EUROPEAN CHEMICALS AGENCY

Helsinki, 09 July 2018

Addressee: [redacted]

Decision number: CCH-D-2114412576-50-01/F
Substance name: Tall oil
EC number: 232-304-6
CAS number: 8002-26-4
Registration number: [redacted]
Submission number: [redacted]
Submission date: 10/12/2013
Registered tonnage band: Over 1000

DECISION ON A COMPLIANCE CHECK

Based on Article 41 of Regulation (EC) No 1907/2006 (the REACH Regulation), ECHA requests you to submit information on:[1]

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

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

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

4. **Extended one-generation reproductive toxicity study (Annex X, Section 8.7.3.; test method: EU B.56./OECD TG 443) in rats, oral route with the registered substance specified as follows:**
   - **Ten weeks premating exposure duration for the parental (P0) generation;**
   - **Dose level setting shall aim to induce some toxicity at the highest dose level;**
   - **Cohort 1A (Reproductive toxicity);**
   - **Cohort 1B (Reproductive toxicity) with extension to mate the Cohort 1B animals to produce the F2 generation;**

5. **Ready biodegradability (Annex VII, Section 9.2.1.1.) with the block 10 constituents of the registered substance using one of the following tests;**

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

[1] No testing for endpoints listed in Annexes IX or X to the REACH Regulation may be started or performed at this moment: A decision only becomes legally effective and binding for you after it has been adopted according to Article 51 of the REACH Regulation. ECHA will take the decision either after the date it has become clear that Member State competent authorities have not made any proposals to amend the draft decision or, where proposals to amend it have been made, after the date the Member State Committee reached a unanimous agreement on the draft decision.

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

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

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

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

6. **Long-term toxicity testing on aquatic invertebrates (Annex IX, Section 9.1.5.; test method: Daphnia magna reproduction test, EU C.20./OECD TG 211) with the block 10 constituents of the registered substance meeting P and B criteria;**

7. **Long-term toxicity testing on fish (Annex IX, Section 9.1.6.1.; test method: Fish, early-life stage (FELS) toxicity test, OECD TG 210) with the block 10 constituents of the registered substance meeting P and B criteria;**

8. **Simulation testing on ultimate degradation in surface water (Annex IX, Section 9.2.1.2.; test method: Aerobic mineralisation in surface water – simulation biodegradation test, EU C.25./OECD TG 309) at a temperature of 12 °C with the block 10 constituents of the registered substance unless they are readily biodegradable; the biodegradation of each relevant constituent present in concentration at or above 0.1% (w/w) of the registered UVCB substance or, if not technically feasible, in concentrations as low as technically detectable shall be assessed. This can be done simultaneously during the same study;**

9. **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 block 10 constituents of the registered substance unless they are readily biodegradable; the biodegradation of each relevant constituent present in concentration at or above 0.1% (w/w) of the registered UVCB substance or, if not technically feasible, in concentrations as low as technically detectable shall be assessed. This can be done simultaneously during the same study;**

10. **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 block 10 constituents of the registered substance unless they are readily biodegradable; the biodegradation of each relevant constituent present in concentration at or above 0.1% (w/w) of the registered UVCB substance or, if not technically feasible, in concentrations as low as technically detectable shall be assessed. This can be done simultaneously during the same study;**

11. **Identification of degradation products (Annex IX, 9.2.3.) using an appropriate test method with the block 10 constituents of the registered substance unless they are readily biodegradable;**

12. 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 block 10 constituents of the registered substance meeting P and vP criteria;

You are required to submit the requested information in an updated registration dossier by ***18 July 2022*** except for the information requested under point *1* for a sub-chronic toxicity study (90-day), which shall be submitted in an updated registration dossier by ***16 July 2019***. You may only commence the extended one-generation reproductive toxicity study as requested under point *4* after ***16 October 2019***, unless an indication to the contrary is communicated to you by ECHA before that date. You shall also update the chemical safety report, where relevant. The timeline has been set to allow for sequential testing.

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

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

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Appeal

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

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

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

Appendix 1: Reasons

(ECO)TOXICOLOGICAL INFORMATION

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

Your registration dossier contains for the endpoints sub-chronic toxicity (90-day) study (Annex IX, 8.6.2.) sub-chronic toxicity (90-day) study (Annex IX, Section 8.6.2.), pre-natal developmental toxicity study (Annex IX and X, Section 8.7.2.), extended one-generation reproductive toxicity study (Annex X, Section 8.7.3) and long-term toxicity testing on aquatic invertebrates (Annex IX, Section 9.1.5) adaptation arguments in form of a grouping and read-across approach under Annex XI, Section 1.5. of the REACH Regulation. ECHA has considered first the scientific and regulatory validity of your read-across approach in general before assessing the individual endpoints (sections 1, 2, 3, and 4).

0. Grouping of substances and read-across approach for toxicological and ecotoxicological information

You have sought to adapt the information requirements for a sub-chronic toxicity (90-day) study (Annex IX, Section 8.6.2.), pre-natal developmental toxicity study (Annex IX and X, Section 8.7.2.), extended one-generation reproductive toxicity study (Annex X, Section 8.7.3) and and long-term toxicity testing on aquatic invertebrates (Annex IX, Section 9.1.5) by applying a read-across approach in accordance with Annex XI, Section 1.5. According to Annex XI, Section 1.5., two conditions shall be necessarily fulfilled. Firstly, there needs to be structural similarity between substances which results in a likelihood that the substances have similar physicochemical, toxicological and ecotoxicological properties so that the substances may be considered as a group or category. Secondly, it is required that the relevant properties of a substance within the group may be predicted from data for reference substance(s) within the group (read-across approach). ECHA considers that the generation of information by such alternative means should offer equivalence to prescribed tests or test methods.

Based on the above, a read-across hypothesis needs to be provided. This hypothesis establishes why a prediction for a toxicological or ecotoxicological property is reliable and should be based on recognition of the structural aspects the chemical structures have in common and the differences between the structures of the source and registered substances[3]. This hypothesis explains why the differences in the chemical structures should not influence the toxicological/ecotoxicological properties or should do so in a regular pattern. The read-across approach must be justified scientifically and documented thoroughly, also taking into account the differences in the chemical structures. There may be several lines of supporting evidence used to justify the read-across hypothesis, with the aim of strengthening the case.

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

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

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

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

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

You consider to achieve compliance with the REACH information requirements for the registered substance Distilled Tall Oil (DTO) using data of structurally similar substances Crude Tall Oils (CTO), Phytosterol ester (EC number not given), TOFA (EC no 263-107-3), Gum rosin (EC number not given), Stanol fatty acid esters (EC number not given) and Rosin (CAS no 8050-09-0, EC number not given), hereafter the 'source substances'.

Your dossier contains read-across documentation as a separate attachment. This document is a list of studies provided for different endpoints for the registered substance (DTO – target substance) and for one of the sources substances of the read-across Crude Tall Oils (CTO). However, the other source substances are not covered in that document. In the Chemical Safety report a justification that addresses DTO and CTO has been given.

Concerning the other source substances of the read-across, you have not justified the read-across, or provided hypothesis and to explain how the prediction of the properties of the target substance of the read-across can be done.

B. ECHA's analysis of the grouping and read-across approach

Structural similarity

The target substance (DTO) is a mixture of abietic acids and fatty acid. For three of the other source substances, i.e. Gum rosin, TOFA and Rosin, no information on composition or structure has been provided. Hence, the structural similarity of the target and sources substances cannot be established. Concerning the fourth substance, Phytosterol esters, you have reported that it contains [redacted] total sterols and the percentage of total fatty acids is

[redacted]. As the registered substance does not contain sterols, ECHA considers that chemical and structural similarity between the registered substance and Phytosterol esters has not been demonstrated. Therefore, the first prerequisite of the read-across, namely that there needs to be structural similarity between substances, which results in a likelihood that the substances have similar toxicological properties, has not been met.

Crude Tall Oil is chemically different from the sources substances, which you have used for your read-across. Data on those substances, have been provided for the endpoints listed above. ECHA considered that the compositional information and the list of properties of CTO and DTO that you have provided have limited relevance for the read-across approach, which you propose for the four human health endpoints and for long-term toxicity to aquatic invertebrates listed above. CTO is chemically different from the other source substances for which you have provided studies to fulfil the information requirements by using read-across.

Read-across hypothesis and prediction of toxicological properties

ECHA considers that you have not provided a read-across hypothesis, which would provide the basis whereby you predict the properties of the registered substance from the source substances for the endpoints specified above.

You have not explained and justified how the relevant toxic properties of the registered (target) substance may be predicted from data on the source substances. On the contrary, the available studies indicate that the toxicological profiles of the source and target substances are not similar. For example, in the OECD TG 422 screening study made with the registered substance the following effects were observed: Increased male liver weight, increases in bilirubin and alkaline phosphatase, small decreases in albumin, white blood cell count and ovary weight in females, whereas no toxicity was observed in any of the studies made with sources substances.

An additional issue related to the prediction is that the available evidence suggests that the target substance is more toxic than the source substances. The difference of the toxicity between the source and target substances is up to two orders of magnitude. For example, the NOAEL in the OECD 422 study made with the registered substance was 100 mg/kg, whereas NOAEL obtained in the sub-chronic toxicity study with a read-across substance, TOFA, was 12,500 mg/kg.

The respective NOAELs of the studies provided, as well as an evaluation of the quality of the studies, are given in the endpoint-related sections of Appendix 1 below.
In your comment to the draft decision sent on 22 September 2017, you explained that since the time of the original submission of distilled tall oil (DTO) dossier, the consortium has generated new GLP compliant toxicity studies with Rosin (CAS 8050-09-7).

You consider that because Rosin is a component of DTO, read-across from studies made with Rosin may be relevant. The NOAELs for DTO and Rosin appear to be within the same order of magnitude and more similar than are the NOAELs for DTO and the previous source substance of the read-across.

For the read-across adaptation you are expected to explain and justify, why the differences in the composition do not lead to different toxicities between the target and sources substances of the read-across. The current explanation is considered incomplete.
Moreover, the test data (sub-chronic repeated dose toxicity study and pre-natal developmental toxicity study), which you highlight in your comments is now available for the proposed source substance Rosin (CAS 8050-09-7), has not been included in the dossier

of the registered substances, i.e. distilled tall oil. Therefore, ECHA considered that the information requirement for the three endpoints sub-chronic toxicity study (90-day), oral route, pre-natal developmental toxicity study in a first species, Pre-natal developmental toxicity study in a second species, Extended one-generation reproductive toxicity study have not been met with the data provided by the registrant.

C. Conclusion

As described above, ECHA has recognized that there are structural dissimilarities and differences in (eco)toxic properties between the source and target substances, and therefore you have not been able to demonstrate that a reliable prediction for (eco)toxicological properties of the registered substance can be made. Furthermore, you have not provided a well-founded hypothesis of (bio)transformation of the source and target substances to a common compound(s).

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

A "sub-chronic toxicity study (90 day)" is a standard information requirement as laid down in Annex IX, Section 8.6.2. of the REACH Regulation. Adequate information on this endpoint needs to be present in the technical dossier for the registered substance to meet this information requirement.

You have sought to adapt this information requirement according to Annex XI, Section 1.1.2. You have provided the following justification for the adaptation: "*In accordance with Section 1.1.2 of REACH Annex XI, the 90-day sub-chronic toxicity study (required in Section 8.6.2) does not need to be conducted because existing data are adequate for the purposes of classification and labelling and risk assessment.*" To support your adaptation you have provided the following information:

- Key study: "combined repeated dose toxicity study with the reproduction/developmental toxicity screening test with the registered substance", rat, oral (OECD TG 422); GLP, [redacted], 2002 (study report).
- A sub-chronic toxicity study with a read-across substance phytosterol ester was provided, rats, feeding ("closely following OECD TG 408"). Urine analysis is missing in this study.
- A sub-chronic toxicity study with a read-across substance TOFA, 61790-12-3 was provided, rats, feeding (similar to OECD TG 408). Urine analysis and histopathology are missing in this study.
- A non-guideline short-term study was provided, made with a read-across substance Gum rosin, rats, feeding (a non-guideline study). The quality of this study is compromised, because no specific results (e.g. on urine analysis, clinical chemistry and histopathology) are reported.

In addition, you have also sought to adapt this information requirement according to Annex XI, Section 1.5. of the REACH Regulation.

ECHA notes that the adaptation according to Annex XI, 1.1.2. requirement includes "adequate and reliable coverage of the key parameters" as a condition to be considered when examining whether the data - in this case the screening study OECD 422 - would be equivalent to the data generated by the corresponding test methods referred to in Article

13(3) of the REACH Regulation, in this case a sub-chronic toxicity study.

ECHA has considered, whether the information from the first study specified above, "combined repeated dose toxicity study with the reproduction/developmental toxicity screening test" study (OECD TG 422) with the registered substance ([redacted] 2002) meets the information requirement according to Annex XI, 1.1.2. ECHA has found that this study does not provide the information required by Annex IX, Section 8.6.2., because the duration of that study is shorter than 90 days, which is required according to Annex IX, Section 8.6.2.

Hence, the data generated from the OECD TG 422 screening studies are not considered as equivalent to the data generated in the sub-chronic toxicity study and consequently, do not meet the general rules for adaptation of annex XI, Section 1.1.2. Therefore, your adaptation of the information requirement according to Annex XI, 1.1.2. is rejected.

Concerning three studies made with read-across source substances as specified above, ECHA has evaluated the information you provided on read-across according to the provision of REACH Annex XI, Section 1.5. However, as explained in Appendix 1, section 0 of this decision, ECHA does not consider the read-across justification to be a reliable basis to predict the properties of the target substance and consequently, ECHA rejected the adaptation, which refers to Annex XI, 1.5. Therefore, ECHA has concluded that the information provided with the source substances cannot be used to adapt this information requirement.

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

ECHA has evaluated the most appropriate route of administration for the study. Based on the information provided in the technical dossier and/or in the chemical safety report, ECHA considers that the oral route - which is the preferred one as indicated in ECHA Guidance on information requirements and chemical safety assessment (July 2017) Chapter R.7a, section R.7.5.4.3 - is the most appropriate route of administration. More specifically, even though the information indicates that human exposure to the registered substance by the inhalation route is likely, the available information does not indicate a specific concern for local effects in the respiratory tract that would require information derived by the inhalation route. Hence, the test shall be performed by the oral route using the test method EU B.26./OECD TG 408.

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

Therefore, pursuant to Article 41(1) and (3) of the REACH Regulation, you are requested to submit the following information derived with the registered substance subject to the present decision: Repeated dose 90-day oral toxicity study (test method: EU B.26./OECD TG 408) in rats.

Notes for your consideration

ECHA notes that a revised version of OECD TG 408 was adopted this year by the OECD. This revised version contains enhancements of certain endocrine disrupting relevant parameters. You should test in accordance with the revised version of the guideline as published on the OECD website for adopted test guidelines (https://www.oecd-

ilibrary.org/environment/oecd-guidelines-for-the-testing-of-chemicals-section-4-health-effects_20745788).

Related to this endpoint ECHA has examined the DNEL derivation and has used ECHA Guidance R.8 (*Version of November 2012*) as the reference. Your approach in the DNEL derivation has been that you have chosen a 2-year oral rat study done with one constituent in distilled tall oil as the starting point for the DNEL derivation. However, the read-across from this substance was found unacceptable as pointed out in chapter 0 above. One reasons for the rejection of the read-across is that, according to the information you have provided, the target substance is more toxic that the source substances of the read-across. Therefore, the derivation of the DNEL cannot be based on the study made with the sources substance, as you have proposed.

Furthermore, ECHA notes that the assessment factors (AF) applied were neither derived in accordance to the default assessment factors recommended in the ECHA Guidance R.8 for DNEL derivation nor did you provide a full justification for the derivation of DNELs, which would be in line with Annex I, 1.4.1.

In particular, you have considered allometric scaling to address the uncertainty arising from interspecies variation due to differences in metabolic rate in the derivation of DNELs for long-term systemic effects via inhalation and dermal routes for workers, but you have not applied the additional default assessment factor of 2.5 to address the remaining interspecies differences.

If no substance specific data are available, the additional factor of 2.5 for other interspecies differences is to cover the uncertainty of toxicokinetic differences not related to metabolic rate and toxicodynamic differences. Furthermore, you have not given any justification for that.

As explained above, the information provided on DNEL for the registered substance in the chemical safety report does not meet the general provisions for preparing a chemical safety report as described in Annex I, 1.4.1.

Consequently, you should revise the DNELs for workers by applying a correct starting point for the DNEL derivation using the assessment factors recommended by ECHA that are appropriate in this case as specified above. Subsequently, you should re-assess the related risks.

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

A "pre-natal developmental toxicity study" (test method EU B.31./OECD TG 414) for a first species is a standard information requirement as laid down in Annex IX, Section 8.7.2. of the REACH Regulation. Adequate information on this endpoint needs to be present in the technical dossier for the registered substance to meet this information requirement.

You have sought to adapt this information requirement according to Annex XI, Section 1.1.2. You have provided the following justification for the adaptation: "*In accordance with Section 1.1.2 of REACH Annex XI, the pre-natal developmental toxicity study (required in Section 8.7.2) does not need to be conducted because existing data are adequate for the purposes of classification and labelling and risk assessment.*" To support your adaptation you have provided the following information:

- Key study: "combined repeated dose toxicity study with the reproduction/developmental toxicity screening test", rat, oral (equivalent or similar to OECD TG 422; GLP) with the registered substance, [redacted], 2002 (study report), rel. 1
- Supporting study: "pre-natal developmental toxicity study", rat, oral (equivalent or similar to OECD TG 415) with the analogue substance stanol fatty acid esters (EC or CAS number were not given), Slesinski 1999, (publication), rel. 1

In addition, ECHA notes that you have also sought to adapt this information requirement according to Annex XI, Section 1.5. of the REACH Regulation.

ECHA notes that the adaptation according to Annex XI, 1.1.2., requirement includes "*adequate and reliable coverage of the key parameters*" as a condition to be considered, when examining whether the data - in this case the screening study - would be equivalent to the data generated by the corresponding test methods referred to in Article 13(3), in this case a pre-natal developmental toxicity study.

ECHA has considered, whether the information from the "combined repeated dose toxicity study with the reproduction/developmental toxicity screening test" study (OECD TG 422) with the registered substance ([redacted] 2002) would meet the information requirement according to Annex XI, 1.1.2. ECHA has found that this study does not provide the information required by Annex IX, Section 8.7.2., because it does not cover key parameters of a pre-natal developmental toxicity study, such as examinations of foetuses for skeletal and visceral alterations. Furthermore, OECD 422 study has a lower statistical power that the OECD 414 study, which is required by Annex IX, Section 8.7.2. Therefore, this study cannot be used as a reliable basis to conclude that a substance does not cause pre-natal developmental toxicity.

Hence, the data generated from the OECD TG 422 screening studies are not considered as equivalent to the data generated in the pre-natal developmental toxicity test and consequently, do not meet the general rules for adaptation of annex XI, Section 1.1.2.

Therefore, your adaptation of the information requirement according to Annex XI, 1.1.2 is rejected.

Concerning the "supporting study" specified above, ECHA has evaluated the information you provided on read-across according to the provision of REACH Annex XI, Section 1.5. However, as explained in Appendix 1, section 0 of this decision, ECHA does not consider the read-across justification to be a reliable basis to predict the properties of the target substance and consequently, ECHA rejected the adaptation as set out in Annex XI, 1.5. Therefore, ECHA has concluded that the information provided with the source substance stanol fatty acid esters (Slesinski 1999) cannot be used to adapt this information requirement. As explained above, the information provided on this endpoint for the registered substance in the technical dossier does not meet the information requirement. Consequently there is an information gap and it is necessary to provide information for this endpoint.

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

ECHA considers that the oral route is the most appropriate route of administration for substances except gases to focus on the detection of hazardous properties on reproduction as indicated in ECHA *Guidance on information requirements and chemical safety assessment* (July 2017) Chapter R.7a, Section R.7.6.2.3.2. Since the substance to be tested is a liquid, ECHA concludes that testing should be performed by the oral route.

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

Notes for your consideration

ECHA notes that a revised version of OECD TG 414 was adopted this year by the OECD. This revised version contains enhancements of certain endocrine disrupting relevant parameters. You should test in accordance with the revised version of the guideline as published on the OECD website for adopted test guidelines (https://www.oecd-ilibrary.org/environment/oecd-guidelines-for-the-testing-of-chemicals-section-4-health-effects_20745788).

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

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

The technical dossier contains information on a pre-natal developmental toxicity study in rat by the oral route using the the analogue substance stanol fatty acid esters (EC or CAS number were not given) as test material. However, as explained above in Appendix 1, section 0 of this decision, your adaptation of the information requirement is rejected.

There is no information provided for a pre-natal developmental toxicity study in a second species.

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

According to the test method EU B.31./OECD TG 414, the rat is the preferred rodent species and the rabbit the preferred non-rodent species. On the basis of this default consideration, ECHA considers testing should be performed with rabbits or rats as a second species, depending on the species tested in the first pre-natal developmental toxicity study.

ECHA considers that the oral route is the most appropriate route of administration for substances except gases to focus on the detection of hazardous properties on reproduction as indicated in ECHA *Guidance on information requirements and chemical safety assessment* (July 2017) Chapter R.7a, Section R.7.6.2.3.2. Since the substance to be tested is a liquid, ECHA concludes that testing should be performed by the oral route.

Therefore, pursuant to Article 41(1) and (3) of the REACH Regulation, you are requested to

submit the following information derived with the registered substance subject to the present decision: Pre-natal developmental toxicity study (test method: EU B.31./OECD TG 414) in second species (rat or rabbit) by the oral route.

Notes for your consideration

You are reminded that before performing a pre-natal developmental toxicity study in a second species you must consider the specific adaptation possibilities of Annex X, Section 8.7., column 2 and general adaptation possibilities of Annex XI. If the results of the test in the first species with other available information enable such adaptation, testing in the second species should be omitted and the registration dossier should be updated containing the corresponding adaptation statement.

ECHA notes that a revised version of OECD TG 414 was adopted this year by the OECD. This revised version contains enhancements of certain endocrine disrupting relevant parameters. You should test in accordance with the revised version of the guideline as published on the OECD website for adopted test guidelines (https://www.oecd-ilibrary.org/environment/oecd-guidelines-for-the-testing-of-chemicals-section-4-health-effects_20745788).

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

The basic test design of an extended one-generation reproductive toxicity study (test method EU B.56./OECD TG 443 with Cohorts 1A and 1B, without extension of Cohort 1B to include a F2 generation, and without Cohorts 2A, 2B and 3) is a standard information requirement as laid down in column 1 of 8.7.3., Annex X. If the conditions described in column 2 of Annex X are met, the study design needs to be expanded to include the extension of Cohort 1B, Cohorts 2A/2B, and/or Cohort 3. Further detailed guidance on study design and triggers is provided in the ECHA *Guidance on information requirements and chemical safety assessment* Chapter R.7a, Section R.7.6 (July 2017).

Adequate information on this endpoint needs to be present in the technical dossier for the registered substance to meet this information requirement.

a) The information provided

You have sought to adapt this information requirement according to Annex XI, Section 1.1.2. You have provided the following justification for the adaptation: "*In accordance with Section 1.1.2 of REACH Annex XI, the 2-generation reproductive toxicity study (required in Section 8.7.3) does not need to be conducted because existing data are adequate for the purposes of classification and labelling and risk assessment*". To further support your adaptation you have provided the following information:

- Key study: "*screening for reproductive/developmental toxicity*", rat, oral ("equivalent or similar" to OECD TG 422; GLP) with the registered substance, [redacted], 2002 (study report), reliability 1,
- Supporting study: "*screening for reproductive / developmental toxicity*", rat, oral ("equivalent or similar to" OECD TG 421; GLP) with the registered substance, [redacted]

[redacted], 2002 (publication), reliability 1,

- Supporting study: "*two-generation reproductive toxicity*", rat, oral (OECD TG 416; GLP) with the analogue substance Phytosterol ester, DH Waalkens-Beredsen et al., 1999 (publication), reliability 2, and

- Supporting study: "*two-generation reproductive toxicity*", rat, oral (equivalent or similar to OECD TG 416; not GLP) with the analogue substance TOFA, EC No 263-107-3, Tegeris, 1990 (publication), reliability 2.

In addition, ECHA notes that you have also sought to adapt this information requirement according to Annex XI, Section 1.5. of the REACH Regulation.

ECHA has evaluated the screening studies with respect to Annex XI, Section 1.1.2. and the information you provided on read-across with respect to Annex XI, Section 1.5.

Evaluation approach and conclusion

Use of existing data

ECHA notes that the adaptation according to Annex XI, 1.1.2., requirement includes "*adequate and reliable coverage of the key parameters*", and "*exposure duration*" as the conditions (among others) to be considered if the data - in this case the screening studies - would be equivalent to the data generated by the corresponding test methods referred to in Article 13(3), in this case extended one-generation reproductive toxicity study.

ECHA considers if the information from the "*screening for reproductive / developmental toxicity*" studies (OECD TG 422/421) with the registered substance ([redacted] 2002, and [redacted] 2002) would meet the information requirement according to Annex XI, 1.1.2.

ECHA notes that screening studies (OECD TG 422 and 421) do not cover key elements, such as exposure duration, life stages and statistical power of an extended one-generation reproductive toxicity study. More specifically, the main missing key elements are: 10 weeks pre-mating exposure duration, at least 20 pregnant females per group, and an extensive postnatal evaluation of the F1 generation.

Hence, the data generated from the OECD TG 422/421 screening studies are not considered as equivalent to the data generated from the extended one-generation reproductive toxicity study and consequently, do not meet the general rules for adaptation of annex XI, Section 1.1.2.

Therefore, your adaptation of the information requirement according to Annex XI, 1.1.2 is rejected.

Read-across

ECHA has evaluated the information you provided on read-across according to the provision of REACH Annex XI, Section 1.5. ECHA has considered whether the information you have provided with the source substances are sufficient to predict the properties of the registered substance with respect to reproductive toxicity from the source substances Phytosterol ester

and TOFA. For these two substances you have provided a two-generation reproductive toxicity study OECD 416.

However, as explained in Appendix 1, section 0 of this decision, ECHA does not consider the read-across justification to be a reliable basis to predict the properties of the target substance and consequently, ECHA rejected the adaptation as set out in Annex XI, 1.5., for the reason discussed under section *"Grouping of substances and read-across approach for toxicological and (ecotoxicological) information".*

As explained above, the information provided on this endpoint for the registered substance in the technical dossier does not meet the information requirement. Consequently there is an information gap and it is necessary to provide information for this endpoint. Thus, an extended one-generation reproductive toxicity study according Annex X, Section 8.7.3., is required. The following refers to the specifications of this required study.

b) The specifications for the study design

Information from studies to be conducted before the extended one-generation reproductive toxicity study

The sub-chronic toxicity study shall be conducted before the extended one-generation reproductive toxicity study and the results from that study shall be used, among other relevant information, to decide on the study design of the extended one-generation reproductive toxicity study following ECHA *Guidance on information requirements and chemical safety assessment* Chapter R.7a, Section R.7.6 (July 2017).

The sub-chronic toxicity study may provide information on effects that is relevant for triggers (e.g. weight changes and histopathological observations of organs as indication(s) of one or more modes of action related to endocrine disruption which may meet the toxicity-trigger for extension of Cohort 1B or as evidence of specific mechanism/modes of action and/or neurotoxicity and/or immunotoxicity which may meet the particular concern criteria for developmental neurotoxicity and/or developmental immunotoxicity cohorts).

Premating exposure duration and dose-level setting

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

Ten weeks premating exposure duration is required if there is no substance specific information in the dossier supporting shorter premating exposure duration as advised in the ECHA *Guidance on information requirements and chemical safety assessment* Chapter R.7a, Section R.7.6 (July 2017). In this specific case ten weeks exposure duration is supported by the lipophilicity of the substance to ensure that the steady state in parental animals has been reached before mating.

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

dose levels.

If there is no existing relevant data to be used for dose level setting, it is recommended that results from a conducted range-finding study (or range finding studies) are reported with the main study. This will support the justifications of the dose level selections and interpretation of the results.

Extension of Cohort 1B

If the column 2 conditions of 8.7.3., Annex X are met, Cohort 1B must be extended, which means that the F2 generation is produced by mating the Cohort 1B animals. This extension provides information also on the sexual function and fertility of the F1 animals. The extension is inter alia required, if *"the use of the registered substance is leading to significant exposure of consumers and professionals"* (column 2, first paragraph, lit. (a) of section 8.7.3., Annex X) and if *"there are indications that the internal dose for the registered substance will reach a steady state in the test animals only after an extended exposure"* (column 2, first paragraph, lit. (b), second indent of section 8.7.3., Annex X).

The use of the registered substance in the joint submission is leading to significant exposure of professionals because the registered substance is used by professionals as bitumen emulsion, construction of roads, adhesives and seals, lubricants and greases, metal working fluids (PROCs 10, 11, 13, 14, 17, 18 and 19).

Furthermore, there are indications that the internal dose for the registered substance will reach a steady state in the test animals only after an extended exposure. More specifically, you have provided partition coefficient of 4.9 – 7.7 at pH 2, and 3.2 – 6.8 at pH 5-6, which indicates bioaccumulative potential of the substance.

Therefore, ECHA concludes that Cohort 1B must be extended to include mating of the animals and production of the F2 generation because the uses of the registered substance is leading to significant exposure of professionals and there are indications that the internal dose for the registered substance will reach a steady state in the test animals only after an extended exposure.

The study design must be justified in the dossier and, thus, the existence/non-existence of the conditions/triggers must be documented.

Species and route selection

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

ECHA considers that the oral route is the most appropriate route of administration for substances except gases to focus on the detection of hazardous properties on reproduction as indicated in ECHA *Guidance on information requirements and chemical safety assessment* (July 2017) Chapter R.7a, Section R.7.6.2.3.2. Since the substance to be tested is a liquid, ECHA concludes that testing should be performed by the oral route.

c) Outcome

Therefore, pursuant to Article 41(1) and (3) of the REACH Regulation, you are requested to

submit the following information derived with the registered substance subject to the present decision: Extended one-generation reproductive toxicity study (test method EU B.56./OECD TG 443), in rats, oral route, according to the following study-design specifications:

- Ten weeks premating exposure duration for the parental (P0) generation;
- Dose level setting shall aim to induce some toxicity at the highest dose level;
- Cohort 1A (Reproductive toxicity);
- Cohort 1B (Reproductive toxicity) with extension to mate the Cohort 1B animals to produce the F2 generation;

Currently, the inclusion of Cohorts 2A and 2B (developmental neurotoxicity) and Cohort 3 (developmental immunotoxicity) are not requested. However, the sub-chronic toxicity study (90-day) requested in this decision (request *1*) and/or any other relevant information may trigger changes in the study design. Therefore, the sub-chronic toxicity study (90-day) is to be conducted first and the study results submitted to ECHA in a dossier update by ***16 July 2019***.

If, on the basis of this update and/or other relevant information, a need for changes to the study design is identified, ECHA will inform you by ***16 October 2019*** (i.e. within three months after expiry of the 12-month deadline to provide the sub-chronic toxicity study (90-day)) of its intention to initiate a new decision making procedure under Articles 41, 50 and 51 of the REACH Regulation to address the design of the extended one-generation reproductive toxicity study. If you do not receive a communication from ECHA by ***16 October 2019***, the request of the present decision for the extended one-generation reproductive toxicity study remains effective and you may commence the conduct of the study and the results will need to be submitted by the deadline given in this decision ***18 July 2022***.

Notes for your consideration

When submitting the study results of the sub-chronic toxicity study (90-day) you are invited to also include in the registration update your considerations whether changes in the study design are needed (see also *ECHA Guidance on information requirements and chemical safety assessment Chapter R.7a, Section R.7.6 (*July 2017).

Furthermore, after having commenced the extended one-generation reproduction toxicity study in accordance with the ECHA decision, you may also expand this study to address a concern identified during the conduct of it and also due to other scientific reasons in order to avoid a conduct of a new study. The justification for the changes in the study design must be documented. The study design must be justified in the dossier and, thus, the existence/non-existence of the conditions/ triggers must be documented.

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

"Ready biodegradability" is a standard information requirement as laid down in Annex VII, section 9.2.1.1. of the REACH Regulation. Adequate information on this endpoint needs to be present in the technical dossier for the registered substance to meet this information requirement.

In the technical dossier you have provided a study record for the registered UVCB substance (OECD 301 F test) from 1999 where 73.2 % degradation of the UVCB substance (based on O2 consumption) was reached in 28 days.

In your PBT assessment you conclude that: *"None of the constituents meet the PBT/vPvB criteria when considered individually, but the constituents present in block 10 (Abietal block) do, if their total abundance is taken into consideration."* ECHA notes, that you have not provided any study record for ready biodegradation specifically for the block 10 constituents in the dossier. ECHA further notes, that the provided ready biodegradability study does not provide the information required by Annex VII, Section 9.2.1.1. for block 10 constituents of the registered substance, because the block 10 constituents sum up only [redacted] (w/w) of the registered UVCB substance.

Hence, the ready biodegradability studies performed with the registered substance do not allow to conclude on the biodegradability of the block 10 constituents.

ECHA notes that based on the information in the technical dossier, even if the registered UVCB substance is readily biodegradable, there is still a PBT concern based on the identified block 10 constituents that potentially meet the PBT screening criteria.

According to ECHA *Guidance on information requirements and chemical safety assessment* (version 3.0, June 2017), Chapter R11: *"Constituents, impurities and additives should normally be considered relevant for the PBT/vPvB assessment when they are present in concentration of ≥ 0.1% (w/w)."* The guidance further explains that it also applies to fractions/blocks of UVCB substances, where individual concentrations are < 0.1% (w/w). Hence, the concentrations of the constituents with P, B and T (or vP and vB) properties should be summed up in order to compare with the threshold of 0.1 % (w/w).

ECHA notes that the concentration of block 10 in your UVCB substance exceeds the limit of 0.1% (w/w) as mentioned in the guidance.

Therefore, ECHA considers that you have identified a PBT concern for block 10 of the UVCB substance and therefore further testing on the block 10 constituents is considered necessary to confirm the PBT status of the UVCB substance.

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

Regarding the test method, depending on the substance profile (here, physical-chemical properties of the block 10 constituents of the registered substance), you may conclude on ready biodegradability, by applying the most appropriate and suitable test guideline among those listed in the ECHA *Guidance on information requirements and chemical safety assessment, Chapter R.7b* (version 4.0, June 2017) and in the paragraph below. The test guidelines include the description of their applicability domain. ECHA notes that you may consider performing also measurements of primary degradation and degradation/ transformation products as these measurements may provide additional information for persistency assessment. While only one of the OECD test guidelines (OECD TG 301 C) includes obligatory determination of primary degradation, the measurements of primary degradation and degradation/transformation products can be included also in any other OECD TGs for ready biodegradation test as additional measurements. Due to the low water solubility (<0.1 mg/l) of most of the block 10 constituents you should consult Appendix

R.7.9-3 of the ECHA Guidance on information requirements and chemical safety assessment Chapter R7.b (version 4.0, June 2017) for possible modifications.

Therefore, pursuant to Article 41(1) and (3) of the REACH Regulation, you are requested to perform one of the following tests with the block 10 constituents of the registered substance subject to the present decision:

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

or

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

or

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

or

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

or

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

Notes for your consideration

As a first step of clarifying the PBT/vPvB status of the block 10 constituents you may conduct the ready biodegradability study requested above. If the block 10 constituents (or the sum of the constituents) exceeding 0.1% (w/w) concentration are shown to be readily biodegradable (with or without fulfilling the 10-d window) there is no need to provide the information requested in sections 6 to 12. However, if you consider that a ready biodegradation study would not provide any valuable information to clarify the P and/or vP status of the block 10 constituents, you may consider starting tiered testing for PBT/vPvB with a simulation study (requests 8, 9 and 10).

You are also advised to consult the ECHA Guidance on information requirements and chemical safety assessment (version 3.0, June 2017), 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. ECHA would like to highlight that PBT assessment of a UVCB may be conducted by testing the whole block of concern or its representative constituents (version 3.0, June 2017, Chapter R.11, Section R.11.4.2.2). In any case you should justify how the tested material covers the whole block as further specified in ECHA Guidance on Chapter R.11.

In your comments on the Member State Competent Authority Proposal for Amendment (PfA) to add the ready biodegradability study request for the block 10 constituents you reiterated your intention to determine the actual concentration of block 10 constituents in the

substance manufactured by all joint registrants to clarify whether they meet the PBT/vPvB screening criteria of 0.1 %. ECHA agrees that if it is documented that none of the constituents alone or the sum of the block 10 constituents meet the PBT/vPvB screening criteria of 0.1 % (w/w) no testing of PBT/vPvB properties is required.

You reemphasised the difficulty of obtaining a representative sample of the block 10 constituents, and noted that instead of testing you may pursue an adaptation using QSAR and/or read-across approaches. ECHA notes that your concern relating to the feasability of testing is addressed in the reasons for request 6 for Long-term toxicity testing on aquatic invertebrates below as is your intention of adapting the PBT/vPvB related requests. ECHA notes further that any adaptation needs to be fully documented and justified and adhere to the rules of the respective annexes (Annex XI section 1.5. for read-across and grouping, and Annex XI section 1.3. for QSARs). Further advice is provided in ECHA Guidance on information requirements and chemical safety assessment (version 1, May 2008), Chapter R.6: QSARs and grouping of chemicals and in ECHA's Read-Across Assessment Framework (https://echa.europa.eu/support/registration/how-to-avoid-unnecessary-testing-on-animals/grouping-of-substances-and-read-across).

You also state that you would like to discuss the information to be submitted with ECHA or the Member States to confirm its acceptability. ECHA notes that such discussion is not foreseen after you have received the decision, and for equal treatment of Registrants ECHA cannot offer such possibility. For more information about the follow-up evaluation process, please see the steps in the Evaluation process (https://echa.europa.eu/regulations/reach/evaluation/steps) and the answers to the most frequently asked questions at ECHA website (https://echa.europa.eu/support/qas-support/browse/-/qa/70Qx/view/scope/REACH/Evaluation).

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

"Long-term toxicity testing on aquatic invertebrates" is a standard information requirement as laid down in Annex IX, Section 9.1.5. of the REACH Regulation. Adequate information on this endpoint needs to be present in the technical dossier for the registered substance to meet this information requirement.

You have sought to adapt this information requirement according to Annex XI, Section 1.5. of the REACH Regulation by providing a study record for a long-term toxicity to aquatic invetebrates (OECD TG 202, part 2) with the analogue substances crude tall oil (EC no 232-304-6).

However, as explained above in Appendix 1, section 0 of this decision, your adaptation of the information requirement cannot be accepted.

Moreover, ECHA notes that the study provided for long-term toxicity to aquatic invertebrates on analogue substance is not compliant due to lack of proper measurements of the test substance in the test media in order to confirm the use nominal concentrations for effect concentrations.

Additionally, in your PBT assessment you conclude that: *"None of the constituents meet the PBT/vPvB criteria when considered individually, but the constituents present in block 10 (Abietal block) do, if their total abundance is taken into consideration."*

According to ECHA *Guidance on information requirements and chemical safety assessment* (July 2017), Chapter R11: "*Constituents, impurities and additives should normally be considered relevant for the PBT/vPvB assessment when they are present in concentration of ≥ 0.1% (w/w).*" The guidance further explains that it also applies to fractions/blocks of UVCB substances, where individual concentrations are < 0.1% (w/w). Hence, the concentrations of the constituents with P, B and T (or vP and vB) properties should be summed up in order to compare with the threshold of 0.1 % (w/w).

ECHA notes that the concentration of block 10 in your UVCB substance exceeds the limit of 0.1% (w/w) as mentioned in the guidance.
Therefore, ECHA considers that you have identified a PBT concern for block 10 of the UVCB substance and therefore, further testing on block 10 is considered necessary to confirm the PBT status of the UVCB substance.

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

According to ECHA *Guidance on information requirements and chemical safety assessment, Chapter R.7b* (version 4.0, June 2017) *Daphnia magna* reproduction test (test method EU C.20. / OECD TG 211) is the preferred test to cover the standard information requirement of Annex IX, Section 9.1.5.

In your comment to the draft decision on the aquatic toxicity and environmental fate related endpoints (sections 6 to 12), you explained that testing of Block 10 constituents is not considered to be technically feasible and synthesizing individual constituents from rosin would not give the same proportions of the constituents present as those found in the registered substance. Therefore you propose that alternatives to testing would be proposed in order to investigate the potential PBT concern for this block of constituents. Additionally you propose to analyse the analytical data to verify the composition of the substance and specifically the composition and concentration of Block 10.

ECHA notes that you may alternatively use Weight of evidence (as already mentioned in the draft decision above), QSAR and/or read-across adaptation possibilities in order to assess the P, B, and T properties of the critical constituents of the registered substance. Due to the technical difficulties you might face, relying on these adaptations may be a useful approach.

ECHA notes that you provided some information on the PBT properties of this crucial block in the dossier, but ECHA is of the opinion that you have not yet completed the PBT assessment of this block, and therefore there is a remaining concern of the PBT properties.

ECHA acknowledges that alternatives to testing may be applicable, however, as there is currently no reliable data on those endpoints in the dossier, ECHA cannot evaluate the alternatives proposed and will therefore not change the requests in the draft decision.

ECHA notes that your comments to the Proposal for Amendment to add a ready biodegradability test as a first step of clarifying the persistency of the block 10 constituents have been addressed in section 5. above.

Therefore, pursuant to Article 41(1) and (3) of the REACH Regulation, you are requested to submit the following information derived with the block 10 constituents of the registered

substance meeting P and B criteria subject to the present decision: Daphnia magna reproduction test (test method: EU C.20./OECD TG 211).

However, if none of the constituents (or sum of constituents) of block 10 exceeding 0.1% (w/w) concentration are identified meeting those criteria, no further testing is necessary. Also, no further testing is necessary, if any of the constituents (or sum of constituents) of block 10 exceeding 0.1% (w/w) concentration would meet vPvB criteria.

Notes for your consideration

Once results of the test on long-term toxicity to aquatic invertebrates are available, you shall revise the chemical safety assessment as necessary according to Annex I of the REACH Regulation.

Due to the low solubility of the substance in water and high partition coefficient you should consult OECD Guidance Document on Aquatic Toxicity Testing of Difficult Substances and Mixtures, ENV/JM/MONO (2000)6 and ECHA *Guidance on information requirements and chemical safety assessment* (version 4.0, June 2017), Chapter R7b, Table R.7.8-3 summarising aquatic toxicity testing of difficult substances for choosing the design of the requested ecotoxicity test(s) and for calculation and expression of the result of the test(s).

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

"Long-term toxicity testing on fish" is a standard information requirement as laid down in Annex IX, Section 9.1.6. of the REACH Regulation. Adequate information on Fish, early-life stage (FELS) toxicity test (Annex IX, 9.1.6.1.), or Fish, short-term toxicity test on embryo and sac-fry stages (Annex IX, 9.1.6.2.), or Fish, juvenile growth test (Annex IX, 9.1.6.3.) needs to be present in the technical dossier for the registered substance to meet this information requirement.

You have sought to adapt this information requirement. You provided the following justification for the adaptation: *"No measured data are available for long-term toxicity of DTO to fish. A data-waiver is considered to be appropriate for this endpoint on the following grounds: - The results from short-term tests indicate that fish, invertebrates and algae are similarly susceptible to the substance. Reliable long-term test data for Crude Tall Oil (CAS No. 8002 -26 -4) show an absence of toxicity to invertebrates at a loading rate of 1 mg/L. The NOELR for algae is also >1 mg/L. - Calculation of PNECs for the aquatic compartment will be based on data for the blocks of constituents rather than on data for the whole substance. Testing for long-term toxicity to fish will not therefore contribute to the database that is required to complete the assessment of the substance."*

While you have not explicitly claimed an adaptation, you have provided information that could be interpreted as an attempt to adapt the information requirement according to Annex XI, Section 1.2.

However, ECHA notes that your adaptation does not meet the specific rules for adaptation of Annex IX, Section 9.1.6., column 2 / general rule for adaptation of Annex XI; Section 1.2 Weight of Evidence because in your PBT assessment you conclude that: *"None of the constituents meet the PBT/vPvB criteria when considered individually, but the constituents present in block 10 (Abietal block) do, if their total abundance is taken into consideration."*

According to ECHA *Guidance on information requirements and chemical safety assessment* (version 3.0, June 2017), Chapter R11: *"Constituents, impurities and additives should normally be considered relevant for the PBT/vPvB assessment when they are present in concentration of ≥ 0.1% (w/w)."* The guidance further explains that it also applies to fractions/blocks of UVCB substances, where individual concentrations are < 0.1% (w/w). Hence, the concentrations of the constituents with P, B and T (or vP and vB) properties should be summed up in order to compare with the threshold of 0.1 % (w/w).

ECHA notes that the concentration of block 10 in your UVCB substance exceeds the limit of 0.1% (w/w) as mentioned in the guidance.

Therefore, ECHA considers that you have identified a PBT concern for block 10 of the UVCB substance and therefore further testing on block 10 is considered necessary to confirm the PBT status of the UVCB substance.

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

According to ECHA *Guidance on information requirements and chemical safety assessment, Chapter R.7b* (version 4.0, June 2017) fish early-life stage (FELS) toxicity test (test method OECD TG 210), fish short-term toxicity test on embryo and sac-fry stages (test method EU C.15. / OECD TG 212) and fish juvenile growth test (test method EU C.14. / OECD TG 215) are the preferred tests to cover the standard information requirement of Annex IX, Section 9.1.6.

However, the FELS toxicity test according to OECD TG 210 is more sensitive than the fish, short-term toxicity test on embryo and sac-fry stages (test method EU C.15 / OECD TG 212), or the fish, juvenile growth test (test method EU C.14. / OECD TG 215), as it covers several life stages of the fish from the newly fertilized egg, through hatch to early stages of growth (see ECHA *Guidance on information requirements and chemical safety assessment* (version 4.0, June 2017), *Chapter R7b, Figure R.7.8-4).*

Moreover, the FELS toxicity test is preferable for examining the potential toxic effects of substances which are expected to cause effects over a longer exposure period, or which require a longer exposure period of time to reach steady state (ECHA *Guidance Chapter R7b,* version 4.0, June 2017).

Your comments to the draft decision on the aquatic toxicity and environment fate related endpoints (sections 6 to 12) have been addressed by ECHA in section 6. above, while your comments to the Proposal for Amendment to add a ready biodegradability test as a first step of clarifying the persistency of the block 10 constituents have been addressed in section 5. above.

Therefore, pursuant to Article 41(1) and (3) of the REACH Regulation, you are requested to submit the following information derived with the block 10 constituents of the registered substance meeting P and B criteria subject to the present decision: Fish, early-life stage (FELS) toxicity test (test method: OECD TG 210).

However, if none of the constituents (or sum of constituents) of block 10 exceeding 0.1% (w/w) concentration are identified meeting those criteria, no further testing is necessary.

Also, no further testing is necessary, if any of the constituents (or sum of constituents) of block 10 exceeding 0.1% (w/w) concentration would meet vPvB criteria.

Notes for your consideration

Before conducting any of the tests mentioned above in points 5-6 you shall consult the ECHA *Guidance on information requirements and chemical safety assessment (version 4.0, June 2017)*, Chapter R7b, Section R.7.8.5 to determine the sequence in which the aquatic long-term toxicity tests are to be conducted and the necessity to conduct long-term toxicity testing on fish.

Once results of the test on long-term toxicity to fish are available, you shall revise the chemical safety assessment as necessary according to Annex I of the REACH Regulation.

ECHA notes that due to lack of effects in short-term studies it is not possible to determine the sensitivity of species. Therefore, the Integrated testing strategy (ITS) outlined in ECHA *Guidance on information requirements and chemical safety assessment* (version 4.0, June 2017), Chapter R7b (Section R.7.8.5 including Figure R.7.8-4), is not applicable in this case and the long-term studies on both invertebrates and fish are requested to be conducted. As the registered substance has a reported low water solubility, long-term studies are indicated.

Due to the low solubility of the substance in water and high partition coefficient you should consult OECD Guidance Document on Aquatic Toxicity Testing of Difficult Substances and Mixtures, ENV/JM/MONO (2000)6 and ECHA *Guidance on information requirements and chemical safety assessment* (version 4.0, June 2017), Chapter R7b, Table R.7.8-3 summarising aquatic toxicity testing of difficult substances for choosing the design of the requested ecotoxicity test(s) and for calculation and expression of the result of the test(s).

8. Simulation testing on ultimate degradation in surface water (Annex IX, Section 9.2.1.2.)

"Simulation testing on ultimate degradation in water" is a standard information requirement as laid down in Annex IX, section 9.2.1.2. of the REACH Regulation. Adequate information on this endpoint needs to be present in the technical dossier for the registered substance to meet this information requirement.

You have sought to adapt this information requirement according to Annex IX, Section 9.2., column 2. You provided the following justification for the adaptation: *"In accordance with Column 2 of REACH Annex IX, the biodegradation in water and sediment study (required in Sections 9.2.1.2 and 9.2.1.4) does not need to be conducted as the substance is readily biodegradable. Identification of degradation products (required in Section 9.2.3) is also not necessary."*

However, ECHA notes that your adaptation does not meet the specific rules for adaptation of Column 2 of Annex IX, Sections 9.2 and 9.2.1.2. because in your PBT assessment you conclude that: *"None of the constituents meet the PBT/vPvB criteria when considered individually, but the constituents present in block 10 (Abietal block) do, if their total abundance is taken into consideration."*

According to Annex IX, Section 9.2.1.2, column 2 of the REACH Regulation, simulation testing on ultimate degradation in surface water does not need to be conducted if the

substance is highly insoluble in water or is readily biodegradable. ECHA notes that based on the information in the technical dossier, even if the registered substance is readily biodegradable as also discussed in sections 8, 9 and 10 there is still a PBT concern based on the identified block 10 constituents that meet the PBT screening criteria.

Furthermore, ECHA notes that you have not provided any adequate justification in your chemical safety assessment (CSA) or in the technical dossier for why there is no need to investigate further the degradation of the substance and its degradation products.
As explained further below, ECHA considers that the information is needed for the PBT/vPvB assessment and for the identification of the degradation products in relation to the PBT/vPvB assessment.

According to ECHA *Guidance on information requirements and chemical safety assessment* (version 3.0, June 2017), Chapter R11: "*Constituents, impurities and additives should normally be considered relevant for the PBT/vPvB assessment when they are present in concentration of ≥ 0.1% (w/w).*" The guidance further explains that it also applies to fractions/blocks of UVCB substances, where individual concentrations are < 0.1% (w/w). Hence, the concentrations of the constituents with P, B and T (or vP and vB) properties should be summed up in order to compare with the threshold of 0.1 % (w/w).

ECHA notes that the concentration of block 10 in your UVCB substance exceeds the limit of 0.1% (w/w) as mentioned in the guidance.

Therefore, ECHA considers that you have identified a PBT concern for block 10 of the UVCB substance and therefore further testing on block 10 constituents is considered necessary to confirm the PBT status of the UVCB substance.

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 4.0, June 2017) Aerobic mineralisation in surface water – simulation biodegradation (test method EU C.25. / OECD TG 309) is the preferred test to cover the standard information requirement of Annex IX, Section 9.2.1.2.

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 the 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 4.0, June 2017) 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 309. Therefore, the test should be performed at the temperature of 12°C.

In the OECD TG 309 Guideline two test options, the "pelagic test" and the "suspended sediment test", are described. ECHA considers that the pelagic test option should be followed as that is the recommended option for P assessment. The amount of suspended solids in the pelagic test should be representative of the level of suspended solids in EU surface water. The concentration of suspended solids in the surface water sample used should therefore be approximately 15 mg dw/L. Testing natural surface water containing between 10 and 20 mg SPM dw/L is considered acceptable. Furthermore, when reporting the non-extractable residues (NER) in your test results you should explain and scientifically justify the extraction procedure and solvent used obtaining a quantitative measure of NER.

Your comments to the draft decision on the aquatic toxicity and environment fate related endpoints (sections 6 to 12) have been addressed by ECHA in section 6. above, while your comments to the Proposal for Amendment to add a ready biodegradability test as a first step of clarifying the persistency of the block 10 constituents have been addressed in section 5. above.

Therefore, pursuant to Article 41(1) and (3) of the REACH Regulation, you are requested to submit the following information derived with the block 10 constituents of the registered substance subject to the present decision: Aerobic mineralisation in surface water – simulation biodegradation test (test method: EU C.25./OECD TG 309); the biodegradation of each relevant constituent present in concentration at or above 0.1% (w/w) of the registered UVCB substance or, if not technically feasible, in concentrations as low as technically detectable shall be assessed. This can be done simultaneously during the same study.

However, if the constituents (or sum of the constituents) of block 10 exceeding 0.1% (w/w) concentration are identified meeting the readily biodegradability criteria, no further degradation testing is necessary.

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

"Soil simulation testing" is a standard information requirement as laid down in Annex IX, section 9.2.1.3. of the REACH Regulation for substances with a high potential for adsorption to soil. Most of the block 10 constituents of the registered substance have low water solubility (<0.1mg/l) and high partition coefficient (log Kow >4), indicating high adsorptive properties. Therefore, 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., column 2. You provided the following justification for the adaptation: "*In accordance with Column 2 of REACH Annex IX, the biodegradation in soil study (required in Section 9.2.1.3) does not need to be conducted as the substance is readily biodegradable.*"

However, ECHA notes that your adaptation does not meet the specific rules for adaptation of Column 2 of Annex IX, Sections 9.2 and 9.2.1.3 because in your PBT assessment you conclude that: "*None of the constituents meet the PBT/vPvB criteria when considered individually, but the constituents present in block 10 (Abietal block) do, if their total abundance is taken into consideration.*"

According to Annex IX, Section 9.2.1.3, column 2 of the REACH Regulation, simulation testing on soil does not need to be conducted if the substance is readily biodegradable or if direct or indirect exposure of soil is unlikely. ECHA notes that based on the information in the technical dossier, even if the registered substance is readily biodegradable there is still a PBT concern based on the identified block 10 constituents that meet the PBT screening criteria.

Regarding the exposure to soil, most of the block 10 constituents of the registered substance have low water solubility (<0.1mg/l) and high partition coefficient (log Kow >4), indicating high adsorptive properties. Furthermore, based on the uses reported in the technical dossier, ECHA considers that such uses are reported for which soil exposure cannot be excluded e.g. Environmental Release Category (ERC) 8f, 9b, 10a, 10b, 11a, 11b and also that the exposure estimations that you provided in the Chemical Safety Report (CSR) indicate that there is exposure to soil in number of your exposure scenarios (RCR's > 1). ECHA therefore considers that you have not demonstrated that soil exposure is unlikely.

ECHA notes also that you have not provided any adequate justification in your chemical safety assessment (CSA) or in the technical dossier for why there is no need to investigate further the degradation of the substance and its degradation products. As explained further below, ECHA considers that the information is needed for the PBT/vPvB assessment and for the identification of the degradation products in relation to the PBT/vPvB assessment.

According to ECHA *Guidance on information requirements and chemical safety assessment* (version 3.0, June 2017), Chapter R11: "*Constituents, impurities and additives should normally be considered relevant for the PBT/vPvB assessment when they are present in concentration of ≥ 0.1% (w/w).*"

The guidance further explains that it also applies to fractions/blocks of UVCB substances, where individual concentrations are < 0.1% (w/w). Hence, the concentrations of the constituents with P, B and T (or vP and vB) properties should be summed up in order to compare with the threshold of 0.1 % (w/w).

ECHA notes that the concentration of block 10 in your UVCB substance exceeds the limit of 0.1% (w/w) as mentioned in the guidance.

Therefore, ECHA considers that you have identified a PBT concern for block 10 of the UVCB substance and therefore further testing is considered necessary on block 10 constituents to confirm the PBT status of the UVCB substance.

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 4.0, June 2017) 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 4.0, June 2017) 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.

Simulation tests performed in sediment or in soil possibly imply the formation of non-extractable residues (NER). These residues (of the parent substance and/or transformation products) are bound to the soil or to the sediment particles. NERs may potentially be re-mobilised as parent substance or transformation product unless they are irreversibly bound or incorporated into the biomass. When reporting the non-extractable residues (NER) in your test results you should explain and scientifically justify the extraction procedure and solvent used obtaining a quantitative measure of NER.

Your comments to the draft decision on the aquatic toxicity and environment fate related endpoints (sections 6 to 12) have been addressed by ECHA in section 6. above, while your comments to the Proposal for Amendment to add a ready biodegradability test as a first step of clarifying the persistency of the block 10 constituents have been addressed in section 5. above.

Therefore, pursuant to Article 41(1) and (3) of the REACH Regulation, you are requested to submit the following information derived with the block 10 constituents of the registered substance subject to the present decision: Aerobic and anaerobic transformation in soil (test method: EU C.23./OECD TG 307). The biodegradation of each relevant constituent present in concentration at or above 0.1% (w/w) of the registered UVCB substance or, if not technically feasible, in concentrations as low as technically detectable shall be assessed. This can be done simultaneously during the same study.

However, if the constituents (or sum of the constituents) of block 10 exceeding 0.1% (w/w) concentration are identified meeting the readily biodegradability criteria, no further degradation testing is necessary.

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

In accordance with Articles 10(a) and 12(1) of the REACH Regulation, a technical dossier registered at more than 1000 tonnes per year must contain, as a minimum, the information specified in Annexes VII to X to the REACH Regulation. The information to be generated for the dossier must fulfil the criteria in Article 13(4) of the same regulation.
"Sediment simulation testing" is a standard information requirement as laid down in Annex IX, section 9.2.1.4. of the REACH Regulation for substances with a high potential for adsorption to sediment. Most of the block 10 constituents of the registered substance have low water solubility (<0.1mg/l) and high partition coefficient (log Kow >4), indicating high

adsorptive properties. Therefore, 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., column 2. You provided the following justification for the adaptation: "In accordance with Column 2 of REACH Annex IX, the biodegradation in water and sediment study (required in Sections 9.2.1.2 and 9.2.1.4) does not need to be conducted as the substance is readily biodegradable. Identification of degradation products (required in Section 9.2.3) is also not necessary."

However, ECHA notes that your adaptation does not meet the specific rules for adaptation of Column 2 of Annex IX, Sections 9.2 and 9.2.1.3. because in your PBT assessment you conclude that: *"None of the constituents meet the PBT/vPvB criteria when considered individually, but the constituents present in block 10 (Abietal block) do, if their total abundance is taken into consideration."*

According to Annex IX, Section 9.2.1.4, column 2 of the REACH Regulation, simulation testing on soil does not need to be conducted if the substance is readily biodegradable or if direct or indirect exposure of sediment is unlikely. ECHA notes that based on the information in the technical dossier, even if the registered substance is readily biodegradable there is still a PBT concern based on the identified block 10 constituents that meet the PBT screening criteria.

Regarding exposure of sediment, most of the block 10 constituents of the registered substance have low water solubility (<0.1mg/l) and high partition coefficient (log Kow >4), indicating high adsorptive properties.

Furthermore, based on the uses reported in the technical dossier, ECHA considers that such uses are reported for which sediment exposure cannot be excluded e.g. Environmental Release Category (ERC) 8f, 9b, 10a, 10b, 11a, 11b and also that the exposure estimations that you provided in the Chemical Safety Report (CSR) indicate that there is exposure to soil in number of your exposure scenarios (RCR's > 1). ECHA therefore considers that you have not demonstrated that sediment exposure is unlikely.

ECHA notes also that you have not provided any adequate justification in your chemical safety assessment (CSA) or in the technical dossier for why there is no need to investigate further the degradation of the substance and its degradation products. As explained further below, ECHA considers that the information is needed for the PBT/vPvB assessment and for the identification of the degradation products in relation to the PBT/vPvB assessment.

However, ECHA notes that your adaptation does not meet the specific rules for adaptation of Annex IX, Section 9.1.6., column 2 / general rule for adaptation of Annex XI; Section 1.2 Weight of Evidence because in your PBT assessment you conclude that: *"None of the constituents meet the PBT/vPvB criteria when considered individually, but the constituents present in block 10 (Abietal block) do, if their total abundance is taken into consideration."*

According to ECHA *Guidance on information requirements and chemical safety assessment* (version 3.0, June 2017), Chapter R11: *"Constituents, impurities and additives should normally be considered relevant for the PBT/vPvB assessment when they are present in concentration of ≥ 0.1% (w/w)."* The guidance further explains that it also applies to fractions/blocks of UVCB substances, where individual concentrations are < 0.1% (w/w).

Hence, the concentrations of the constituents with P, B and T (or vP and vB) properties should be summed up in order to compare with the threshold of 0.1 % (w/w).

ECHA notes that the concentration of block 10 in your UVCB substance exceeds the limit of 0.1% (w/w) as mentioned in the guidance.

Therefore, ECHA considers that you have identified a PBT concern for block 10 of the UVCB substance and therefore further testing on block 10 constituents is considered necessary to confirm the PBT status of the UVCB substance.

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 4.0, June 2017) 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 4.0, June 2017) 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.

Simulation tests performed in sediment or in soil possibly imply the formation of non-extractable residues (NER). These residues (of the parent substance and/or transformation products) are bound to the soil or to the sediment particles. NERs may potentially be re-mobilised as parent substance or transformation product unless they are irreversibly bound or incorporated into the biomass. When reporting the non-extractable residues (NER) in your test results you should explain and scientifically justify the extraction procedure and solvent used obtaining a quantitative measure of NER.

Your comments to the draft decision on the aquatic toxicity and environment fate related endpoints (sections 6 to 12) have been addressed by ECHA in section 6. above, while your comments to the Proposal for Amendment to add a ready biodegradability test as a first step of clarifying the persistency of the block 10 constituents have been addressed in section 5. above.
Therefore, pursuant to Article 41(1) and (3) of the REACH Regulation, you are requested to submit the following information derived with the block 10 constituents of the registered substance subject to the present decision: Aerobic and anaerobic transformation in aquatic

sediment systems (test method: EU C.24./OECD TG 308). The biodegradation of each relevant constituent present in concentration at or above 0.1% (w/w) of the registered UVCB substance or, if not technically feasible, in concentrations as low as technically detectable shall be assessed. This can be done simultaneously during the same study.

However, if the constituents (or sum of the constituents) of block 10 exceeding 0.1% (w/w) concentration are identified meeting the readily biodegradability criteria, no further degradation testing is necessary.

Notes for your consideration for Sections 8, 9 and 10

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 4.0, June 2017) and Chapter R.11, Section R.11.4.1.1 (version 3.0, June 2017) 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 3.0, June 2017), 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.

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

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

The identification of the degradation products is a standard information requirement according to column 1, Section 9.2.3. of Annex IX 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., column 2. You provided the following justification for the adaptation: "*In accordance with Column 2 of REACH Annex IX, the biodegradation in water and sediment study (required in Sections 9.2.1.2 and 9.2.1.4) does not need to be conducted as the substance is readily biodegradable. Identification of degradation products (required in Section 9.2.3) is also not necessary.*".

ECHA notes that in your adaptation you propose that it is not necessary to obtain information on the degradation products because in your PBT assessment you conclude that: "*None of the constituents meet the PBT/vPvB criteria when considered individually, but the constituents present in block 10 (Abietal block) do, if their total abundance is taken into consideration.*"

According to Annex IX, Section 9.2.3., column 2 of the REACH Regulation, identification of degradation products is not needed if the substance is readily biodegradable. ECHA notes that based on the information in the technical dossier, even if the registered substance is readily biodegradable as also discussed in section 7, 8 and 9 above there is still a PBT concern based on the identified block 10 constituents that meet the PBT screening criteria.

Furthermore, ECHA notes that you have not provided any justification in your chemical safety assessment (CSA) or in the technical dossier for why there is no need to provide information on the degradation products. ECHA considers that this information is needed in relation to the PBT/vPvB assessment and risk assessment.

According to ECHA *Guidance on information requirements and chemical safety assessment* (version 3.0, June 2017), Chapter R11: "*Constituents, impurities and additives should normally be considered relevant for the PBT/vPvB assessment when they are present in concentration of ≥ 0.1% (w/w).*" The guidance further explains that it also applies to fractions/blocks of UVCB substances, in which individual concentrations are < 0.1% (w/w). Hence, the concentrations of the constituents with P, B and T (or vP and vB) properties should be summed up in order to compare with the threshold of 0.1 % (w/w).
ECHA notes that the concentration of block 10 in your UVCB substance exceeds the limit of 0.1% (w/w) as mentioned in the guidance.

Therefore, ECHA considers that you have identified a PBT concern for block 10 of the UVCB substance and therefore further testing on block 10 constituents is considered necessary to confirm the PBT status of the UVCB substance.

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.

Regarding appropriate and suitable test method, the methods will have to be substance-specific. When analytically possible, identification, stability, behaviour, molar quantity of metabolites relative to the parent compound should be evaluated. In addition, degradation half-life, log Kow and potential toxicity of the metabolite may be investigated. You may obtain this information from the relevant degradation studies also requested in this decision, or by some other measure. You will need to provide a scientifically valid justification for the chosen method.

Your comments to the draft decision on the aquatic toxicity and environment fate related endpoints (sections 6 to 12) have been addressed by ECHA in section 6. above, while your comments to the Proposal for Amendment to add a ready biodegradability test as a first step of clarifying the persistency of the block 10 constituents have been addressed in section 5. above.

Therefore, pursuant to Article 41(1) and (3) of the REACH Regulation, you are requested to submit the following information derived with the block 10 constituents of the registered substance meeting subject to the present decision: Identification of the degradation products (Annex IX, Section 9.2.3.) by using an appropriate and suitable test method, as explained above in this section.

However, if the constituents (or sum of constituents) of block 10 exceeding 0.1% (w/w) concentration are found to be readily biodegradable (request 5. above), identification of degradation products is not necessary.

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

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

"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 . You provided the following justification for the adaptation: *"In accordance with Section 1 of REACH Annex XI, the study does not need to be conducted because the bioaccumulation of a UVCB substance of this nature should be evaluated on the basis of the properties of its constituents. A result for the whole substance is not meaningful scientifically for the purpose of assessment of exposure or risk. It is therefore not appropriate to conduct or propose a test for this endpoint. The needs associated with a sound understanding of bioaccumulation are adequately met by the available data on constituents. Reliable bioaccumulation data are characterised by quantitative structure activity relationships (QSARs) for constituents of the substance".*

However, ECHA notes that your adaptation does not meet the specific rules for adaptation of Annex XI, Section 1 because in your PBT assessment you conclude that: *"None of the constituents meet the PBT/vPvB criteria when considered individually, but the constituents present in block 10 (Abietal block) do, if their total abundance is taken into consideration."*

According to ECHA *Guidance on information requirements and chemical safety assessment* (version 3.0, June 2017), Chapter R11: *"Constituents, impurities and additives should normally be considered relevant for the PBT/vPvB assessment when they are present in concentration of ≥ 0.1% (w/w)."* The guidance further explains that it also applies to fractions/blocks of UVCB substances, where individual concentrations are < 0.1% (w/w). Hence, the concentrations of the constituents with P, B and T (or vP and vB) properties should be summed up in order to compare with the threshold of 0.1 % (w/w).

ECHA notes that the concentration of block 10 in your UVCB substance exceeds the limit of 0.1% (w/w) as mentioned in the guidance.

Therefore, ECHA considers that you have identified a PBT concern for block 10 of the UVCB substance and therefore further testing is considered necessary on block 10 constituents to confirm the PBT status of the UVCB substance.

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

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

According to ECHA *Guidance on information requirements and chemical safety assessment, Chapter R.7c* (version 3.0, June 2017) bioaccumulation in fish: aqueous and dietary

exposure (test method EU C.13. / OECD TG 305) is the preferred test to cover the standard information requirement of Annex IX, Section 9.3.2. 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. You shall also attempt to estimate the corresponding BCF value from the dietary test data by using the approaches given in Annex 8 of the OECD 305 TG. In any case you shall report all data derived from the dietary test as listed in the OECD 305 TG.

Your comments to the draft decision on the aquatic toxicity and environment fate related endpoints (sections 6 to 12) have been addressed by ECHA in section 6. above, while your comments to the Proposal for Amendment to add a ready biodegradability test as a first step of clarifying the persistency of the block 10 constituents have been addressed in section 5. above.

Therefore, pursuant to Article 41(1) and (3) of the REACH Regulation, you are requested to submit the following information derived with the block 10 constituents of the registered substance meeting P and vP criteria subject to the present decision
Bioaccumulation in fish: aqueous or dietary bioaccumulation fish test (test method: OECD TG 305).

However, if none of the constituents (or sum of constituents) of block 10 exceeding 0.1% (w/w) concentration are identified meeting those criteria, no further testing is necessary.

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 3.0, June 2017), 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. In particular, you are advised to first conclude whether the registered substance may fulfil the REACH Annex XIII criteria of being persistent or very persistent, and then to consult the PBT assessment for Weight-of-Evidence determination and integrated testing strategy for bioaccumulation assessment. You should revise the PBT assessment when information on bioaccumulation is available.

Deadline to submit the requested information in this decision

In the draft decision communicated to you the total time indicated to provide the requested information was 42 months from the date of adoption of the decision.

In your comments on the Proposal for Amendment, you requested an extension of additional 18 months to allow for analytical work related to obtaining the block 10 constituents required for requests relating to aquatic toxicity and environmental fate (sections 5 to 12).

ECHA notes that the timeline given in the initial draft decision allowed for the PBT related requests 6 to 12 to be carried out in tiered fashion, including time for example for analytical method development and interpretation of results. ECHA does hence not consider an extension of 18 months justified. However, in comparison to the initial draft decision the deadline is extended by six months due to the addition of the ready biodegradation request (request 5). The total deadline is therefore set to 48 months from the adoption of the decision.

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

The compliance check was initiated on 29 March 2017.

On 22 August 2017 ECHA notified you of the draft decision and invited you to provide comments. You provided comments within the timeline indicated by ECHA.

The ECHA Secretariat reviewed the comments and modified Appendix 1: Reasons of the draft decision whilst Decision (Information required) was not amended.

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.

Your comments on the proposed amendment(s) were taken into account by the Member State Committee.

The Member State Committee reached a unanimous agreement on the draft decision in its MSC-59 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. This compliance check decision does not prevent ECHA from initiating further compliance checks on the present registration at a later stage.

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

3. In relation to the information required by the present decision, the sample of the substance used for the new tests 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 tests 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 tests must be suitable to assess these grades. Finally there must be adequate information on substance identity for the sample tested and the grades registered to enable the relevance of the tests to be assessed.