals, Section R.6.2.2.1.f
[3] ECHAs read-across assessment framework https://echa.europa.eu/documents/10162/13628/raaf_en.pdf

ECHA has evaluated the provided information also for its applicability to read-across when different compounds are predicted to have the same type of effects (below, *2.*) (RAAF[3] scenario 2).

2. Missing supporting information to compare properties of the substances

As indicated above, ECHA understands that your read-across hypothesis might be based on the assumption that the structurally similar substances cause the same type of effect(s). In this context, relevant, reliable and adequate information allowing to compare the properties of the Substance and of the source substance(s) is necessary to confirm that both substance cause the same type of effects. Such information can be obtained, for example, from bridging studies of comparable design and duration for the Substance and of the source substance(s).

You have provided two studies with the source substance-1, a one-generation reproductive toxicity study (OECD TG 415, 1993) and a pre-natal developmental toxicity study (OECD TG 414, 1993). Furthermore, you have provided a sub-chronic repeated dose toxicity study with the source substance-1 (OECD TG 408, 2010).

In your comments on the draft decision you explain that information on the Substance is being generated (OECD TG 408) and intended to be generated (OECD TG 421) for selected endpoints, which could be used as bridging studies to strengthen your read-across adaptation, provided that the results support your hypothesis. Furthermore you refer to results from an OECD TG 414 study with source substance-3 to predict properties of the Substance.

You have not provided studies with the Substance for these endpoints. Therefore, the data set reported in the technical dossier does not include relevant, reliable and adequate information for the Substance to be compared with the source substances to support your read-across hypothesis.

Furthermore you do not substantiate your comments on the draft decision with any of the above mentioned information from other source substances. ECHA acknowledges that you have newly introduced source substance-2 as a close structural analogue, but you have not provided any information from which to predict properties of the Substance. With your comments on the draft decision you have introduced source substance-3 as a less close structural analogue, but not provided reliable documentation of the information from which to predict properties of the Substance.

ECHA observes that a subchronic toxicity study (OECD TG 408) may not cover the investigations made with studies targeted at toxicity to reproduction and fertility. Furthermore, a screening study for reproductive/developmental toxicity study investigates litter size and post-natal development, but not pre-natal developmental effects. Therefore both of these studies may be of no or only limited usefulness as bridging studies for read-across adaptations to fulfil the requests in this decision.

In summary, the information in your comments on the draft decision is not sufficient for ECHA to make an assessment. Please note that this decision does not take into account updates of the registration dossiers after the date on which you were notified of the draft decision according to Article 50(1) of REACH (see section 5.4. of ECHA's Practical Guide "How to act in Dossier Evaluation). It is in your discretion to generate and provide the necessary supporting information in order to justify your read-across adaptation. If you do so, you are responsible for demonstrating the fulfilment of the requirements of REACH Annex XI, Section 1.5, or Annex VIII, Section 8.7.1, column 2.

In the absence of such information, you have not established that the Substance and of the

source substance(s) are likely to have similar properties. Therefore you have not provided sufficient supporting information to strengthen the rationale for the read-across.

B. Predictions for ecotoxicological properties

You have provided the following reasoning for the prediction of aquatic toxicity:

- *"Examination of the data and theoretical considerations confirm that Farnesane and Farnesene will be classified as non-polar narcotics, which suggests that their ecotoxicity to aquatic organisms ought to be reasonably well predicted.*
- *Farnesane is non-toxic at the limit of solubility to all aquatic organisms in acute and chronic exposures, the former based on read-across from Farnesene and the latter based on comparison of aquatic solubility with available experimental data.*
- *Farnesene is tested as non-toxic in acute tests, examination of its probable aquatic solubility clearly suggests it would not be acutely toxic to any aquatic organisms.*
- *Farnesene is slightly more soluble than Farnesane, less hydrophobic and probably toxic at higher concentrations in chronic assessments, disregarding any solubility issues. Based on the predicted aquatic solubility, and comparing predictions and read-across to similar predictions for Farnesane, would suggest that Farnesene would be unlikely to be toxic to aquatic organisms in chronic exposures."*

You read-across between the structurally similar substances, 2,6,10-trimethyldodecane (Farnesane), EC No. 622-542-2 (CAS No. 3891-98-3) as source substance and the Substance as target substance.

ECHA understands that you predict the properties of the Substance using a read-across hypothesis which assumes that different compounds have the same type of effects. The properties of your Substance are predicted based on a worst-case approach.

ECHA notes the following shortcoming with regards to prediction(s) of aquatic toxicity.

Relevant supporting information

Annex XI, Section 1.5 of the REACH Regulation states that *"physicochemical properties, human health effects and environmental effects or environmental fate may be predicted from data for reference substance(s)"*. For this purpose *"it is important to provide supporting information to strengthen the rationale for the read-across"*[4]. The set of supporting information should allow to verify the crucial aspects of the read-across hypothesis and establish that the properties of the Substance can be predicted from the data on the source substance(s).

a) Absence of relevant supporting information

Supporting information must include bridging studies to compare properties of the Substance and source substances and information to confirm your claimed worst-case prediction.

As indicated above, your read-across hypothesis is based on the assumption that the structurally similar substances cause the same type of effect(s). In this context, relevant, reliable and adequate information allowing to compare the properties of the Substance and of the source substance(s) is necessary to confirm that both substances cause the same type of effects. Such information can be obtained, for example, from bridging studies of comparable design and duration for the Substance and of the source substance(s).

[4] Guidance on information requirements and chemical safety assessment Chapter R.6: QSARs and grouping of Chemicals, Section R.6.2.2.1.f

In the registration dossier you have reported results of long-term toxicity tests with fish and aquatic invertebrates for the source substance. There is no information on long-term toxicity to fish and aquatic invertebrates available for the Substance.

Furthermore, in the read-across justification you note that both, source substance and the Substance, exibit the same mode of action - non-polar narcosis and you compare sensitivity between these two substances based on short-term aquatic toxicity information (toxic effect concentrations from experimental studies and estimated by QSAR models).

However, poorly water soluble substances require longer time to reach steady-state conditions. Hence, the short-term tests may not give a true measure of toxicity for this type of substances and the long-term test is required. As both, source substance and the Substance, based on the data provided in the dossier can be regarded as poorly soluble in water (solubility in water for the source substance is 0.25 µg /l and for the Substance is below 0.1 mg/L), information from the short-term aquatic toxicity studies cannot be considered for such type of substances as relevant and cannot be used for species sensitivity determination and for the read-across justification.

Thus, there is no relevant supporting information strengthening the rationale for the proposed read-across available.

b) Supporting information contradicting to the worst-case consideration

As indicated above, your read-across hypothesis is based on the assumption that the source substance constitutes a worst-case for the prediction of the property under consideration of the Substance. In this context, relevant, reliable and adequate information allowing to compare the properties of the Substance and of the source substance(s) is necessary to confirm a conservative prediction of the properties of the Substance from the data on the source substance(s). Such information can be obtained, for example, from bridging studies of comparable design and duration for the Substance and of the source substance(s).

In the long-term toxicity to fish study record in the registration dossier you have noted the following: "*Accordingly, read across of Farnesane data for long-term aquatic toxicity to fish is a reasonable and conservative approach for predicting Farnesene toxicity since alkenes are generally more toxic than alkanes. It is generally agreed that aromatic hydrocarbons are the most toxic, followed by cycloalkanes, olefins, and alkanes. (Laws, Edward. Aquatic Pollution, An Introductory Text, Third Edition, New York, John Wiley and Sons, 2000, 449-450).*".

In this phrase two contradicting statements are provided "*read across of Farnesane data for long-term aquatic toxicity to fish is a reasonable and conservative approach for predicting Farnesene toxicity*" (this also is proposed in the read-across justification document: "*Farnesene is slightly more soluble than Farnesane, less hydrophobic and probably toxic at higher concentrations in chronic assessments*") and you also state that "*alkenes are generally more toxic than alkanes*".

Your last statement is confirmed by the Handbook of Environmental Engineering, Frank R. Spellman, 2016 which also states that "*alkenes are generally more toxic than alkanes*". Farnesene (the Substance) is an alkene, so if it is more toxic than Farnesane (alkane) the proposed read-across cannot be considered as conservative.

Thus, there is contradicting information to the hypothesis that the proposed read-across is a worst-case for the Substance available in the registration dossier and scientific literature. Therefore, your conservative prediction is not confirmed.

C. Conclusions on the read-across approach

As explained above, based on your dossier and your comments on the draft decision, you have not established that relevant properties of the Substance can be predicted from data on the analogue substances. Therefore, your adaptation does not comply with the general rules of adaptation as set out in Annex XI, Section 1.5. and your grouping and read-across approach is rejected.

Appendix A: Reasons to request information required under Annex VII of REACH

1. Long-term toxicity testing on aquatic invertebrates (triggered by Annex VII, Section 9.1.1., column 2)

For poorly water soluble substances (e.g. water solubility below 1 mg/L or below the detection limit of the analytical method of the test substance) long-term toxicity study on aquatic invertebrates must be considered instead of the short-term toxicity test (Annex VII, Section 9.1.1., Column 2).

In your dossier you adapted standard information requirement for the Long-term toxicity testing on aquatic invertebrates by applying a read-across approach in accordance with Annex XI, Section 1.5 and have reported a long-term toxicity study with aquatic invertebrates with source substance (2,6,10-trimethyldodecane (Farnesane), EC No. 622-542-2, CAS No. 3891-98-3).

We have assessed this information and identified the following issue:

Poorly water soluble substances require longer time to reach steady-state conditions. Hence, the short-term aquatic toxicity tests may not give a true measure of toxicity for this type of substances and the long-term test is required.

The Substance is poorly water soluble (water solubility is below 0.1 mg/L).

As concluded in Appendix on Reasons common to several requests, Section 1 above, your adaptation does not comply with the general rules of adaptation as set out in Annex XI, Section 1.5. and your read-across approach is rejected.

Therefore, the information requirement is not fulfilled.

Please refer to ECHAs response to your comment on the draft decision in Appendix C, Section 2.

Study design

The Substance is difficult to test due to the water solubility of <0.1 mg/l at 20 °C, high adsorption potential (log K_{ow} > 6.5) and high potential for evaporation (estimated Henry's law constant equal to 2.27E+005 Pa-m3/mole). OECD TG 211 specifies that, for difficult to test substances, you must consider the approach described in OECD GD 23 or other approaches, if more appropriate for your substance. In all cases, the approach selected must be justified and documented. Due to the properties of Substance, it may be difficult to achieve and maintain the desired exposure concentrations. Therefore, you must monitor the test concentration(s) of the Substance throughout the exposure duration and report the results. If it is not possible to demonstrate the stability of exposure concentrations (i.e. measured concentration(s) not within 80-120% of the nominal concentration(s)), you must express the effect concentration based on measured values as described in OECD TG 211. In case a dose-response relationship cannot be established (no observed effects), you must demonstrate that the approach used to prepare test solutions was adequate to maximise the concentration of the Substance in the test solution.

2. Growth inhibition study aquatic plants

Growth inhibition study aquatic plants is an information requirement under Annex VII to REACH (Section 9.1.2).

You have adapted the standard information requirement according to Annex XI, Section 1.2. of REACH (weight of evidence).

In support of your adaptation, you have provided experimental study conducted according to the EU Method C.3/OECD TG 201 with the Substance used as test material.

We have assessed this information and identified the following issues:

Annex XI, Section 1.2 states that there may be sufficient weight of evidence from "*several independent sources of information*".

You have only provided one source of information.

Irrespective of this deficiency, which in itself could lead to the rejection of the adaptation, ECHA has assessed the provided source of information.

Relevance of provided information

The weight of evidence must fulfill the information requriement based on relevant and reliable sources of information. These sources of information must provide sufficient weight to conclude that the Substance has or has not the dangerous property investigated by the required study.

To fulfil the information requirement, normally a study according to OECD TG 201, and the requirements of OECD GD 23 (ENV/JM/MONO(2000)6/REV1) if the substance is difficult to test, must be provided.The key parameter investigated by this test are:

- the concentrations of the test material leading to a 50% and 0% (or 10%) inhibition of growth at the end of the test. Growth must be expressed as the logarithmic increase in biomass (average specific growth rate) during the exposure period.

The information provided in your dossier is similar to OECD TG 201.

Provided study may provide relevant information on the concentrations of the test material leading to an inhibition of algae growth at the end of the test. However, the reliability of this information is significantly affected by the number of deficiencies.

Reliability of provided information

The OECD TG 201 and the OECD Guidance 23, ENV/JM/MONO(2000)6/REV1 require information on the following:

- OECD TG 201 specifies that, for difficult to test substances, you must consider the approach described in OECD GD 23 or other approaches, if more appropriate for your substance. In all cases, the approach selected must be justified and documented.
- If the test material is tested at the saturation concentration, evidence must be provided that all reasonable efforts have been taken to achieve a saturation concentration, which include:
  1) an analytical method validation report demonstrating that the analytical method is appropriate, and
  2) information on the saturation concentrations of the test material in water and in the test solution, and
  3) a description of the method used to prepare the test solution, and
  4) the results of a preliminary experiment demonstrating that the test solution preparation method is adequate to maximize the concentration of the test material in solution.
- Exposure concentrations should be confirmed and their stability demonstrated by

analysis unless the dissolved concentration is less than the limit of quantification of the most sensitive analytical method.

The Substance is difficult to test due to the water solubility of <0.1 mg/l at 20 °C, high potential for adsorption to organic matter (log Kow above 6.5) and potential to evaporate (estimated Henry's law constant equal to 2.27E+005 Pa-m3/mole). Therefore application of specific methods, as described in the OECD Guidance 23, would be necessary for the test solution preparation, as it is expected that considerable losses will occur during preparation of the test solutions and during the exposure period.

In the dossier you note the following:

- *"a saturated solution was prepared by stirring an excess (50 mg/l) of test item in culture medium for a period of 24 hours prior to removing any undissolved test item present by filtration";*
- *"The results obtained from the pre-study media preparation trial conducted indicated that a saturated solution method of preparation followed by the removal of any undissolved test item by filtration was most appropriate for this test item."*
- *"The method of chemical analysis developed for use during the range-finding test was considered to be insufficiently sensitive to detect the low dissolved test item concentrations present."*

There are various methods for the test solution preparation described in the OECD Guidance 23. E.g. four methods of test solution preparation which have been applied to poorly water-soluble test chemicals are described in this guidance. As noted above, the Substance posses a set of properties which make it difficult to test. Therefore combination of its properties should be considered when the methods for test solution preparation are examined and the adequate method which would maximize the concentration of the test material in solution is selected for the test.

You have not explained in the dossier how the method of test solution preparation by stirring (which would increase losses of the volatile Substance by evaporation) has been chosen as the most appropriate to achieve a saturation concentration and how the analytical method for verification of test concentrations of the Substance was identified to be the most sensitive method.

Thus, you have not justified and documented in the dossier:

- the selection of testing approach in regard of various properties of the Substance which make it difficult to test;
- that all reasonable efforts have been taken to achieve a saturation concentration (e.g. by choosing the test solution preparation method which would be adequate to maximize the concentration of the Substance in solution);
- why the selected analytical method for the Substance determination in the test solution is the most sensitive method.

In your comments on the draft decision, you provide details concerning your pre-study media preparation trial and the use of the techniques employed in the definitive study. You note that the analytical method was validated for use in this study, had good precision if measurable levels were detected, the limit of quantification (LOQ) was determined to be 84 times lower than the predicted water solubility of the Substance and the lower than expected recovery of the Substance was attributed to the volatility of the Substance. You further note that "*the main study was undertaken in closed vessels to limit evaporation but there is no detail on whether the conditions during the solution preparation stage were sufficient to limit volatilisation of the test substance*".

You provide results of the measured concentrations in the pre-study test solutions which indicate that the Substance in concentrations of 1.39-4.03 mg/l was found after centrifugation while pre-treatment by filtration resulted in concentrations always being <LOQ. You further explain that "*The results from the centrifuged test item were far in excess of the predicted water solubility and so were treated with caution. From these results, it was decided to stir the solution for 24-hours and use filter paper to remove the undissolved test item*".

Summarising, you indicate your intention to establish the most suitable method for the test media preparation for the long-term toxicity studies on aquatic invertebrates and fish and to compare this method with the one used in the original study for this endpoint reported in the registration dossier to see whether "*the methods used in this study are comparable and appropriate*" or "*if a more suitable method of test item media preparation is found then the test may be repeated*".

When you consider and select approach for the aquatic toxicity testing of the Substance (either approaches described in OECD GD 23 or other approaches), in a case of the presence of the Substance above measured/predicted water solubility limit, you should analyse (and report in the registration dossier) if a truly dissolved concentration is detected and therefore, such method of preparation of the test solutions could be used in the study or it could not be used (e.g. because crystals, aggregates, micelles, etc. are formed). It is not explained why you considered that not a truly dissolved concentration after centrifugation was measured in the pre-study and this method was not employed during the definitive study.

Furthermore, as noted in OECD Guidance 23 in respect of volatile substances "*as a general rule, test vessels should be sealed during preparation and exposure and the headspace kept to a minimumor eliminated*" which might have not be followed during the solution preparation step.

Therefore, ECHA considers that the choices for the method of the test solution preparation and for the analytical method for the definitive study are not justified. Consequently, the estimation of reliable effect concentrations from the results of the reported study is not possible.

Therefore, reported study is considered not reliable. Consequently, it is not possible to conclude, based on provided information, either in your dosier or your comments on the draft decision, whether the Substance has or has not the particular dangerous property foreseen to be investigated in an OECD TG 201 study.

Therefore, the information requirement is not fulfiled.

Study design

OECD TG 201 specifies that for difficult to test substances OECD GD 23 must be followed. As already explained above, the Substance is difficult to test. Therefore, you must fulfil the requirements described in 'Study design' under Section on Long-term toxicity testing on aquatic invertebrates (Appendix A 1.).

3. Ready biodegradability

Ready biodegradability is an information requirement in Annex VII to REACH (Section 9.2.1.1.).

You have provided results of three ready biodegradability studies, all conducted with the Substance according to the OECD TG 301B (CO2 Evolution Test).

We have assessed this information and identified the following issue(s):

To fulfil the information requirement, a study must comply with the OECD TG 301 or 310 (Article 13(3) of REACH). Therefore, for a study according to OECD TG 301, the following requirements must be met:

- The test material falls into the applicability domain of the selected test method. In this regard, OECD TG 301 specifies that OECD TG 301B is not applicable to volatile substances.

The Substance is considered volatile (according to OECD GD 23 if Henry law constant is greater than 100 Pa.m3/mol, more than 50% of the test chemical could be lost from the water phase within 3-4 hours). Estimated Henry's law constant of the Substance is equal to 2.27E+005 Pa-m3/mole. Thus, the submitted studies conducted according to OECD TG 301B are not applicable for the Substance and information provided is not appropriate to conclude on the ready biodegradability of the Substance.

Therefore, the information requirement is not fulfilled.

In your comments to the draft decision, you agree to undertake an appropriate ready biodegradation study such as the OECD 301C, OECD 301D, OECD 301F or OECD 310. In addition, you indicate that Henry's law constant data will also be added to the registration dossier in order to provide justification for the selection of the method.

Study design

Appropriate test guidelines are selected based on the applicability domain of the test guidelines and properties of the substance (ECHA Guidance Chapter R.7b, Section 7.9. and OECD TG 301 and OECD TG 310). For volatile substances the test guidelines OECD TG 301 C, D and F, as well as OECD TG 310 apply.

Appendix B: Reasons to request information required under Annex VIII of REACH

1. Screening for reproductive/developmental toxicity

A Screening for reproductive/developmental toxicity study (test method: EU B.63/OECD TG 421 or EU B.64/OECD TG 422) is a standard information requirement under Annex VIII to REACH, if there is no evidence from analogue substances, QSAR or *in vitro* methods that the Substance may be a developmental toxicant. There is no information available in your dossier indicating that your Substance may be a developmental toxicant.

You have adapted this information requirement by using a Grouping of substances and read-across approach under Annex XI, Section 1.5. In support of your adaptation you provided a one-generation reproductive toxicity study (OECD TG 415, 1993) with an analogue substance.

As explained in the Appendix on Reasons common to several requests your adaptation is rejected.

In your comments on the draft decision, you indicate your intention to conduct a screening for reproductive/developmental toxicity study (OECD TG 421) with the Substance. Please refer to ECHAs reply to your comment in the Appendix on "Reasons common to several requests", section **1.A.**2., concerning the impact on your attempted adaptation of this information requirement.

Based on the above, the information you provided do not fulfil the information requirement.

A study according to the test method EU B.63/OECD TG 421 or EU B.64/OECD TG 422 must be performed in rats with oral[5] administration of the Substance.

[5] ECHA Guidance R.7a, Section R.7.6.2.3.2.

Appendix C: Reasons to request information required under Annex IX of REACH

1. Pre-natal developmental toxicity study in one species

A Pre-natal developmental toxicity (PNDT) study (OECD TG 414) in one species is a standard information requirement under Annex IX to REACH.

You have adapted this information requirement by using a Grouping of substances and read-across approach under Annex XI, Section 1.5. In support of your adaptation you provided a pre-natal developmental toxicity study (OECD TG 414, 1993) with an analogue substance. In your comments on the draft decision, you indicate your intention to improve your read-across adaptation (see Appendix "Reasons common to several requests", Section **1.A.**2).

As explained in the Appendix on Reasons common to several requests your adaptation, as submitted in your dossier and with your comments on the draft decision, is rejected.

Based on the above, the information you provided do not fulfil the information requirement.

A PNDT study according to the test method OECD TG 414 must be performed in rats as preferred species with oral[6] administration of the Substance.

2. Long-term toxicity testing on aquatic invertebrates

Long-term toxicity testing on aquatic invertebrates is an information requirement under Annex IX to REACH (Section 9.1.5.).

In your dossier you adapted standard information requirement for the Long-term toxicity testing on aquatic invertebrates by applying a read-across approach in accordance with Annex XI, Section 1.5 and have reported a long-term toxicity study with aquatic invertebrates with source substance (2,6,10-trimethyldodecane (Farnesane), EC No. 622-542-2, CAS No. 3891-98-3).

We have assessed this information and identified the following issue:

As concluded in Appendix on Reasons common to several requests, Section 1 above, your adaptation does not comply with the general rules of adaptation as set out in Annex XI, Section 1.5. and your read-across approach is rejected.

Therefore, the information requirement is not fulfilled.

In your comments to the draft decision, you agree to perform an OECD TG 211 study and note that considering poor solubility in water, high adsorption and volatilisation potential of the Substance "*the study design will be adapted as far as reasonably practicable to take account of this in accordance with OECD Technical Guidance No. 23*".

Study design

OECD TG 211 specifies that for difficult to test substances OECD GD 23 must be followed. As already explained above, the Substance is difficult to test. Therefore, you must fulfil the requirements described in 'Study design' under Section on Long-term toxicity testing on aquatic invertebrates (Appendix A 1.).

[6] ECHA Guidance R.7a, Section R.7.6.2.3.2.

3. Long-term toxicity testing on fish

Long-term toxicity testing on fish is an information requirement under Annex IX to REACH (Section 9.1.6.).

In your dossier you adapted standard information requirement for the Long-term toxicity testing on fish by applying a read-across approach in accordance with Annex XI, Section 1.5 and have reported a long-term toxicity study with fish with source substance (2,6,10-trimethyldodecane (Farnesane), EC No. 622-542-2, CAS No. 3891-98-3).

We have assessed this information and identified the following issue:

As concluded in Appendix on Reasons common to several requests, Section 1 above, your adaptation does not comply with the general rules of adaptation as set out in Annex XI, Section 1.5. and your read-across approach is rejected.

Therefore, the information requirement is not fulfilled.

In your comments to the draft decision, you agree to perform an OECD TG 210 study and note that considering poor solubility in water, high adsorption and volatilisation potential of the Substance "*the study design will be adapted as far as reasonably practicable to take account of this in accordance with OECD Technical Guidance No. 23*".

Study design

OECD TG 210 specifies that for difficult to test substances OECD GD 23 must be followed. As already explained above, the Substance is difficult to test. Therefore, you must fulfil the requirements described in 'Study design' under Section on Long-term toxicity testing on aquatic invertebrates (Appendix A. 1.).

4. Soil simulation testing

Soil simulation testing is an information requirement under Annex IX to REACH (Section 9.2.1.3.) for substances with a high potential for adsorption to soil.

The Substance has a low water solubility (<0.1 mg/l at 20 °C) and high octanol-water parttioning coefficient (log K_{ow} > 6.5) and therefore has high potential for adsorption to soil.

You have provided an adaptation under Annex IX, Section 9.2.1.3., Column 2 with the following justification: "*Farnesene has very low water solubility (~ 11 µg/L) and data show a clear potential to degrade in the environment. Significant soil exposure is considered unlikely and the material is unlikely to be persistent.*"

We have assessed this information and identified the following issue:

Rejection of adaptation

Under Section 9.2.1.3., Column 2 of Annex IX to REACH, the study may be omitted if direct and indirect exposure of soil is unlikely.

The chemical safety report (CSR) provided by you indicates that releases to soil are not equal to zero as well as predicted environmental concentrations in agricultural soil are not equal to zero. Therefore, direct and/or indirect exposure of soil is not unlikely and your adaption is rejected.

Triggering of the testing by needs of chemical safety assessment (CSA)

Under Section 9.2., Column 2 of Annex IX to REACH, the study may be omitted if the chemical safety assessment (CSA) does not indicate the need for further biotic degradation testing. The CSA does indicate such need (Annex I, Section 4; Annex XIII, Section 2.1) if, for instance, the substance is a potential PBT/vPvB substance (ECHA Guidance R.11.4). This is the case if the Substance itself or any of its constituent or impurity present in concentration ≥ 0.1% (w/w) or relevant transformation/degradation product meets the following criteria:

- it is potentially persistent or very persistent (P/vP) as:
  - it is not readily biodegradable (i.e. <60/70% degradation in an OECD TG 301 or 310);
- it is potentially bioaccumulative or very bioaccumulative (B/vB) as:
  - it has a high potential to partition to lipid storage (log K_{ow} > 4.5);
- it meets the T criteria set in Annex XIII: long-term aquatic toxicity NOEC or EC_{10} < 0.01 mg/L or classification as carc. 1A or 1B, muta. 1A or 1B, repro. 1A, 1B or 2, or STOT RE 1 or 2.

Your registration dossier provides the following:

- no adequate ready biodegradability data, so there is no possibility to conclude that substance is not P/vP;
- the Substance is potentially bioaccumulative or very bioaccumulative (B/vB) as it has a high potential to partition to lipid storage (Log K_{ow} of >6.5 based on OECD TG 117);
- no adequate long-term aquatic toxicity data, so it is not possible to conclude on the toxicity of the Substance.

The information above indicates that the Substance is a potential PBT/vPvB substance. Furthermore, the Substance has low water solubility (<0.1 mg/l at 20 °C) and high log Kow (log K_{ow} > 6.5), indicating high potential to adsorb to soil.

Therefore, the chemical safety assessment (CSA) indicates the need for further degradation investigation. Based on the adsorptive properties of the Substance, soil represents a relevant environmental compartment.

In your comments to the draft decision, you propose to follow the testing strategy for the persistence assessment advised in ECHA Guidance R.11, to conduct a ready biodegradability study first in order to investigate on whether the Substace is ready biodegradable or a soil simulation study is required for the persistence assessment under the PBT/vPvB assessment. On this basis, the information requirement is not fulfilled.

Study design

Under Annex XIII, the information must be based on data obtained under conditions relevant for the PBT/vPvB assessment. Therefore:

- You must perform the OECD TG 307 test using four soils representing a range of relevant soils (*i.e.* varying in their organic content, pH, clay content and microbial biomass).
- You must perform the test at the temperature of 12°C, the average environmental temperature for the EU (ECHA Guidance R.16, Table R.16-8). Performing the test at this temperature is in line with the applicable test conditions of the OECD TG 307.

Non-extractable residues (NER) must be quantified in all simulation studies. The reporting of results must include a scientific justification of the used extraction procedures and solvents.

By default, total NER is regarded as non-degraded Substance. However, if reasonably justified and analytically demonstrated a certain part of NER may be differentiated and quantified as irreversibly bound or as degraded to biogenic NER. Such fractions could be regarded as removed when calculating the degradation half-life(s) (ECHA Guidance R.11).

5. Identification of degradation products

Identification of degradation products is an information requirement under Annex IX to REACH (Section 9.2.3.).

You have not provided information on the identity of transformation/degradation products for the Substance.

On this basis, the information requirement is not fulfilled.

This information is required for the purpose of the PBT/vPvB assessment (Annex I, Section 4) and the risk assessment (Annex I, Section 6) of the Substance.

In your comment to the draft decision, you propose to conduct a ready biodegradability study first in order to investigate on whether the Substace is ready biodegradable or "*if the substance is not readily biodegradable then the appropriate simulation studies would be conducted and used to fill this endpoint*".

Study design

Regarding the selection of appropriate and suitable test method(s), the method(s) will have to be substance-specific. Identity, stability, behaviour, and molar quantity of the degradation/transformation products relative to the Substance must be evaluated and reported, when analytically possible. In addition, degradation half-life, log Kow and potential toxicity of the transformation/degradation products may need to be investigated. You may obtain this information from the degradation study requested in Sections on Soil simulation testing (Appendix C) or by some other measure. If any other method is used for the identification of the transformation/degradation products, you must provide a scientifically valid justification for the chosen method.

To determine the degradation rate of the Substance, the requested study according to OECD TG 307 (Sections on Soil simulation testing (Appendix C)) must be conducted at 12 °C and at test material application rates reflecting realistic assumptions. However, to overcome potential analytical limitations with the identification and quantification of major transformation/degradation products, you may consider running a parallel test at higher temperature (but within the frame provided by the test guideline) and at higher application rate (e.g. 10 times).

6. Bioaccumulation in aquatic species

Bioaccumulation in aquatic species, preferably in fish, is an information requirement under Annex IX to REACH (Section 9.3.2.).

You have provided an adaptation under Annex IX, Section 9.3.2., Column 2 with the following justification: "*Farnesene has very low water solubility (~ 11 µg/L) and data show a clear potential to degrade in the environment. Chronic toxicity data on a related material do not indicate effects at the limit of solubility. Significant exposure of the aquatic environment or sediment is thus unlikely and the material is not considered to be persistent.*"

We have assessed this information and identified the following issue:

Under Section 9.3.2., Column 2 of Annex IX to REACH, the study may be omitted if direct and indirect exposure of the aquatic compartment is unlikely.

The CSR provided by you indicates that releases to water are not equal to zero as well as predicted environmental concentrations in sediment are not equal to zero. Therefore, direct and/or indirect exposure of aquatic compartment is not unlikely. Furthermore, as noted in respective sections above, there is no adequate data on long-term aquatic toxicity provided in the dossier and the Substance is potentially persistent or very persistent. Thus, your adaption is rejected.

Moreover, as already explained under Section on Soil simulation testing (Appendix C) above, the Substance is a potential PBT/vPvB substance and therefore, CSA indicates the need for further bioaccumulation testing.

In your comments to the draft decision, you note that the Substance has a high log Kow and EPISUITE V4.10 (EPA, 2012) predicts a bioconcentration factor (BCF) of 10940 L/kg for the Substance. You propose to conduct persistence assessment first before deciding if bioaccumulation study is required. You further note that "*will also update the PNECs and exposure assessments to show that bioaccumulation in the environment is not an issue*". In addition, you propose to report the EPISUITE predictions in the dossier and classify the substance as vB. Finally, you note that the study with exposure via the aqueous route likely would not be feasible and only the dietary test will be possible "*which in turn creates issues when interpreting the information considering the PBT assessment criteria*".

ECHA notes that if the predictions by QSAR model are used to adapt standard information requirement the conditions listed in Annex XI, section 1.3 should be met. However, information on bioaccumulation should also be adequate for the purpose of PBT/vPvB assessment. The information relevant for the assessment of B or vB properties is listed in Annex XIII, section 3.2.2 and the predictions by QSAR models are not listed there as individual detached source of information allowing to conclude on B or vB properties. It is explained in ECHA Guidance R.11, section R.11.4.1.2.1 that the standard aquatic bioaccumulation test requirement cannot be adapted according to Column 2 of Annex IX, section 9.3.2 and/or REACH Annex XI, if the PBT/vPvB assessment shows that a bioaccumulation test in aquatic species is necessary (and it is technically feasible). However, as noted in Annex XIII introductory part and in the Guidance R.11 data generated by application of QSAR models can be used in a Weight-of-Evidence approach for the B and vB assessment.

Finally, as noted below under *Study design* you must attempt to estimate the corresponding BCF value from the dietary test according to Annex 8 of the OECD 305 TG and OECD Guidance Document on Aspects of OECD TG 305 on Fish Bioaccumulation_(ENV/JM/MONO(2017)16).

On this basis, the information requirement is not fulfilled.

Study design

Bioaccumulation in fish: aqueous and dietary exposure (test method EU C.13. / OECD TG 305) is the preferred test to investigate bioaccumulation (ECHA *Guidance, Chapter R.7c, R.7.10.3.1*). Exposure via the aqueous route (OECD TG 305-I) must be conducted unless it can be demonstrated that:

- a stable and fully dissolved concentration of the test substance in water cannot be maintained within ± 20% of the mean measured value, and/or
- the highest achievable concentration is less than an order of magnitude above the limit of quantification (LoQ) of a sensitive analytical method.

This test set-up is preferred as it allows for a direct comparison with the B and vB criteria of Annex XIII of REACH. If it can be justified that testing through aquatic exposure is technically not possible and you may conduct the study using the dietary exposure route (OECD 305-III), you must then attempt to estimate the corresponding BCF value from the dietary test data according to Annex 8 of the OECD 305 TG and OECD Guidance Document on Aspects of OECD TG 305 on Fish Bioaccumulation_(ENV/JM/MONO(2017)16). In any case you must report all data derived from the dietary test as listed in the OECD TG 305-III.

Appendix D: Requirements to fulfil when conducting and reporting new tests for REACH purposes

A. Test methods, GLP requirements and reporting

1. Under Article 13(3) of REACH, all new data generated as a result of this decision must be conducted according to the test methods laid down in a European Commission Regulation or to international test methods recognised by the Commission or ECHA as being appropriate.

2. Under Article 13(4) of REACH, ecotoxicological and toxicological tests and analyses must be carried out according to the GLP principles (Directive 2004/10/EC) or other international standards recognised by the Commission or ECHA.

3. Under Article 10(a)(vi) and (vii) of REACH, all new data generated as a result of this decision must be reported as study summaries, or as robust study summaries, if required under Annex I of REACH. See ECHA Practical Guide on How to report robust study summaries[7].

B. Test material

Before generating new data, you must agree within the joint submission on the chemical composition of the material to be tested (Test Material) which must be relevant for all the registrants of the Substance.

1. Selection of the Test material(s)

   The Test Material used to generate the new data must be selected taking into account the following:
   - the variation in compositions reported by all members of the joint submission,
   - the boundary composition(s) of the Substance,
   - the impact of each constituent/ impurity on the test results for the endpoint to be assessed. For example, if a constituent/ impurity of the Substance is known to have an impact on (eco)toxicity, the selected Test Material must contain that constituent/ impurity.

2. Information on the Test Material needed in the updated dossier
   - You must report the composition of the Test Material selected for each study, under the "Test material information" section, for each respective endpoint study record in IUCLID.
   - The reported composition must include all constituents of each Test Material and their concentration values and other parameters relevant for the property to be tested.

This information is needed to assess whether the Test Material is relevant for the Substance and whether it is suitable for use by all members of the joint submission.

Technical instructions on how to report the above is available in the manual on How to prepare registration and PPORD dossiers[8].

[7] https://echa.europa.eu/practical-guides
[8] https://echa.europa.eu/manuals

Appendix E: General recommendations when conducting and reporting new tests for REACH purposes

A. Strategy for the PBT/vPvB assessment

You are advised to consult ECHA Guidance R.7b (Section R.7.9.), R.7c (Section R.7.10) and R.11 on PBT assessment to determine the sequence of the tests needed to reach the conclusion on PBT/vPvB. The guidance provides advice on 1) integrated testing strategies (ITS) for the P, B and T assessments and 2) the interpretation of results in concluding whether the Substance fulfils the PBT/vPvB criteria of Annex XIII.

In particular, you are advised to first conclude whether the Substance fulfils the Annex XIII criteria for P and vP, and then continue with the assessment for bioaccumulation. When determining the sequence of simulation degradation testing you are advised to consider the intrinsic properties of the Substance, its identified uses and release patterns as these could significantly influence the environmental fate of the Substance. You must revise your PBT assessment when the new information is available.

Appendix F: Procedure

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

ECHA followed the procedure detailed in Articles 50 and 51 of REACH.

The compliance check was initiated on 22 May 2019.

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

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

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

As no amendments were proposed, ECHA adopted the decision under Article 51(3) of REACH.

Appendix G: List of references - ECHA Guidance[9] and other supporting documents

Evaluation of available information
Guidance on information requirements and chemical safety assessment, Chapter R.4 (version 1.1., December 2011), referred to as ECHA Guidance R.4 where relevant.

QSARs, read-across and grouping
Guidance on information requirements and chemical safety assessment, Chapter R.6 (version 1.0, May 2008), referred to as ECHA Guidance R.6 where relevant.

Read-across assessment framework (RAAF, March 2017)[10]

RAAF - considerations on multiconstituent substances and UVCBs (RAAF UVCB, March 2017)[10]

Physical-chemical properties
Guidance on information requirements and chemical safety assessment, Chapter R.7a (version 6.0, July 2017), referred to as ECHA Guidance R.7a in this decision.

Toxicology
Guidance on information requirements and chemical safety assessment, Chapter R.7a (version 6.0, July 2017), referred to as ECHA Guidance R.7a in this decision.

Guidance on information requirements and chemical safety assessment, Chapter R.7c (version 3.0, June 2017), referred to as ECHA Guidance R.7c in this decision.

Environmental toxicology and fate
Guidance on information requirements and chemical safety assessment, Chapter R.7a (version 6.0, July 2017), referred to as ECHA Guidance R.7a in this decision.

Guidance on information requirements and chemical safety assessment, Chapter R.7b (version 4.0, June 2017), referred to as ECHA Guidance R.7b in this decision.

Guidance on information requirements and chemical safety assessment, Chapter R.7c (version 3.0, June 2017), referred to as ECHA Guidance R.7c in this decision.

PBT assessment
Guidance on information requirements and chemical safety assessment, Chapter R.11 (version 3.0, June 2017), referred to as ECHA Guidance R.11 in this decision.

Guidance on information requirements and chemical safety assessment, Chapter R.16 (version 3.0, February 2016), referred to as ECHA Guidance R.16 in this decision.

Data sharing
Guidance on data-sharing (version 3.1, January 2017), referred to as ECHA Guidance on data sharing in this decision.

OECD Guidance documents[11]

[9] https://echa.europa.eu/guidance-documents/guidance-on-information-requirements-and-chemical-safety-assessment
[10] https://echa.europa.eu/support/registration/how-to-avoid-unnecessary-testing-on-animals/grouping-of-substances-and-read-across
[11] http://www.oecd.org/chemicalsafety/testing/series-testing-assessment-publications-number.htm

Guidance Document on aqueous-phase aquatic toxicity testing of difficult test chemicals – No 23, referred to as OECD GD 23.

Guidance document on transformation/dissolution of metals and metal compounds in aqueous media – No 29, referred to as OECD GD 29.

Guidance Document on Standardised Test Guidelines for Evaluating Chemicals for Endocrine Disruption – No 150, referred to as OECD GD 150.

Guidance Document supporting OECD test guideline 443 on the extended one-generation reproductive toxicity test – No 151, referred to as OECD GD 151.

Appendix H: Addressees of this decision and the corresponding information requirements applicable to them

You must provide the information requested in this decision for all REACH Annexes applicable to you.

Registrant Name	Registration number	Highest REACH Annex applicable to you
[redacted]	[redacted]	[redacted]
[redacted]	[redacted]	[redacted]
[redacted]	[redacted]	[redacted]
[redacted]	[redacted]	[redacted]

Where applicable, the name of a third party representative (TPR) may be displayed in the list of recipients whereas ECHA will send the decision to the actual registrant.