Helsinki, 16 November 2016

Addressee: [redacted]

Decision number: CCH-D-2114347533-50-01/F
Substance name: 2,6,10-trimethyldodecane
EC number: 622-542-2
CAS number: 3891-98-3
Registration number: [redacted]
Submission number: [redacted]
Submission date: 06.02.2015
Registered tonnage band: 100-1000T

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. **Composition (Annex VI, Section 2.3.) of the registered substance;**
   - **Identification and quantification of the impurities**

2. **Description of the analytical methods (Annex VI, Section 2.3.7.) of the registered substance;**
   - **Peak table**

3. **In vitro cytogenicity study in mammalian cells (Annex VIII, Section 8.4.2., test method: OECD TG 473) or in vitro micronucleus study (Annex VIII, Section 8.4.2., test method: OECD TG 487) with the registered substance;**

4. **Soil simulation testing (Annex IX, Section 9.2.1.3.; test method: Aerobic and anaerobic transformation in soil, EU C.23./OECD TG 307) at a temperature of 12 °C with the registered substance;**

5. **Sediment simulation testing (Annex IX, Section 9.2.1.4.; test method: Aerobic and anaerobic transformation in aquatic sediment systems, EU C.24./OECD TG 308) at a temperature of 12 °C with the registered substance;**

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

7. **Long-term toxicity to terrestrial invertebrates (Annex IX, Section 9.4.1., column 2; test method: Earthworm reproduction test (Eisenia fetida/Eisenia andrei), OECD TG 222, or Enchytraeid reproduction test, OECD TG 220, with the registered substance;**

8. **Long-term toxicity testing on plants (Annex IX, Section 9.4.3., column 2; test method: Terrestrial plants, growth test, OECD TG 208, with at least six species tested (with as a minimum two monocotyledonous species and four dicotyledonous species), or, Soil Quality – Biological Methods – Chronic toxicity in higher plants, ISO 22030) with the registered substance;**

9. **Effects on soil micro-organisms (Annex IX, Section 9.4.2.; test method: Soil microorganisms: nitrogen transformation test, EU C.21/OECD TG 216 with the registered substance.**

You may adapt the testing requested above according to the specific rules outlined in Annexes VI to X and/or according to the general rules contained in Annex XI 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 **23 November 2018**. 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[1] by Ofelia Bercaru, Head of Unit, Evaluation E3

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

Appendix 1: Reasons

1. 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.

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

In that respect, according to chapter 4.2 of the Guidance for identification and naming of substances under REACH and CLP (Version: 1.3, February 2014) – referred to as "the Guidance" thereinafter, you shall note that, for well-defined substances, the following applies:

- Each main constituent (i.e. the constituent present at ≥80% for mono-constituent substance or each constituent present at ≥10% and 80% for multi-constituent substance) shall be identified and reported individually; and

- Each impurity present at ≥1% or relevant for the classification and/or PBT assessment of the registered substance shall be identified and reported individually.

- For each constituent, the typical, minimum and maximum concentration levels shall be specified regardless of the substance type.

In the present dossier, you identified the registered substance as 2,6,10-trimethyldodecane and specified a minimum concentration level of [redacted]% (w/w) for the main constituent. However, you did not report the presence of any impurity in the composition.

ECHA notes that up to [redacted] % of the composition has therefore not been accounted for. Furthermore, the analytical data attached in the dossier was not sufficient to quantify the substance composition (as further explained in the following reason).

ECHA therefore concludes that the compositional information has not been provided to the required level of detail.

You are accordingly requested to correct the information provided on the composition of the registered substance and especially the part of the composition that is not reported, including impurities.

Regarding how to report the composition of the registered substance in IUCLID, the following applies: you shall report individually any impurity required to be identified and specify at least one of the following identifiers: chemical name, CAS number, EC number and/or molecular formula, as well as the minimum, maximum and typical concentration, in the appropriate fields in Section 1.2 of the IUCLID dossier.

Further technical details on how to report the composition of well-defined substances in IUCLID are available in the Data Submission Manual – Part 18: How to report the substance identity in IUCLID 5 for registration under REACH (version: 2.0, July 2012) on the ECHA website.

You shall ensure that the composition is verifiable and therefore supported by a description of the analytical methods for the identification and quantification of the constituents required to be reported, as required under Annex VI.2.3.7. of the REACH Regulation. The description shall be sufficient for the methods to be reproduced and shall therefore include details of the experimental protocol followed, any calculation made and the results obtained.

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

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.

Annex VI, section 2.3. of the REACH Regulation requires that each registration dossier contain the Description of the analytical methods used for the identification of the substance and, where appropriate, for the identification of impurities and additives sufficient information for establishing the composition of the registered substance and therefore its identity. Adequate information needs to be present in the technical dossier for the registered substance to meet this information requirement.

You did not include a sufficiently detailed description of the analytical method used for the identification of the substance. More specifically, ECHA notes that you have submitted the chromatogram recorded on your substance in the attachment "[redacted]".

In the absence of the peak table containing the retention times, peak areas, area % and the identification of the peaks, the provided information concerning the chromatographic method description and the results thereof is not sufficient to verify the presence and quantity of the constituents reported in section 1.2 of the IUCLID dossier.

ECHA therefore concludes that the compositional information has not been provided to the required level of detail.

In order to comply with the REACH requirements, you shall provide, as part of the detailed description of the analytical method used to identify the quantitative composition of the substance, the peak table containing the retention times, peak areas, area % and the identification of the peaks. The chromatographic method can be used to derive the quantitative composition but also alternative methods can be used. The results of the quantitative method together with the interpretation of the results, calculations (if relevant) shall also be provided.

As for the reporting of the peak table containing the retention times, peak areas, area % and the identification of the peaks in the registration dossier, the information should be included in IUCLID section 1.4.

3. In vitro cytogenicity study in mammalian cells or in vitro micronucleus study (Annex VIII, Section 8.4.2.)

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

An "*In vitro* cytogenicity study in mammalian cells or an *in vitro* micronucleus study" is a standard information requirement as laid down in Annex VIII, Section 8.4.2. of the REACH Regulation. Adequate information on this endpoint needs to be present in the technical dossier for the registered substance to meet this information requirement.

In the technical dossier you have provided a study record for an "*In vitro mammalian chromosome aberration assay in human peripheral blood lymphocytes (HPBL)"* (BioReliance, 2013). However, this study does not provide the information required by Annex VIII, Section 8.4.2., because it is not considered to be reliable for the reasons described below.

For this chromosomal aberration test, the chosen solvent was water and the tested concentrations were 5, 10, 20, 35, 70, 100 ug/mL. The choice of solvent and of tested concentrations was justified in the robust study summary by the following statement: "*Water was used as the vehicle based on the solubility of the test article and compatibility with the target cells. In a visual solubility test conducted at BioReliance, the test article was soluble in water at a concentration of approximately 50 mg/mL*". In the study summary "*Farnesane was concluded to be negative for the induction of structural and numerical chromosome aberrations in the non activated test system in the in vitro mammalian chromosome aberration test using human peripheral blood lymphocytes. In the S9-activated test system, Farnesane was clastogenic at 100 µg/mL with precipitation at the end of treatment. The biological relevence of response observed at single precipitating dose level is questionable*".

ECHA notes that the water solubility of the substance measured for the chromosomal aberration test (i.e. 50 mg/mL) is not consistent with the physico chemical data provided in the registered dossier for this substance: in IUCLID section 4.8. (Water solubility), it is stated that the '*water solubility of Farnesane is very low and between 0.25 µg/L to 4.4 µg/L. Farnesane is therefore considered essentially insoluble in water.*' Compared to these data, the water solubility mentioned for the chromosomal aberration test is seven orders of magnitude higher. It is unclear to ECHA how this discrepancy in water solubility can be explained, and how concentrations as high as 50 or 100 µg/mL can be achieved in the chromosomal aberration assay by using water as a solvent.

In ECHA's view, since the test substance is a colourless liquid, the lack of solubility may not have been detected using the "*visual solubility test*" performed by the laboratory. ECHA acknowledges that the OECD TG 473 says "*liquid test substances may be added directly to the test systems and/or diluted prior to treatment*". However, according to the physico-chemical data provided in the dossier, the substance cannot be diluted in water or aqueous media to obtain an acceptable concentration.

ECHA notes that two other in vitro genotoxicity tests performed on the registered substance are reported in the IUCLID dossier: an Ames test and a mouse lymphoma assay.

- The Ames test [redacted] was conducted on this substance using an organic solvent (ethanol). The study summary reports that "*solubility of the test article was checked in tissue culture water, Dimethyl sulfoxide, 95% Ethanol (EtOH) and Acetone. The test article was freely soluble at a concentration of 50 µl/ml in 95% EtOH and Acetone*". ECHA notes that 50 µl/mL corresponds to 38.7 mg/mL (considering a density of 0.7735 as indicated in IUCLID section 4.4).

- The mouse lymphoma assay ([redacted]) was performed using another organic solvent (acetone). The executive summary states that "*The maximum dose level used was limited by the onset of greasy / oily precipitate effectively reducing exposure of the test item to the cells. Overall, precipitate of the test item was observed at and above 51 µg/mL in the Mutagenicity Test*". The tested concentrations ranged from 4.25 to 68 µg/mL. Considering that 0.5% of acetone was added to the culture medium, the maximum concentration of the test substance in acetone used for the test was 13.6 mg/mL.
- The concentrations of the substance in the two organic solvents (ethanol or acetone) used for testing appears to be of the same order of magnitude (38.7 mg/mL and 13.6 mg/mL, respectively).
- ECHA considers that the fact that the testing laboratories performing the Ames test and the MLA did not choose water as the solvent for their study is an indication that they considered that water was not ensuring a sufficient solubility, hence a sufficient reliability to conduct the test.

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

ECHA considers that the *in vitro* mammalian chromosome aberration test (test method OECD TG 473)[2] and the *in vitro* mammalian cell micronucleus test (OECD TG 487) are appropriate to address the standard information requirement of Annex VIII, Section 8.4.2. of the REACH Regulation.

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 vitro* mammalian chromosome aberration test (test method: OECD TG 473) or *in vitro* mammalian cell micronucleus study (test method: OECD TG 487).

4. Soil simulation testing (Annex IX, Section 9.2.1.3.)

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

"Soil simulation testing" is a standard information requirement as laid down in Annex IX, section 9.2.1.3. 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.

You have sought to adapt this information requirement according to Annex IX, Section 9.2.1.3., column 2. You provided the following justification for the adaptation: "*In accordance with column 2 of REACH Annex IX, the soil simulation testing does not need to be conducted as direct and indirect exposure of soil is unlikely*."

[2] Only the OECD TG is mentioned since it has recently been updated while the corresponding EU test method has not yet been updated.

However, ECHA notes that your adaptation does not meet the specific rules for adaptation of Annex IX, Section 9.2.1.3., column 2 because the registered substance has low water solubility (0.25 µg/L), high partition coefficient (log Pow 7.2) and high adsorption coefficient (log Koc, soil 6.5), indicating adsorptive properties. In addition, based on the uses reported in the technical dossier, ECHA considers that such use is reported for which soil exposure cannot be excluded (Environmental Release Category (ERC) 8a). ECHA therefore considers that you have not demonstrated that soil exposure is unlikely.

Furthermore, as the substance is not readily biodegradable and no quantitative risk assessment for environment as a whole has been submitted it is not possible to determine whether risks to soil may occur. ECHA thus considers that you have not justified why there is no need to investigate further the degradation of the substance and its degradation products in his chemical safety assessment (CSA) nor in the technical dossier. ECHA considers further that information on degradation is needed for the PBT/vPvB assessment as based on the information currently available on the registered substance it is not possible to conclude whether the substance is PBT/vPvB. ECHA notes that a request to study bioaccumulation is also included in this decision.

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 requirements. Consequently there is an information gap and it is necessary to provide information for this endpoint.

According to ECHA *Guidance on information requirements and chemical safety assessment, Chapter R.7b* (version 3.0, February 2016) Aerobic and anaerobic transformation in soil (test method EU C.23. / OECD TG 307) is the preferred test to cover the standard information requirement of Annex IX, Section 9.2.1.3.

One of the purposes of the simulation test is to provide the information that must be considered for assessing the P/vP properties of the registered substance in accordance with Annex XIII of REACH Regulation to decide whether it is persistent in the environment. Annex XIII also indicates that "*the information used for the purposes of assessment of the PBT/vPvB properties shall be based on data obtained under relevant conditions*". The Guidance on information requirements and chemical safety assessment R.7b (version 3.0, February 2016) specifies that simulation tests "attempt to simulate degradation in a specific environment by use of indigenous biomass, media, relevant solids [...], and a typical temperature that represents the particular environment".

The Guidance on information requirements and chemical safety assessment Chapter R.16 on Environmental Exposure Estimation, Table R.16-8 (version 3.0 February 2016) indicates 12°C (285K) as the average environmental temperature for the EU to be used in the chemical safety assessment. Performing the test at the temperature of 12°C is within the applicable test conditions of the Test Guideline OECD TG 307. Therefore, the test should be performed at the temperature of 12°C.

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: Aerobic and anaerobic transformation in soil (test method: EU C.23./OECD TG 307).

Notes for your consideration

Before conducting the requested tests you are advised to consult the ECHA Guidance on information requirements and chemical safety assessment, Chapter R7b, Sections R.7.9.4 and R.7.9.6 (version 3.0, February 2016) and Chapter R.11, Section R.11.4.1.1 (version 2.0, November 2014) on PBT assessment to determine the sequence in which the simulation tests are to be conducted and the necessity to conduct all of them. The order in which the simulation biodegradation tests are performed needs to take into account the intrinsic properties of the registered substance and the identified use and release patterns which could significantly influence the environmental fate of the registered substance.

In accordance with Annex I, Section 4, of the REACH Regulation you should revise the PBT assessment when results of the tests detailed above is available. You are also advised to consult the ECHA Guidance on information requirements and chemical safety assessment (version 2.0, November 2014), Chapter R.11, Section R.11.4.1.1. and Figure R. 11-3 on PBT assessment for the integrated testing strategy for persistency assessment in particular taking into account the degradation products of the registered substance.

5. Sediment simulation testing (Annex IX, Section 9.2.1.4.)

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

"Sediment simulation testing" is a standard information requirement as laid down in Annex IX, section 9.2.1.4. 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.

You have sought to adapt this information requirement according to Annex IX, Section 9.2.1.4., column 2. You provided the following justification for the adaptation; "*In accordance with column 2 of REACH Annex IX, the simulation testing on ultimate degradation in surface waters does not need to be conducted as the substance is highly insoluble in water.*"

ECHA notes that in your adaptation for simulation testing on ultimate degradation in surface waters and sediment you have only addressed the surface waters. ECHA notes that your adaptation does not meet the specific rules for adaptation of Annex IX, Section 9.2.1.4., column 2 for sediment because the registered substance has high partition coefficient (log Pow 7.2) and high adsorption coefficient (log Koc, soil 6.5), indicating adsorptive properties. In addition, based on the uses reported in the technical dossier, ECHA considers that due to wide dispersive uses and substance properties sediment exposure cannot be excluded. ECHA therefore considers that you have not demonstrated that sediment exposure is unlikely.

Furthermore, as the substance is not readily biodegradable and no quantitative risk assessment for environment as a whole has been submitted it is not possible to determine whether risks to sediment may occur. ECHA thus considers that you have not justified why there is no need to investigate further the degradation of the substance and its degradation products in the chemical safety assessment (CSA) nor in the technical dossier.

ECHA considers further that information on degradation is needed for the PBT/vPvB assessment as based on the information currently available on the registered substance it is not possible to conclude whether the substance is PBT/vPvB. ECHA notes that a request to study bioaccumulation is also included in this decision.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 requirements. Consequently there is an information gap and it is necessary to provide information for this endpoint.

According to ECHA *Guidance on information requirements and chemical safety assessment, Chapter R.7b* (version 3.0, February 2016) Aerobic and anaerobic transformation in aquatic sediment systems (test method EU C.24. / OECD TG 308) is the preferred test to cover the standard information requirement of Annex IX, Section 9.2.1.4.

One of the purposes of the simulation test is to provide the information that must be considered for assessing the P/vP properties of the registered substance in accordance with Annex XIII of REACH Regulation to decide whether it is persistent in the environment. Annex XIII also indicates that "*the information used for the purposes of assessment of the PBT/vPvB properties shall be based on data obtained under relevant conditions*". The Guidance on information requirements and chemical safety assessment R.7b (version 3.0, February 2016) specifies that simulation tests "attempt to simulate degradation in a specific environment by use of indigenous biomass, media, relevant solids [...], and a typical temperature that represents the particular environment". The Guidance on information requirements and chemical safety assessment Chapter R.16 on Environmental Exposure Estimation, Table R.16-8 (version 3.0 February 2016) indicates 12°C (285K) as the average environmental temperature for the EU to be used in the chemical safety assessment. Performing the test at the temperature of 12°C is within the applicable test conditions of the Test Guideline OECD TG 308. Therefore, the test should be performed at the temperature of 12°C.

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: Aerobic and anaerobic transformation in aquatic sediment systems (test method: EU C.24./OECD TG 308).

Notes for your consideration

Before conducting the requested tests you are advised to consult the ECHA Guidance on information requirements and chemical safety assessment, Chapter R7b, Sections R.7.9.4 and R.7.9.6 (version 3.0, February 2016) and Chapter R.11, Section R.11.4.1.1 (version 2.0, November 2014) on PBT assessment to determine the sequence in which the simulation tests are to be conducted and the necessity to conduct all of them. The order in which the simulation biodegradation tests are performed needs to take into account the intrinsic properties of the registered substance and the identified use and release patterns which could significantly influence the environmental fate of the registered substance.

In accordance with Annex I, Section 4, of the REACH Regulation you should revise the PBT assessment when results of the tests detailed above is available. You are also advised to consult the ECHA Guidance on information requirements and chemical safety assessment (version 2.0, November 2014), Chapter R.11, Section R.11.4.1.1. and Figure R. 11-3 on PBT assessment for the integrated testing strategy for persistency assessment in particular taking into account the degradation products of the registered substance.

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

Pursuant to Articles 10(a) and 12(1) of the REACH Regulation, a technical dossier registered at 100 to 1000 tonnes per year shall contain as a minimum the information specified in Annexes VII to IX of the REACH Regulation. The information to be generated for the dossier must fulfil the criteria in Article 13(4) of the same 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 according to Annex XI, Section 1.3. You provided modelled data using EpiSuite v4.11 and specifically BCFBAF v 3.01. You conclude that "QSAR modelled BCF values for farnesane are in the range 1074 L/Kg wet-wt (Arnot-Gobas Upper Trophic) to 1944 L/Kg wet-wt (regression method). Based on these estimates, farnesane is not expected to be bioaccumulative."

However, ECHA notes that your adaptation does not meet the general rule for adaptation of Annex XI; Section 1.3. The results (BCF of 1074 L/Kg wet-wt (Arnot-Gobas Upper Trophic) and 1944 L/Kg wet-wt (regression method) were reproduced correctly. Uncertainty of the prediction is estimated by ECHA to be around ±1.0 log units based on the general performance of the models when predicting compounds outside the training set but within its applicability domain. Taking into account this uncertainty, ECHA is of the opinion that the prediction cannot be used to adapt this information requirement. It is noted that the worst case prediction with Arnot-Gobas model predicts a value above the B threshold. We noted that the log Kow on which the prediction is based is calculated. A manual input of a value of 6.5 leads to much higher prediction values, raising uncertainty with the final BCF prediction.

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 according to REACH requirement Annex XI, Section 1.3, and Annex IX, Section 9.3.2. 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 (OECD TG 305) is the preferred test to cover the standard information requirement of Annex IX, Section 9.3.2. ECHA Guidance defines further that results obtained from a test with aqueous exposure can be used directly for comparison with the B and vB criteria of Annex XIII of REACH Regulation and can be used for hazard classification and risk assessment. Comparing the results of a dietary study with the REACH Annex XIII B and vB criteria is more complex and has higher uncertainty. Therefore, the aqueous route of exposure is the preferred route and shall be used whenever technically feasible. If you decided to conduct the study using the dietary exposure route, you shall provide scientifically valid justification for your decision. Data obtained from a dietary study will also need to be used to estimate BCF values.

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)

Notes for your consideration

Before conducting the above test you are advised to consult the ECHA *Guidance on information requirements and chemical safety assessment* (version 2.0, November 2014), Chapter R.11.4. and Figure R.11-4 on the PBT assessment for further information on the integrated testing strategy for the bioaccumulation assessment of the registered substance. You should revise the PBT assessment when information on bioaccumulation is available.

7. Long-term toxicity to terrestrial invertebrates (Annex IX, Section 9.4.1., column 2)

"Effects on terrestrial organisms" is a standard information requirement as laid down in Annex IX, Section 9.4. of the REACH Regulation. Adequate information on effects on short-term toxicity to invertebrates (Annex IX, Section 9.4.1.), effects on soil micro-organisms (Annex IX, Section 9.4.2.), and short-term toxicity to plants (Annex IX, Section 9.4.3.) needs to be present in the technical dossier for the registered substance to meet the information requirements. Column 2 of Annex IX, Section 9.4 specifies that long-term toxicity testing shall be considered by the Registrant instead of short-term, in particular for substances that have a high potential to adsorb to soil or that are very persistent.

You have waived the standard information requirements of Annex IX, section 9.4. using the following justification: "*In accordance with column 2 of REACH Annex IX, the short term toxicity to invertebrates study does not need to be conducted as direct and indirect exposure of the soil compartment is not expected. Furthermore significant adsorption to soil is not expected and farnesane does biodegrade over time.*"

ECHA notes that on the contrary to your waiving statement, the registered substance has a high partition coefficient (log Kow 7.5) and high adsorption coefficient (log Koc, soil 6.5), indicating adsorptive properties. In addition, based on the uses reported in the technical dossier, ECHA considers that such use is reported for which soil exposure cannot be excluded (Environmental Release Category (ERC) 8a). ECHA therefore considers that you have not demonstrated that soil exposure is unlikely.

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 requirements. Consequently there is an information gap and it is necessary to provide information for this endpoint. According to section R.7.11.5.3., Chapter R.7c of the ECHA *Guidance on information requirements and chemical safety assessment* (version 2.0, November 2014), substances that are ionisable or have a log K_{ow}/K_{oc} >5 are considered highly adsorptive, whereas substances with a half-life >180 days are considered very persistent in soil. According to the evidence presented within the Registration dossier, the substance has a high potential to adsorb to soil ($logP_{ow}$ 7.5). Therefore ECHA considers that the column II adaptation for Annex IX, section 9.4 regarding long-term testing instead of short-term testing, is applicable to this substance.

Based upon the available aquatic toxicity information and the physico-chemical properties of the substance and in relation to section R.7.11.6. of the above-mentioned guidance, ECHA considers that the substance would fall into soil hazard category 4. In the context of an integrated testing strategy for soil toxicity, the Guidance advocates performing long-term toxicity tests according to the information requirements of Annex IX and that the lowest value obtained should be used to derive the PNEC soil.

The earthworm reproduction test (OECD TG 222), Enchytraeid reproduction test (OECD TG 220), and Collembolan reproduction test (OECD TG 232) are each considered capable of generating information appropriate for the fulfilment of the information requirements for long-term toxicity testing to terrestrial invertebrates. ECHA is not in a position to determine the most appropriate test protocol, since this decision is dependent upon species sensitivity and substance properties. You are to apply the most appropriate and suitable test guideline among those listed above. However ECHA notes that when log Kow >5 and log Koc >4, as in this case, the test OECD 232 is not appropriate as the dominant route of exposure for Collembolans is via pore water.

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: Earthworm reproduction test (*Eisenia fetida/Eisenia andrei*) (test method: OECD TG 222), or Enchytraeid reproduction test (test method: OECD TG 220).

8. Long-term toxicity to plants (Annex IX, Section 9.4.3., column 2)

"Effects on terrestrial organisms" is a standard information requirement as laid down in Annex IX, Section 9.4. of the REACH Regulation. Adequate information on effects on short-term toxicity to invertebrates (Annex IX, Section 9.4.1.), effects on soil micro-organisms (Annex IX, Section 9.4.2.), and short-term toxicity to plants (Annex IX, Section 9.4.3.) needs to be present in the technical dossier for the registered substance to meet the information requirements. Column 2 of Annex IX, Section 9.4 specifies that long-term toxicity testing shall be considered by the Registrant instead of short-term, in particular for substances that have a high potential to adsorb to soil or that are very persistent.

You have waived the standard information requirements of Annex IX, section 9.4. using the following justification: "*In accordance with column 2 of REACH Annex IX, the short term toxicity to plants study does not need to be conducted as direct and indirect exposure of the soil compartment is not expected. Furthermore significant adsorption to soil is not expected and farnesane does biodegrade over time.*"

ECHA notes that on the contrary to your waiving statement, the registered substance has a high partition coefficient (log Kow 7.5) and high adsorption coefficient (log Koc, soil 6.5), indicating adsorptive properties. In addition, based on the uses reported in the technical dossier, ECHA considers that such use is reported for which soil exposure cannot be excluded (Environmental Release Category (ERC) 8a). ECHA therefore considers that you have not demonstrated that soil exposure is unlikely.

As established within point (7) above, the Guidance advocates performing long-term toxicity tests according to the information requirements of Annex IX and that the lowest value obtained should be used to derive the PNEC soil.

OECD TG guideline 208 (Terrestrial plants, growth test) considers the need to select the number of test species according to relevant regulatory requirements, and the need for a reasonably broad selection of species to account for interspecies sensitivity distribution. For long-term toxicity testing, ECHA considers six species as the minimum to achieve a reasonably broad selection. Testing shall be conducted with species from different families, as a minimum with two monocotyledonous species and four dicotyledonous species, selected according to the criteria indicated in the OECD TG 208 guideline. You should consider if testing on additional species is required to cover the information requirement.

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: Terrestrial plants, growth test (test method: OECD TG 208), with at least six species tested (with as a minimum two monocotyledonous species and four dicotyledonous species), or, Soil Quality – Biological Methods – Chronic toxicity in higher plants (test method: ISO 22030).

9. Effects on soil micro-organisms (Annex IX, Section 9.4.2.)

"Effects on terrestrial organisms" is a standard information requirement as laid down in Annex IX, Section 9.4. of the REACH Regulation. Adequate information on effects on short-term toxicity to invertebrates (Annex IX, Section 9.4.1.), effects on soil micro-organisms (Annex IX, Section 9.4.2.), and short-term toxicity to plants (Annex IX, Section 9.4.3.) needs to be present in the technical dossier for the registered substance to meet the information requirements. Column 2 of Annex IX, Section 9.4 specifies that long-term toxicity testing shall be considered by the Registrant instead of short-term, in particular for substances that have a high potential to adsorb to soil or that are very persistent.

You have waived the standard information requirements of Annex IX, Section 9.4. using the following justification: "*In accordance with column 2 of REACH Annex IX, the effects on soil microorganisms study does not need to be conducted as direct and indirect exposure of the soil compartment is unlikely. Furthermore significant adsorption to soil is not expected and farnesane does biodegrade over time.*"

ECHA notes that on the contrary to your waiving statement, the registered substance has a high partition coefficient (log Kow 7.5) and high adsorption coefficient (log Koc, soil 6.5), indicating adsorptive properties. In addition, based on the uses reported in the technical dossier, ECHA considers that such use is reported for which soil exposure cannot be excluded (Environmental Release Category (ERC) 8a). ECHA therefore considers that you have not demonstrated that soil exposure is unlikely.

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

ECHA notes that the tests requested under points (7 and 8) above are not sufficient to address this standard information requirement. ECHA concludes that the effects on soil microorganisms need to be ascertained by performing a relevant test.

According to section R.7.11.3.1. of the above-mentioned guidance, the nitrogen transformation test is considered sufficient for most non-agrochemicals.

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: Soil microorganisms: nitrogen transformation test (test method: EU C.21./OECD TG 216)

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 7 April 2016.

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

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

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

ECHA notified the draft decision to the competent authorities of the Member States for 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 in its MSC-50 written procedure and ECHA took the decision according to Article 51(6) of the REACH Regulation.

Appendix 3: Further information, observations and technical guidance

1. The substance subject to the present decision is provisionally listed in the Community rolling action plan (CoRAP) for start of substance evaluation in 2018.

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

3. 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.

4. In relation to the information required by the present decision, the sample of the 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 compositions manufactured or imported by the joint registrants. It is the responsibility of all joint registrants who manufacture or import the same substance to agree on the appropriate composition of the test material and to document the necessary information on their substance composition. In addition, it is important to ensure that the particular sample of the substance tested in the new 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.