EUROPEAN CHEMICALS AGENCY

Helsinki, 26 January 2021

Addressees
Registrant(s) of [redacted]_2013 as listed in the last Appendix of this decision

Date of submission of the dossier subject to this decision
21/01/2013

Registered substance subject to this decision ("the Substance")
Substance name: 2,4,7,9-tetramethyldec-5-yne-4,7-diol
EC number: 204-809-1
CAS number: 126-86-3

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 ***31 October 2022*** for the requests A.1 and B.1; by the deadline of ***3 May 2023*** for the requests A.5-6 and B.4-5; and by the deadline of ***31 October 2024*** for all the remaining requests.

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

A. 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

2. Adsorption/ desorption screening (Annex VIII, Section 9.3.1.; test method: OECD TG 106)

3. Long-term toxicity testing on invertebrates also requested below (triggered by Annex VIII, Section 9.1.3., column 2)

4. Long-term toxicity testing on fish also requested below (triggered by Annex VIII, Section 9.1.3., column 2)

5. Simulation testing on ultimate degradation in surface water also requested below (triggered by Annex VIII, Section 9.2.)

6. Identification of degradation products also requested below (triggered by Annex VIII, Section 9.2.)

7. Bioaccumulation in aquatic species also requested below (triggered by Annex I, sections 0.6.1. and 4.; Annex XIII, Section 2.1.)

B. 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 or rabbit)

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. Simulation testing on ultimate degradation in surface water (Annex IX, Section 9.2.1.2.; test method: EU C.25./OECD TG 309) at a temperature of 12 °C

5. Identification of degradation products (Annex IX, 9.2.3)

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

7. Long-term toxicity testing on terrestrial invertebrates (triggered by Annex IX, Section 9.4.1., column 2; test method: OECD TG 222 or 220 or 232)

   Or

   Long-term toxicity to terrestrial plants (triggered by Annex IX, Section 9.4.3., column 2; test method: OECD TG 208 with at least six species or ISO 22030)

8. Effects on soil micro-organisms (Annex IX, Section 9.4.2.; test method: EU C.21./OECD TG 216, OR test method: EU C.21./OECD TG 216 and test method: EU C.22./ OECD TG 217)

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, for registration at 1-10 tonnes per year (tpa);
- the information specified in Annexes VII and VIII to REACH, for registration at 10-100 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 information provided for effects on terrestrial organisms and for long-term aquatic toxicity**

You have provided the same information for the following standard information requirements:

1. Long-term toxicity testing on aquatic invertebrates (Annex IX, Section 9.1.5.)
2. Long-term toxicity testing on fish (Annex IX, Section 9.1.6.)
3. Long-term toxicity testing on terrestrial invertebrates (triggered by Annex IX, Section 9.4., column 2)
4. Effects on soil micro-organisms (Annex IX, Section 9.4.2)
5. Long-term toxicity to terrestrial plants (triggered by Annex IX, Section 9.4.)

That is the following: *"2,4,7,9-Tetramethyldec-5-yne-4,7-diol is used as a co-formulant in plant protection products. In-field use of plant protection products can result in exposure to agricultural soil or to edge-of-field water bodies mainly as a result of spray drift (spray formulations only). Therefore, in accordance with the requirements under REACH, it is necessary to conduct risk characterisation for the potentially exposed compartments if the substance meets the criteria for classification as dangerous according to Directive 67/548/EEC or Directive 1999/45/EC, or is assessed to be a PBT or vPvB. However, it is believed that the potential for environmental effects associated with this use of 2,4,7,9-Tetramethyldec-5-yne-4,7-diol is already inherently addressed as part of the registration procedure for plant protection products under Directive 91/414/EEC."*

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

Rejection of the adaptation on the basis of identified uses of the Substance

According to Article 15 of REACH active substances and co-formulants manufactured or imported for use in plant protection products only and included either in Annex I to Council Directive 91/414/EEC or in Commission Regulation (EEC) No 3600/92, Commission Regulation (EC) No 703/2001, Commission Regulation (EC) No 1490/2002, or Commission Decision 2003/565/EC and for any substance for which a Commission Decision on the completeness of the dossier has been taken pursuant to Article 6 of Directive 91/414/EEC shall be regarded as being registered and the registration as completed for manufacture or import for the use as a plant protection product and therefore as fulfilling the REACH registration requirements.

In the registration dossier, including the CSR, you do not specify that your registration covers the identified use of the substance in plant protection products, only.

Therefore, ECHA understands that there are other uses than only the use in plant protection products covered by the registration dossier. Therefore, your adaptation based on the use of the Substance in the plant protection products under Directive 91/414/EEC is not acceptable.

Thus, your adaptation is rejected.

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

1. Screening study for reproductive/developmental toxicity (Annex VIII, Section 8.7.1.)

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.

Although you do not explicitly claim an adaptation, ECHA understands that the information provided was submitted in order to meet the required information by way of adaptation under Annex, Section XI 1.1.2. This adaptation rule enables registrants to claim that the data from experiments not carried out according to GLP or the test methods referred to in Article 13(3) can be considered equivalent to data generated by those test methods where a number of cumulative conditions are met, in particular:

1. Adequate and reliable coverage of the key parameters foreseen to be investigated in the corresponding test methods referred to in Article 13(3), in this case OECD TG 421 or OECD TG 422 examination of key parameters for toxicity such as thyroid hormone assessment (P0 and F1), monitoring of oestrus cycles and examination of offspring parameters such as anogenital distance/number of nipples/areolae in male pups and functional observations such as sensory reactivity to stimuli/assessment of grip strength/assessment of motor activity;
2. Exposure duration comparable to or longer than the corresponding test methods referred to in Article 13(3);
3. Adequate and reliable documentation of the study is provided;
4. Adequacy for the purpose of classification and labelling and/or risk assessment.

In this regard, you have provided a Single Generation Reproduction Study in the Rat (F0-F1a) with 91-Day Feeding Study (F1a Rats) (1979, no guideline or GLP compliant).

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

1. The above key parameters of a OECD TG 421 or OECD TG 422 are not met by the provided study.

2. In the study you have provided the animals had different exposure durations: "from cohabitation until 20th day of breeding (males) or when litters were weaned at 21 days of age (females) and pups until 91 days. The study does not have a required exposure duration according to OECD TG 421 because the exposure does not cover two weeks of premating. Therefore it does not fulfil the criteria set in EU B.63/OECD TG 421 or EU B.64/OECD TG 422.

Based on the above, the provided information cannot be considered to be adequate for classification and labelling and/or risk assessment.

Therefore, your adaptation is rejected and the information requirement is not fulfilled.

In your comments to the draft decision, you agree to carry out a Screening study for reproductive/developmental toxicity (OECD 422 or OECD 421). You indicate a preference to perform an OECD 422 study.

Based on the above, the information you provided do not fulfil the information requirement and your adaptation under Annex XI, section 1.1.2 is rejected.

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[2] administration of the Substance.

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

Adsorption/desorption screening is an information requirement under Annex VIII to REACH (Section 9.3.1.).

You have adapted this information requirement according to Annex XI, Section 1.3. of the REACH Regulation and you have provided:

(i) a key study to estimate the Log Koc of the registered substance by calculation (KOCWIN Program (v2.00), Estimation Programs Interface Suite™ United States Environmental Protection Agency, Washington, DC, USA. version 4.00)

We have assessed this information and identified the following issues:

Annex XI, Section 1.3. states that results obtained from valid QSAR models may be used instead of testing when the following cumulative conditions are met:

1. results are derived from a QSAR model whose scientific validity has been established;
2. the substance falls within the applicability domain of the QSAR model;
3. adequate and reliable documentation of the applied method is provided; and the results are adequate for classification and labelling and/or risk assessment.

According to ECHA's Practical guide "How to use and report (Q)SARs", section 3.4, a QSAR Model Reporting Format (QMRF) and a QSAR Prediction Reporting Format (QPRF) are required to establish the scientific validity of the model, to verify that the Substance falls within the applicability domain of the model, and to assess the adequacy of the prediction for the purposes of classification and labelling.

You have not included a QMRF and a QPRF in your dossier. You have provided an estimated Log Koc based on KOCWIN Program (V2.00) without any information on the scientific validity of this approach nor on the applicability domain of that QSAR model and how the Substance would fall within that domain.

In the absence of information, you have not established that that the above conditions for an adaptation under Annex XI, Section 1.3 are met.

ECHA further observes that based on the properties of the Substance it is surface active (32.7 mN/m). As indicated in ECHA Guidance on information requirements and chemical safety assessment (version 6.0., July 2017), Chapter R.7a, Section R.7.1.15.3.: *'...measured values will normally be needed for surface active substances (e.g. surfactants)'.* This property would need to be considered in establishing the scientific validity and applicability of the model.

Therefore, your adaptation of the information requirement cannot be accepted.

Therefore the information provided does not fulfil the information requirement.

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

In your comment to the draft decision, you agree to carry out a study onadsorption/desorption using a batch equilibrium method.

Batch equilibrium method (OECD 106) is to be used for surface active substances, as indicated in the ECHA Guidance on information requirements and chemical safety assessment (version 6.0., July 2017), Chapter R.7a, Section R.7.1.15.3.

3. Long-term toxicity testing on aquatic invertebrates

Long-term aquatic toxicity testing as described in Annex IX shall be considered if the chemical safety assessment according to Annex I indicates the need to investigate further effects on aquatic organisms (Annex VIII, Section 9.1.3., column 2).

You have provided the following information in the dossier on long-term fish toxicity: *"2,4,7,9-Tetramethyldec-5-yne-4,7-diol is used as a co-formulant in plant protection products. In-field use of plant protection products can result in exposure to agricultural soil or to edge-of-field water bodies mainly as a result of spray drift (spray formulations only).Therefore, in accordance with the requirements under REACH, it is necessary to conduct risk characterisation for the potentially exposed compartments if the substance meets the criteria for classification as dangerous according to Directive 67/548/EEC or Directive 1999/45/EC, or is assessed to be a PBT or vPvB. However, it is believed that the potential for environmental effects associated with this use of 2,4,7,9-Tetramethyldec-5-yne-4,7-diol is already inherently addressed as part of the registration procedure for plant protection products under Directive 91/414/EEC."*

This information requirement is triggered in case the chemical safety assessment (CSA) indicates the need for further investigation on long-term aquatic toxicity (Annex I, Section 4; Annex XIII, Section 2.1), such as if the substance is a potential PBT 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 ready biodegradability tests, e.g. an OECD 301), and
  - it shows <70% degradation within 7 days in an inherent biodegradation test OECD 302B;
- it is potentially bioaccumulative or very bioaccumulative (B/vB) as:
  - for some groups of substances (e.g. organometals, ionisable substances, surfactants) other partitioning mechanisms may drive bioaccumulation (e.g. binding to protein/cell membranes) and high potential for bioaccumulation cannot be excluded solely based on its potential to partition to lipid;

Your registration dossier provides the following

- the Substance is not readily biodegradable, as concluded by you in the registration dossier on the basis of OECD TG 301 B test (5% degradation after 28 days) and ISO DIS 9439 test which is similar to OECD TG 301 B (enhanced test with 8-12 % degradation after 60 days);
- The Substance is not inherently biodegradable (6% degradation after 28 days in OECD TG 302B);
- the Substance is a surfactant and therefore high potential for bioaccumulation cannot be excluded based on water-octanol partitioning coefficient.

Furthermore, the information in your dossier is currently incomplete and therefore:

- it is not possible to conclude on the persistence of the Substance (see Appendix B Section 4.), and
- there is no adequate data to conclude on bioaccumulation potential of the Substance (see Appendix B Section 6.).

The information above indicates that the Substance is a potential PBT/vPvB substance. Therefore, the CSA indicates the need for long-term aquatic toxicity investigation.

For ECHA's response, to your comments to the draft decision regarding this request, see request B.2. below.

The examination of the available information or adaptations, as well as the selection of the requested test and the test design are addressed in Appendix B Section 2.

4. Long-term toxicity testing on fish

Long-term aquatic toxicity testing as described in Annex IX shall be considered if the chemical safety assessment according to Annex I indicates the need to investigate further effects on aquatic organisms (Annex VIII, Section 9.1.3., column 2).

You have provided the following information in the dossier on long-term fish toxicity: *"2,4,7,9-Tetramethyldec-5-yne-4,7-diol is used as a co-formulant in plant protection products. In-field use of plant protection products can result in exposure to agricultural soil or to edge-of-field water bodies mainly as a result of spray drift (spray formulations only).Therefore, in accordance with the requirements under REACH, it is necessary to conduct risk characterisation for the potentially exposed compartments if the substance meets the criteria for classification as dangerous according to Directive 67/548/EEC or Directive 1999/45/EC, or is assessed to be a PBT or vPvB. However, it is believed that the potential for environmental effects associated with this use of 2,4,7,9-Tetramethyldec-5-yne-4,7-diol is already inherently addressed as part of the registration procedure for plant protection products under Directive 91/414/EEC."*

This information requirement is triggered in case the CSA indicates the need for further investigation on long-term aquatic toxicity (Annex I, Section 4; Annex XIII, Section 2.1), such as if the substance is a potential PBT substance (ECHA Guidance R.11.4).

As already explained in the Appendix A Section 3 above, the Substance is a potential PBT/vPvB substance. Therefore, the CSA indicates the need for long-term aquatic toxicity investigation.

In your comments to the draft decision, you agree to carry out a study on long-term toxicity testing on fish only, if this is triggered, i.e. in case the CSA (including PBT/vPvB assessment and risk characterisation) indicates the need to investigate further effects on aquatic organisms.

The examination of the available information or adaptations, as well as the selection of the requested test and the test design are addressed in Appendix B Section 3.

5. Simulation testing on ultimate degradation in surface water

Further degradation testing must be considered if the chemical safety assessment (CSA) according to Annex I indicates the need to investigate further the degradation of the substance (Annex VIII, Section 9.2., Column 2).

You have provided the following information in the dossier on the degradation simulation in water: "*Due to an enhanced biodegradation test according to International Standard ISO 9439, Annex D, the test substance is supposed to persist in the environment. Therefore, further testing on biodegradation is supposed to not reveal any further useful information for the assessment of the substance. Hence, no testing on soil/sediment/surface water biodegradation is performed.*"

This information requirement is triggered in case the chemical safety assessment (CSA) indicates the need for further degradation investigation (Annex I, Section 4; Annex XIII, Section 2.1), such as if the substance is a potential PBT/vPvB substance (ECHA Guidance R.11.4).

As already explained in the Appendix A Section 3. above, the Substance is a potential PBT/vPvB substance. Therefore, the CSA indicates the need for further degradation investigation.

For ECHA's response, to your comments to the draft decision regarding this request, see request B.4. below.

The examination of the available information or adaptations, as well as the selection of the requested test and the test design are addressed in Appendix B Section 4.

6. Identification of degradation products

Further degradation testing must be considered if the chemical safety assessment (CSA) according to Annex I indicates the need to investigate further the degradation of the substance (Annex VIII, Section 9.2., Column 2).

You have provided the following information in the dossier on the degradation products: "*Due to an enhanced biodegradation test according to International Standard ISO 9439, Annex D, the test substance is supposed to persist in the environment. Therefore, further testing on biodegradation is supposed to not reveal any further useful information for the assessment of the substance. Hence, no testing on soil/sediment/surface water biodegradation is performed.*"

This information requirement is triggered in case the chemical safety assessment (CSA) indicates the need for further degradation investigation (Annex I, Section 4; Annex XIII, Section 2.1), such as if the substance (itself or any of its constituent or impurity present in concentration ≥ 0.1% (w/w) or relevant transformation/degradation product) is a potential PBT/vPvB substance (ECHA Guidance R.11.4).

As already explained in the Appendix A Section 3. above, the Substance is a potential PBT/vPvB substance. Therefore, the CSA indicates the need for further degradation investigation including identification of degradation products.

For ECHA's response, to your comments to the draft decision regarding this request, see request B.5. below.

The examination of the available information or adaptations, as well as the selection of the requested test and the test design are addressed in Appendix B Section 5.

7. Bioaccumulation in aquatic species

Bioaccumulation in aquatic species is required for the purpose of PBT/vPvB assessment (Annex I, Sections 0.6.1 and 4 to REACH).

You have provided the following information in the dossier on bioaccumulation:

- Key study with analogue substance, Surfynol 124 (non-guideline study - Bioconcentration test of chemical substances in fish and shellfish, 2010)

This information requirement is triggered in case the chemical safety assessment (CSA) indicates the need for further investigation on bioaccumulation in aquatic species (Annex I, Section 4; Annex XIII, Section 2.1), such as if the substance is a potential PBT/vPvB substance (ECHA Guidance R.11.4).

As already explained in the Appendix A Section 3. above, the Substance is a potential PBT/vPvB substance. Therefore, the CSA indicates the need for bioaccumulation investigation.

For ECHA's response, to your comments to the draft decision regarding this request, see request B.6. below.

The examination of the available information or adaptations, as well as the selection of the requested test and the test design are addressed in Appendix B Section 6.

Appendix B: 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.

Although you do not explicitly claim an adaptation, ECHA understands that the information provided was submitted in order to meet the required information by way of adaptation under Annex, Section XI 1.1.2. This adaptation rule enables registrants to claim that the data from experiments not carried out according to GLP or the test methods referred to in Article 13(3) can be considered equivalent to data generated by those test methods where a number of cumulative conditions are met, in particular:

1. Adequate and reliable coverage of the key parameters foreseen to be investigated in the corresponding test methods referred to in Article 13(3), in this case OECD TG 414: dosing of the Substance from implantation until the day prior to scheduled caesarean section, examination of the dams for weight and histopathology of the thyroid gland/thyroid hormone measurements/gravid uterus weight/uterine content, examination of the foetuses external, skeletal and soft tissue alterations (variations and malformations)/ measurement of anogenital distance in live rodent foetuses;
2. Adequacy for the purpose of classification and labelling and/or risk assessment.

You have provided a Single Generation Reproduction Study in the Rat (Fo-F1a) with 91-Day Feeding Study (F1a Rats) (1979, no guideline or GLP compliant).

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

1. The above key parameters of a OECD TG 414 are not met by the provided study, because you have not provided information following OECD TG 414. Instead, you have provided a "Single Generation Reproduction Study" (no TG, no GLP compliance). In this study, structural malformations and variations are not investigated as required in the PNDT study (OECD TG 414). Furthermore, weight and histopathology of the thyroid gland has not been examined and thyroid hormone measurements have not been conducted as required in OECD TG 414.

Based on the above, the provided information cannot be considered to be adequate for classification and labelling and/or risk assessment.

Therefore, your adaptation is rejected and the information requirement is not fulfilled.

In your comments to the draft decision, you agree to carry out a study on pre-natal developmental toxicity test (PNDT) in one species. You argue that it is justified to perform both studies on reprotoxicity in a stepwise approach and that it has to be started first with the screening study on reproductive/developmental toxicity (see A.1.) following by the PNDT study. Therefore you ask to prolong the timeline to exact date – 24 months from the date of the decision accordingly. Regarding the deadline extension, see ECHA's response in Appendix E below.

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 rat or rabbit as preferred species with oral[3] administration of the Substance.

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

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.).

You have provided following information for the long-term toxicity testing on aquatic invertebrates in the registration dossier: "*"2,4,7,9-Tetramethyldec-5-yne-4,7-diol is used as a co-formulant in plant protection products. In-field use of plant protection products can result in exposure to agricultural soil or to edge-of-field water bodies mainly as a result of spray drift (spray formulations only).Therefore, in accordance with the requirements under REACH, it is necessary to conduct risk characterisation for the potentially exposed compartments if the substance meets the criteria for classification as dangerous according to Directive 67/548/EEC or Directive 1999/45/EC, or is assessed to be a PBT or vPvB. However, it is believed that the potential for environmental effects associated with this use of 2,4,7,9-Tetramethyldec-5-yne-4,7-diol is already inherently addressed as part of the registration procedure for plant protection products under Directive 91/414/EEC."*

We have assessed this information and identified the following issues:

As summarised in the Appendix on Reasons common to several requests, Section on Assessment of your information provided for effects on terrestrial organisms and for long-term aquatic toxicity, your adaptation of this standard information requirement based on use of the Substance in the plant protection products under Directive 91/414/EEC is not acceptable and is rejected.

Under Section 9.1., Column 2, Annex IX to REACH, the study may be omitted if the CSA does not indicate the need for further aquatic toxicity testing. The CSA does indicate such need (Annex I, Section 4; Annex XIII, Section 2.1) if the substance is a potential PBT substance (ECHA Guidance R.11.4).

As already explained in the Appendix A.3 above, the Substance is a potential PBT. Therefore, the CSA indicates the need for long-term aquatic toxicity investigation.

Therefore, you have not demonstrated that the CSA does not indicate the need for further long-term aquatic toxicity testing and your adaption is rejected.

In your comment to the draft decision, you agree to carry out a study on long-term toxicity testing on aquatic invertebrates to investigate further effects on aquatic organisms.

On this basis, the information requirement is not fulfilled.

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.).

You have provided following information for the long-term toxicity testing on fish in the registration dossier: "*2,4,7,9-Tetramethyldec-5-yne-4,7-diol is used as a co-formulant in plant protection products. In-field use of plant protection products can result in exposure to agricultural soil or to edge-of-field water bodies mainly as a result of spray drift (spray formulations only).Therefore, in accordance with the requirements under REACH, it is necessary to conduct risk characterisation for the potentially exposed compartments if the substance meets the criteria for classification as dangerous according to Directive 67/548/EEC*

or Directive 1999/45/EC, or is assessed to be a PBT or vPvB. However, it is believed that the potential for environmental effects associated with this use of 2,4,7,9-Tetramethyldec-5-yne-4,7-diol is already inherently addressed as part of the registration procedure for plant protection products under Directive 91/414/EEC."

We have assessed this information and identified the following issues:

As summarised in the Appendix on Reasons common to several requests, Section on Assessment of your information provided for effects on terrestrial organisms and for long-term aquatic toxicity, your adaptation of this standard information requirement based on use of the Substance in the plant protection products under Directive 91/414/EEC is not acceptable and is rejected.

Under Section 9.1., Column 2, Annex IX to REACH, the study may be omitted if the CSA does not indicate the need for further aquatic toxicity testing. The CSA does indicate such need (Annex I, Section 4; Annex XIII, Section 2.1) if the substance is a potential PBT substance (ECHA Guidance R.11.4).

As already explained in the Appendix A Section 3. above, the Substance is a potential PBT. Therefore, the CSA indicates the need for long-term aquatic toxicity investigation.

Therefore, you have not demonstrated that the CSA does not indicate the need for further long-term aquatic toxicity testing and your adaption is rejected.

In your comment to the draft decision, you agree to carry out a study on long-term toxicity testing on fish only if this is triggered, i.e. in case the CSA (including PBT/vPvB assessment and risk characterisation) indicates the need to investigate further effects on aquatic organisms.

ECHA notes that following the recent Boad of Appeal decision taken for the case (A-011-2018), Annex IX, Section 9.1., Column 2 does not allow omitting the need to submit information on long-term toxicity to fish under Column 1. It must be understood as a trigger for providing further information on long-term toxicity to fish if the chemical safety assessment according to Annex I indicates the need.

On this basis, the information requirement is not fulfilled.

Study design

To fulfil the information requirement for the Substance, the Fish, Early-life Stage Toxicity Test (test method OECD TG 210) is the most appropriate (ECHA Guidance R.7.8.2.).

4. Simulation testing on ultimate degradation in surface water

Simulation testing on ultimate degradation in surface water is an information requirement under Annex IX to REACH (Section 9.2.1.2.).

You have adapted this information requirement according to Annex IX, Section 9.2., Column 2 with the following justification: "*Due to an enhanced biodegradation test according to International Standard ISO 9439, Annex D, the test substance is supposed to persist in the environment. Therefore, further testing on biodegradation is supposed to not reveal any further useful information for the assessment of the substance. Hence, no testing on soil/sediment/surface water biodegradation is performed.*"

We have assessed this information and identified the following issues:

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).

As explained in the Appendix A Section 3. based on negative results of ready and inherent biodegradability studies the Substance is potential P/vP. Futhermore, it is explained in the same section that the Substance is a potential PBT/vPvB substance. Therefore, the CSA indicates the need for further degradation investigation. As explained in the ECHA Guidance R.11, negative results of ready, enhanced ready and inherent biodegradability tests do not allow to conclude on P or vP status of the substance and further degradation investigation is necessary.

Therefore, you have not demonstrated that the CSA does not indicate the need for further biotic degradation testing and your adaption is rejected.

In your comments to the draft decision, you indicate that the data is requested in order to clarify the potential PBT/vPvB properties of the substance. You propose to employ a stepwise approach, i.e. first clarify the bioaccumulation potential of the substance and based on the outcome of it to conclude, whether further examination on degradation of the substance is needed to clarify whether the substance fulfills the PBT/vPvB criteria. You further claim that if the substance does not fulfil the B criterion, the PBT/vPvB characteristics do not apply and consequently a generation of further data for the PBT/vPvB assessment are not necessary.

According to the Annex XIII PBT/vPvB assessment shall also take account of the PBT/vPvB properties of relevant constituents of a substance and relevant transformation/degradation products. Therefore, after addressing bioaccumulation potential only of the major constituent or of some of constituents of the Substance, may not be possible to conclude if the substance is a potential PBT/vPvB substance and consequently, not possible to justify omission of the simulation degradation testing and identification of degradation products.

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 309 test, by following the pelagic test option with natural surface water containing approximately 15 mg dw/L of suspended solids (acceptable concentration between 10 and 20 mg dw/L) (ECHA Guidance R.11).

- 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 309.

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).

Under Annex XIII, you must assess the PBT/vPvB properties of the relevant constituents of the Substance. Therefore, the persistence of each relevant constituent present in concentrations at or above 0.1% (w/w) or, if not technically feasible, in concentrations as low as technically detectable must be assessed. Alternatively, you would have to justify why you consider these not relevant for the PBT/vPvB assessment.

5. Identification of degradation products

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

You have adapted this information requirement according to Annex IX, Section 9.2., Column 2 with the following justification: *"Due to an enhanced biodegradation test according to International Standard ISO 9439, Annex D, the test substance is supposed to persist in the environment. Therefore, further testing on biodegradation is supposed to not reveal any further useful information for the assessment of the substance. Hence, no testing on soil/sediment/surface water biodegradation is performed."*

We have assessed this information and identified the following issues:

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 (itself or any of its constituent or impurity present in concentration ≥ 0.1% (w/w) or relevant transformation/degradation product) is a potential PBT/vPvB substance (ECHA Guidance R.11.4).

As explained in the Appendix A Section 3. based on negative results of ready and inherent biodegradability studies the Substance is potential P/vP. Futhermore, it is explained in the same section that the Substance is a potential PBT/vPvB substance. Therefore, the CSA indicates the need for further degradation investigation. As explained in the ECHA Guidance R.11, negative results of ready, enhanced ready and inherent biodegradability tests, does not allow conclude on P or vP status of the substance and further degradation investigation is necessary.

Therefore, you have not demonstrated that the CSA does not indicate the need for further biotic degradation testing including identification of degradation products and your adaption is rejected.

For ECHA's response, to your comments to the draft decision regarding this request, see request B.4. above.

On this basis, the information requirement is not fulfilled.

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 K_{ow} and potential toxicity of the transformation/degradation may need to be investigated. You may obtain this information from the degradation study requested in the Appendix B, Section 4 on simulation testing on ultimate degradation in surface water 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 309 (Appendix B, Section on simulation testing on ultimate degradation in surface water) must be conducted at 12°C and at a test concentration < 100 µg/L. 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, *e.g.* 20°C) and at higher application rate (*i.e.* > 100 µg/L).

6. Bioaccumulation in aquatic species

Bioaccumulation in aquatic species is a standard information requirement under Annex IX to REACH (Section 9.3.2.).

In the registration dossier you have provided following information on bioaccumulation:

- Adaptation for this information requirement by using Grouping of substances and read-across approaches under Annex XI, Section 1.5. and in support of your adaptation you have provided following information for this endpoint in your dossier:

- Key study with analogue substance Surfynol 124 (non-guideline study - Bioconcentration test of chemical substances in fish and shellfish, 2010)

We have assessed this information and identified the following issues:

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 (addressed under 'Scope of the grouping'). 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)').

Additional information on what is necessary when justifying a read-across approach can be found in the ECHA Guidance[4] and related documents[5, 6].

A. Scope of the grouping

i. Description of the grouping

In your registration dossier you have formed a group (category) of 'Acetylenic geminalic diols'. You have provided a read-across justification document in IUCLID Section 0.

For the purpose of this decision, the following abbreviations are used for the group members:

[4] Guidance on information requirements and chemical safety assessment Chapter R.6: QSARs and grouping of Chemicals. 2008 (May) ECHA, Helsinki. 134. pp. Available online: https://echa.europa.eu/documents/10162/13632/information_requirements_r6_en.pdf/77f49f81-b76d-40ab-8513-4f3a533b6ac9

[5] Read-Across Assessment Framework (RAAF). 2017 (March) ECHA, Helsinki. 60 pp. Available online: Read-Across Assessment Framework (https://echa.europa.eu/support/registration/how-to-avoid-unnecessary-testing-on-animals/grouping-of-substances-and-read-across)

[6] Read-across assessment framework (RAAF) - considerations on multi-constituent substances and UVCBs. 2017 (March) ECHA, Helsinki. 40 pp. Available online: https://doi.org/10.2823/794394

[1] Surfynol 104 2,4,7,9-tetramethyldec-5-yne-4,7-diol (EC No. 204-809-1) (the Substance);
[2] Surfynol 124 2,5,8,11-tetramethyldodec-6-yne-5,8-diol (EC No. 269-348-0) (source substance for bioaccumulation);
[3] Surfynol 440 ethoxylated 2,4,7,9-tetramethyldec-5-yne-4,7-diol (EC No. 500-022-5);
[4] Surfynol 2502 ethoxylated propoxylated 2,4,7,9-tetramethyldec-5-yne-4,7-diol (EC No. 638-783-1);
[5] Envirogem AD01 2,4,7, 9-tetramethyl-4,7-dodecanediol (EC No. 451-160-7).

You provide the following reasoning for the grouping the substances: *"Acetylenic geminalic diols are considered a chemical category based on structural similarity and similar properties in environmental and biological systems."*

You define the structural basis for the grouping as *"members of the category begin with an acetylene group as their core structure; in one member, this acetylene group has been fully hydrogenated. [...] Alpha to the acetylene are the geminal hydroxyl groups, which can be derivatized with ethoxylates and propoxylates in order to achieve desired functionalities of surfactants. Distal to the geminal hydroxyl groups is either an isobutyl group (methyl isopropyl) or an isopentyl group (ethyl isopropyl). These are short chain alkyls displaying an incremental increase in carbon chain length. All substances have two stereogenic centers (chiral carbons) in alpha-position to the carbon triple bond."* ECHA understands that this is the applicability domain of the grouping and will assess your predictions on this basis.

ii. Assessment of the grouping

ECHA notes the following shortcomings with regards to your grouping approach.

Characterisation of the group members

Annex XI, Section 1.5 of the REACH Regulation provides that *"substances whose physicochemical, toxicological and ecotoxicological properties are likely to be similar or follow a regular pattern as a result of chemical similarity may be considered as group."*

According to the ECHA Guidance, *"in identifying a category, it is important that all potential category members are described as comprehensively as possible"*, because the purity profile and composition can influence the overall toxicity/properties of the potential category members.[7] Therefore, qualitative and quantitative information on the compositions of the category members should be provided to confirm the category membership.

Furthermore, the provided information for categories consisting of UVCB (Unknown or Variable composition, Complex reaction products or of Biological materials) substances needs to include qualitative compositional information of the individual constituents of the category members; as well as quantitative characterisation in the form of information on the concentration of the individual constituents of these substances; to the extent that this is measurable.[8]

You have defined the applicability domain of the category as explained above. Your read-across justification document contains compositional information for the members of your category. Several category members (Surfynol 440, Surfynol 2502) are UVCBs including

[7] Guidance on information requirements and chemical safety assessment Chapter R.6: QSARs and grouping of Chemicals, Section R.6.2.4.1
[8] Guidance on information requirements and chemical safety assessment Chapter R.6: QSARs and grouping of Chemicals, Section R.6.2.5.5

ethoxylated and propoxylated diols of various carbon chain lengths. The degree of ethoxylation or propoxylation is not provided for these category members.

Without consideration of the distribution of the ethoxylation and propoxylation amongst constituents with different carbon chain lengths, and information on the composition of test materials, no qualitative or quantitative comparative assessment of the different category members can be completed. Therefore, the category membership cannot be confirmed.

B. Predictions for properties

You have provided the following reasoning for the prediction of bioaccumulation property: *"Surfynol®124, with the highest octanol/water partition coefficient, was selected to be tested in a bioaccumulation assay in fish, and found to have a low propensity for bioconcentration (BCF < 24). Category members with lower log Kow values would be expected to have lower BCF values. Therefore, these substances can be considered "not bioaccumulative"".*

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 shortcomings with regards to the prediction of the bioaccumulation.

1. 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"*[9]. 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 information to confirm your claimed worst-case prediction.

A log Kow may be used to support assessment of potential for bioaccumulation if the partitioning to lipids is the sole mechanism driving the bioaccumulation potential of a substance. For some groups of substances, such as surfactants, other partitioning mechanisms may drive bioaccumulation (e.g. binding to protein/cell membranes). For this reason log Kow is not considered a valid descriptor of the bioaccumulation potential for such substances (ECHA Guidance R.7c, Appendix R.7.10-3.

In your read-across hypothesis, you indicate that *"Category members with lower log Kow values would be expected to have lower BCF values."*

In the registration dossier, including category justification document, you note that all category members are surfactants. There is no evidence provided in the dossier that the partitioning to lipids is the sole mechanism driving the bioaccumulation potential of these substances.

Therefore, information used by you to support your hypothesis that source substance is the

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

worst-case for the prediction of bioaccumulation of the Substance is not reliable.

In the absence of such reliable supporting information, you have not established that the source substance Surfynol 124 constitutes a worst-case for the prediction of the property under consideration of the Substance. Therefore you have not provided sufficient supporting information to strengthen the rationale for the read-across.

2. *Quality of the source study*

According to Annex XI, Section 1.5., if the grouping concept is applied then in all cases the results to be read across should:

- be adequate for the purpose of classification and labelling and/or risk assessment; and
- have adequate and reliable coverage of the key parameters addressed in the corresponding test method referred to in Article 13(3).

According to the provisions of Annex IX, Section 9.3.2. information on bioaccumulation in aquatic species as specified in the OECD TG 305 shall be provided. In the dossier you indicated that the route of exposure is 'feed', so ECHA understands that the test with dietary exposure of fish was performed. To comply with OECD TG 305 requirements the following requirements must be met:

- Coverage of the key parameter which is the bioaccumulation potential of the test substance in whole fish, which must be determined based on the following parameters:
  1) the uptake rate constant (k_1) and loss rate constants including the depuration rate constant (k_2), and/or
  2) the kinetic bioconcentration factor (BCF_K), and/or
  3) the dietary biomagnification factor (BMF).

- For a test to be valid the following conditions apply:
  1) the concentration of the test substance in fish food before and at the end of the uptake phase is within a range of ± 20% (based on at least three samples at both time points);
  2) a high degree of homogeneity of substance in the spiked food is demonstrated (i.e. less than ± 15% from the mean in at least three sample);
  3) concentrations of test substance is below detection level, or only at typical trace levels, in un-spiked food or control fish tissues;
  4) Mortality or other adverse effects/disease in both control and test group fish should be ≤10% at the end of the test.
- a study can be terminated at the end of the uptake period (or with the second depuration sample) only if:
  1) all validity criteria are fulfilled, and
  2) the lack of uptake is not due to some other shortcoming of the test, and
  3) appropriate justification is provided (*e.g.* analysis of faeces for undigested test substance as part of a "mass balance" approach);
- the analytical method used for the quantification of the test material in the feed and in fish tissues is described;
- the BCF/BMF is based on the total concentration in the fish (*i.e.* per total wet weight of the fish);
- tabulated test material concentration data in fish, mean measured concentration at end of uptake, the derived (overall) depuration rate constant and concentration in fish at start of depuration phase are provided;
- the results of the determination of the test substance in test and control diets at least in triplicate are reported;
- method of estimation of the corresponding BCF value from the dietary test is reported.

However, you have provide a study record without information on the above key parameters and validity criteria.

Without this information, you have not demonstrated that study fulfils the OECD TG 305's key parameters and validity criteria and therefore it is rejected.

C. Conclusions on the read-across approach

As explained above, you have not established that relevant properties of the Substance can be predicted from data on the analogue substance. 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.

In your comments to the draft decision, you note that you will first revise robust study summary of the existing study for the analogue substance and check, whether this study fulfills the information requirement. Additionally, you state you will strengthen the read-across approach for this information requirement. Furthermore, you agree to perform bioaccumulation in aquatic species study, if the existing data do not fulfill the information requirement.

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 Section 1.5 of Annex XI to REACH. If it fails and the resulting data does not support, or even contradict, your read-across hypothesis, you remain responsible for complying with this decision by the set deadline.

Study design

Bioaccumulation in fish: aqueous and dietary exposure (Method EU C.13 / OECD TG 305) is the preferred test to investigate bioaccumulation (ECHA Guidance 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.

You may only conduct the study using the dietary exposure route (OECD 305-III) if you justify and document that testing through aquatic exposure is not technically possible as indicated above. You must then 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).

Under Annex XIII, you must assess the PBT/vPvB properties of the relevant constituents of the Substance. Therefore, the bioaccumulation of each relevant constituent present in concentrations at or above 0.1% (w/w) or, if not technically feasible, in concentrations as low as technically detectable must be assessed. Alternatively, you would have to justify why you consider these not relevant for the PBT/vPvB assessment.

7. Long-term toxicity testing on terrestrial invertebrates OR Long-term toxicity to terrestrial plants

Short-term toxicity testing on invertebrates and plants are an information requirements under Annex IX to REACH (Sections 9.4.1. and 9.4.3. respectively). Long-term toxicity testing on invertebrates and plants must be considered (Annex IX, Section 9.4., Column 2) if the substance has a high potential to adsorb to soil or is very persistent.

You have provided the following information on effects on terrestrial organisms: "*2,4,7,9-Tetramethyldec-5-yne-4,7-diol is used as a co-formulant in plant protection products. In-field use of plant protection products can result in exposure to agricultural soil or to edge-of-field water bodies mainly as a result of spray drift (spray formulations only). Therefore, in accordance with the requirements under REACH, it is necessary to conduct risk characterisation for the potentially exposed compartments if the substance meets the criteria for classification as dangerous according to Directive 67/548/EEC or Directive 1999/45/EC, or is assessed to be a PBT or vPvB. However, it is believed that the potential for environmental effects associated with this use of 2,4,7,9-Tetramethyldec-5-yne-4,7-diol is already inherently addressed as part of the registration procedure for plant protection products under Directive 91/414/EEC* "

We have assessed this information and identified the following issues:

a) Triggering of the long-term toxicity testing

According to ECHA Guidance R.7c, Section R.7.11.6.3. 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 (default setting, unless classified as readily biodegradable) are considered very persistent in soil.

Based on the information provided in the registration dossier and concluded by you, the Substance is not readily biodegradable and there is no half-life of the Substance in soil available, therefore the Substance is considered to be very persistent (ECHA Guidance R.7c).

Thus, the long-term toxicity testing on terrestrial organisms is required.

b) Rejection of adaptation

As summarised in the Appendix on Reasons common to several requests, Section on Assessment of your information provided for effects on terrestrial organisms and for long-term aquatic toxicity, your adaptation of these standard information requirements based on use of the Substance in the plant protection products under Directive 91/414/EEC is not acceptable and is rejected.

c) Rejection of adaptation on the basis of needs of screening risk assessment

According to Annex IX, Section 9.4., Column 2 in the absence of toxicity data for soil organisms, the equilibrium partitioning method (EPM) may be applied to assess the hazard to soil organisms.

According to ECHA Guidance R.7c, Section R.7.11.6, where there is adequate data available to derive a PNEC for aquatic organisms, this PNEC can be used in a screening assessment of risks for soil through the use of the EPM approach.

In the context of an integrated testing strategy for soil toxicity, the Guidance R.7c, Section R.7.11.6 advocates performing an initial screening assessment based upon the EPM, together with a confirmatory long-term soil toxicity test for the substances falling into soil hazard category 3.

In the CSR, predicted no-effect concentration (PNEC) for soil was derived by you by using EPM from the PNEC for aquatic organisms and used to prove safe use of the Substance for soil compartment.

Based on the criteria given in ECHA Guidance R.7c, Section R.7.11.6 and information available in the registration dossier the Substance is considered as not very toxic to aquatic organisms (EC/LC50 > 1 mg/L for algae, daphnia or fish) and as very persistent in soil (as summarised in subsection (a) above). Thus, the Substance would fall into soil hazard category 3.

Therefore, a confirmatory long-term soil toxicity test is needed.

In your comment to the draft decision, you agree to carry out a study on long-term toxicity on terrestrial species in order to evaluate the risk for this compartment.

On this basis, the information requirement is not fulfilled.

Study design

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 requirement for long-term toxicity testing on terrestrial invertebrates.

ECHA notes that when log Kow >5 or log Koc >4, the test OECD 232 is not appropriate as the dominant route of exposure for Collembolans is via pore water.

OECD TG 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.

Terrestrial plants, growth test (OECD TG 208 with at least six species) and Soil Quality – Biological Methods – Chronic toxicity in higher plants (ISO 22030) are each considered capable of generating information appropriate for the fulfilment of the information requirement for long-term toxicity testing on terrestrial plants.

ECHA is not in a position to determine the most appropriate test protocol, since such determination is dependent upon species sensitivity and substance properties. You are to apply the most appropriate and suitable test guideline among those listed above.

8. Effects on soil micro-organisms

Effects on soil micro-organisms is an information requirement under Annex IX to REACH (Section 9.4.2.).

You have provided the following information on effects on terrestrial organisms: "*2,4,7,9-Tetramethyldec-5-yne-4,7-diol is used as a co-formulant in plant protection products. In-field use of plant protection products can result in exposure to agricultural soil or to edge-of-field water bodies mainly as a result of spray drift (spray formulations only). Therefore, in accordance with the requirements under REACH, it is necessary to conduct risk characterisation for the potentially exposed compartments if the substance meets the criteria for classification as dangerous according to Directive 67/548/EEC or Directive 1999/45/EC, or is assessed to be a PBT or vPvB. However, it is believed that the potential for environmental effects associated with this use of 2,4,7,9-Tetramethyldec-5-yne-4,7-diol is already inherently addressed as part of the registration procedure for plant protection products under Directive 91/414/EEC.*"

We have assessed this information and identified the following issue:

a) Triggering of the need for soil micro-organisms testing

ECHA emphasises that the intrinsic properties of soil microbial communities are not addressed through the EPM extrapolation method and therefore the potential adaptation possibility outlined for the information requirement of Annex IX, Section 9.4. does not apply for the present endpoint.

b) Rejection of adaptation

As summarised in the Appendix on Reasons common to several requests, Section on Assessment of your information provided for effects on terrestrial organisms and for long-term aquatic toxicity, your adaptation of these standard information requirements based on use of the Substance in the plant protection products under Directive 91/414/EEC is not acceptable and is rejected.

In your comment to the draft decision, you propose to employ a stepwise approach. In the first step you propose to perform the study on terrestrial species (invertebrates or plants) and based on the outcome of this study, risk assessment for the soil compartment has to be evaluated. You state that only if a risk for the soil is indicated, the soil micro-organisms study would be conducted.

As outlined in Appendix E below, EPM extrapolation is not applicable for this information requirement as the intrinsic properties of soil microorganism communities are not addressed through this method.

On this basis, the information requirement is not fulfilled.

c) Study design

According to ECHA Guidance R.7c, Section R.7.11.3.1., the nitrogen transformation test is considered sufficient for most non-agrochemicals. However, as the substance has identified agrochemical uses, ECHA considers that both the nitrogen (EU C.21./OECD TG 216) and carbon transformation (EU C.22./OECD TG 217) tests should be performed simultaneously.

Appendix C: 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[10].

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[11].

[10] https://echa.europa.eu/practical-guides
[11] https://echa.europa.eu/manuals

Appendix D: 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 E: 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 5 November 2019.

The decision making followed the procedure of Article 51 of the REACH Regulation, as described below:

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

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

Deadline to submit the requested information in this decision

The timeline indicated in the draft decision to provide the information requested is as follows:

A.1, A.5-6, B.1, B.4-5 by the deadline of exact date of 18 months from the date of the decision and all the remaining information listed by the deadline of exact date of 42 months from the date of the decision.

In your comments on the draft decision, you requested an extension of the timeline to 18 months to 30 months for the information requested under A.5-6 and B.4-5. You justified your request on the following grounds:

> *"The timeline of 18 months for the simulation testing on ultimate degradation in surface water and identification of degradation products indicated in the draft decision for submitting the update of the registration dossier containing the information required is too short. Please note, that this substance is considered as difficult to analyze due to its surface-active properties. From experience we are aware that we need to develop and validate sophisticated analytical methods, which is time consuming and will extend the timeframe of the study enormously. Further, this requested test is of a complex nature which requires careful planning and selection of a reliable testing facility who is able to carry out such tests. Experience shows that these activities require a considerable period of time. Last not least, if the proposed sequential testing approach is implemented, also the timeline has to be extended accordingly. For these studies, at least 24 months have to be calculated including experimental setup, synthesis of the radiolabeled substance, analytical work and reporting. It is not clear, if experienced laboratories are able to start such type of studies immediately. Additionally there are the same data requests in other draft decisions on compliance checks for the same group of substances, all within the category. These are: EC 204-809-1; EC 500-022-5; EC 451-160-7 and EC 269-348-0. So it would be best to perform this type of study for all of the relevant substances in the same laboratory. Which might be difficult to deal in parallel and needs additional time for the laboratory. Therefore, we ask to prolong the timeline to at least 30 months."*

In support of your request you provided document from the test laboratory justifying the extension of the deadline. In the document it is explained that the testing might take between 16-26 months.

It is not clear from the documentation whether longer or shorter testing period would be needed for the Substance. Therefore, in order not to delay the testing, mean duration of 21 month for the testing is granted with additional 3 months to cover necessary administrative steps. In respect of the sequential testing, as noted in the Appendix D above, it is advised to first conclude whether the Substance (including relevant constituents and relevant transformation/degradation products) fulfils the Annex XIII criteria for P and vP, and then continue with the assessment for bioaccumulation.

Therefore, on these grounds, ECHA has partially granted the request and set the deadline to 24 months for the information requested under A.5-6 and B.4-5.

For endpoint request B.1. you request an extension of the deadline from 18 to 24 to enable to perform the studies on reprotoxicity in a stepwise approach. However, the present deadline of 18 months already allows for sequential testing.

Therefore, ECHA has not extended the deadline for request B.1.

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 F: List of references - ECHA Guidance[12] 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)[13]

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

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[14]

[12] https://echa.europa.eu/guidance-documents/guidance-on-information-requirements-and-chemical-safety-assessment
[13] https://echa.europa.eu/support/registration/how-to-avoid-unnecessary-testing-on-animals/grouping-of-substances-and-read-across
[14] 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 G: 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]
[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.