EUROPEAN CHEMICALS AGENCY

Helsinki, 13 December 2019

Addressee
Registrant of Tall oil maleated _ EC 268-859 listed in the last Appendix of this decision

Date of submission for the jointly submitted dossier subject of a decision
11/04/2018

Registered substance subject to this decision, hereafter 'the Substance'
Substance name: Tall oil, maleated
EC number: 268-859-6
CAS number: 68152-93-2

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

DECISION ON A TESTING PROPOSAL

Based on Article 40 of Regulation (EC) No 1907/2006 (REACH), ECHA requests that you submit the information listed below by the deadline of ***20 September 2022***.

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

1. Soil simulation testing (Annex IX, Section 9.2.1.3.; test method EU C.23./OECD TG 307) at a temperature of 12 °C with the Substance; including degradation of each relevant constituent present in concentration at or above 0.1% (w/w).

2. Simulation testing on ultimate degradation in surface water (Annex IX, Section 9.2.1.2.; test method EU C.25./OECD TG 309) at a temperature of 12 °C with the Substance; including degradation of each relevant constituent present in concentration at or above 0.1% (w/w);

3. Identification of degradation products (Annex IX, 9.2.3.) using an appropriate test method among those requested above (1-2) with the Substance.

4. Bioaccumulation in aquatic species (Annex IX, Section 9.3.2.; test method OECD TG 305, aqueous exposure) with the Substance; including each relevant constituent present in concentration at or above 0.1% (w/w) and relevant degradation products;

5. 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 Substance;

6. Long-term toxicity on terrestrial invertebrates (Annex IX, Section 9.4.1., column 2; test method: Earthworm reproduction test (OECD TG 222) with the Substance;

7. Long-term toxicity to terrestrial plants (Annex IX, Section 9.4.3., column 2; test method: Terrestrial plant test: seedling emergence and seedling growth test, OECD TG 208 with at least six species tested (with as a minimum two monocotyledonous species and four dicotyledonous species) with the Substance;

8. Effects on soil micro-organisms (Annex IX, Section 9.4.2.; test method: EU C.21/OECD TG 216) with the Substance.

Conditions to comply with the requested information

You are bound by the requests for information applicable to your own registered tonnage of the Substance at the time of evaluation.

The reasons for triggering of the requested information, the testing proposed as well as a design of the requested studies are explained in Appendix A.

The Appendix C entitled Observations and technical guidance addresses the generic approach for the selection and reporting of the test material used to perform the required studies and generic recommendations and guidance.

The studies relating to biodegradation and bioaccumulation (request A.1, A.2 and A.4) are necessary for the PBT assessment. However, to determine the testing needed to reach the conclusion on the persistency and bioaccumulation of the Substance you must consider the conditions described in Appendix C.

You must submit the information requested in this decision by the deadline indicated above in an updated registration dossier and also update the chemical safety report, where relevant, including any changes to classification and labelling, based on the newly generated information. The timeline has been set to allow for sequential testing where relevant.

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.

Approved[1] under the authority of Christel Schillinger-Musset, Director of Hazard Assessment

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

Appendix A: Reasons for the information required from the Registrants subject to Annex IX of REACH

This decision is based on the examination of the testing proposals you submitted. There were no scientific information submitted by third parties.

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

Soil simulation testing is a standard information requirement at Annex IX of REACH for substances with a high potential for adsorption to soil.

You have submitted a testing proposal for a Soil simulation testing (Aerobic and Anaerobic Transformation in Soil, OECD TG 307).

You provided the following justification: *"The substance has shown a log Pow of ~5 and adsorption desorption study showed that the substance has a binding capability to soil with high organic content. Additionally, the substance is used in a way which cannot exclude exposure to soil."*

Screening information provided in your dossier indicate that the Substance may have PBT/vPvB properties. The Substance has a water solubility (376 mg/L), partition coefficient of logPow 4.969 and an adsorption coefficient log Koc 2.95 indicating that it has a potential for adsorption to soil. Therefore, ECHA agrees that soil simulation testing is needed.

The available screening information is not sufficient to conclude on the P/vP properties of the Substance.

Under Article 40(3)(a) of the REACH Regulation, you are requested to carry out the proposed test.

Study design

The proposed OECD TG 307 is an appropriate method to fulfil this information requirement. Annex XIII of the REACH Regulation indicates that information used for PBT/vPvB assessment must be obtained under relevant conditions. Therefore, simulation tests should be performed at the temperature of 12 °C, the average environmental temperature for the EU (ECHA Guidance R.16, Table R.16-8).

Quantification of non-extractable residues (NER) must be carried out in all simulation studies. The reporting of results must include a scientific justification of the used extraction procedures and solvents. By default, total NER is regarded as non-degraded substance. However, if reasonably justified and analytically demonstrated, a certain part of NER may be differentiated and quantified as irreversibly bound or as degraded to biogenic NER. Such fractions can be regarded as removed when calculating the degradation half-life(s) (ECHA Guidance R.11).

Annex XIII of the REACH Regulation requires assessment of relevant constituents of a substance for PBT/vPvB assessment. The biodegradation of each relevant constituent present in concentration at or above 0.1% (w/w) or, if not technically feasible, in concentrations as low as technically detectable must be assessed. This can be done simultaneously during the same study. If you consider that this assessment is not relevant for the PBT/vPvB assessment of the Substance, you must provide a documented justification.

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

Simulation testing on ultimate degradation in surface water is a standard information requirement at Annex IX to REACH.

You have not proposed a testing proposal for this. However, you have adapted this information requirement by stating that the Substance is inherently biodegradable and that this test is not needed for risk assessment nor PBT assessment.

This information requirement is also necessary to establish whether the Substance has or has not the dangerous property you aim at investigating with your testing proposal on soil simulation testing. ECHA has assessed this justification and identified the following issue(s):

A. To adapt the information requirement for simulation testing on ultimate degradation in surface water (Annex IX, Section 9.2.1.2), the substance has to be either highly insoluble in water or readily biodegradable.

   However, based on the information provided in the dossier, the Substance is not readily biodegradable (OECD TG 301B, 44 % degradation after 28 days) and is not highly insoluble in water (water solubility: 376 mg/L).

B. To assess the degradation of the Substance, the P/vP assessment must cover all environmental compartments. Testing should be started with the most relevant compartment which is foreseen to provide the best possibility to conclude the P/vP assessment as being "worst-case" (Section R.11.4.1.1.3 in ECHA Guidance R.11). If the substance and its degradation products are concluded to be non-persistent in the tested environmental compartment it should be verified that there is no concern in remaining compartments and justification shall be provided.

   Since by default the surface water compartment receives a significant amount of emission, testing should start with the OECD TG 309 simulation study, as long as it is technically feasible to conduct the simulation surface water study (Explanatory Notes to Figure R.11-3. Point 4 in ECHA Guidance R.11).

   While you proposed simulation study in soil (point A.1 of the present Decision), you have not justified nor provided supporting evidence on whether results from soil simulation tests would cover the P/vP assessment for all compartments including the aquatic compartment. In addition, you have not justified why the aquatic compartment is not a relevant environmental compartment. You have also not provided any evidence showing that the testing in water is not technically feasible.

Therefore, your adaptation is rejected.

The available screening information is not sufficient to conclude on the P/vP properties of the Substance and the simulation testing on ultimate degradation in surface water is needed.

Study design

OECD TG 309 is an appropriate method for studying the degradation in surface water. However, when performing the OECD TG 309 test, the pelagic test option with natural surface water containing approximately 15 mg dw/L of suspended solids (acceptable concentration between 10 and 20 mg dw/L) must be followed (ECHA Guidance R.11).

The requested simulation tests must be performed under relevant conditions (12°C) and non-extractable residues (NER) must be quantified, for the reasons explained above in section A.1. The biodegradation of each relevant constituent present in concentration at or above 0.1% (w/w) or, if not technically feasible, in concentrations as low as technically detectable,

must be assessed. This can be done simultaneously during the same study. Alternatively, if you consider that this assessment is not relevant for the PBT/vPvB assessment of the Substance, you must provide a documented justification.

If you should encounter technical difficulties to perform the requested OECD TG 309 test, such difficulties and attempted solutions must be clearly demonstrated and documented in the registration dossier.

Therefore, under Article 40(3)(c) of the REACH Regulation, you are requested to carry out this additional test.

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

Identification of the degradation products is a standard information requirement at Annex IX, 9.2.3 of REACH.

ECHA identified the following issue:

According to Section 4 of Annex I to the REACH Regulation the objective of the PBT/vPvB assessment is to determine if the substance assessed in Chemical Safety assessment (CSA) fulfils the criteria set out in Annex XIII. According to Annex XIII, the PBT/vPvB assessment must take account of the PBT/vPvB properties of relevant constituents and relevant transformation and/or degradation products of organic substances. This information requirement is necessary to establish whether the Substance has or has not the dangerous property you aim at investigating with your testing proposal on soil simulation testing.

Screening information provided in your dossier indicates that the Substance may have PBT/vPvB properties. You have not proposed testing for this endpoint. You also have not provided any information on the identification of degradation products, nor an adaptation in accordance with column 2 of Annex IX, Sections 9.2 or 9.2.3 or with the general rules of Annex XI for this standard information requirement.

Therefore, information on identification of degradation products is required.

Under Article 40(3)(c) of the REACH Regulation, you are requested to provide information on degradation products.

Study selection and design

You should obtain this information during the conduct of the simulation studies also requested in this decision (Appendix A, sections 1 and 2 above). If any other method is used for identification of the transformation/degradation products, you must provide a scientifically valid justification for the chosen method.

Identity, stability, behaviour, and molar quantity of the degradation/transformation products relative to the Substance must be evaluated and reported, when analytically possible. In addition, degradation half-life, potential for bioaccumulation and toxicity of the degradation product must be investigated.

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

Bioaccumulation in aquatic species, preferably fish is a standard information requirement at Annex IX of REACH.

You have submitted a testing proposal for a Bioaccumulation in aquatic species test (OECD TG 305-I: Aqueous Exposure Bio-concentration Fish Test) with the Substance with the following justification: "*The substance has shown a log Pow of ~5. Additionally, the substance is used in a way which cannot exclude exposure to soil and water resources. Thus, further investigation of bioaccumulation appears appropriate.*"

Screening information provided in your dossier indicate that the Substance may have PBT/vPvB properties. According to the provided information, the Substance is potentially B/vB (reported logPow = 4.969). Therefore, ECHA agrees that a bioaccumulation in aquatic species testing is required.

ECHA requested your considerations for alternative methods to fulfil the information requirement for bioaccumulation in aquatic species. ECHA notes that you provided your considerations concluding that there were no alternative methods which could be used to adapt the information requirement for which testing is proposed. ECHA has taken these considerations into account.

Under Article 40(3)(a) of the REACH Regulation, you are requested to carry out the proposed test.

Study design

The proposed test: Bioaccumulation in aquatic species test (OECD TG 305-I: Aqueous Exposure Bio-concentration Fish Test) is appropriate to fulfill this information requirement.

Annex XIII of the REACH Regulation requires assessment of relevant constituents of a substance for PBT/vPvB assessment. The bioaccumulation of each relevant constituent present in concentration at or above 0.1% (w/w) or, if not technically feasible, in concentrations as low as technically detectable, must be assessed. This can be done simultaneously during the same study. Alternatively, if you consider these as not relevant for the PBT/vPvB assessment, you must provide a documented justification.

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

Long-term toxicity testing on fish is a standard information requirement in Annex IX to the REACH Regulation.

You have submitted a testing proposal for OECD guideline 210 (Fish, Early-Life Stage Toxicity Test) with the Substance.

ECHA requested your considerations for alternative methods to fulfil the information requirement for bioaccumulation in aquatic species. ECHA notes that you provided your considerations concluding that there were no alternative methods which could be used to adapt the information requirement for which testing is proposed. ECHA has taken these considerations into account.

Therefore, ECHA considers that the proposed study is appropriate to fulfil the information requirement of Annex IX, Section 9.1.6 of the REACH Regulation.

Under Article 40(3)(a) of the REACH Regulation, you are requested to carry out the proposed test.

Test design

The substance is difficult to test due to the adsorptive properties (partition coefficient of logPow 4.969 and an adsorption coefficient log Koc 2.95). OECD TG (210) specifies that for difficult to test substances, the OECD Guidance 23 is to be followed. To get reliable results, the substance properties need to be considered when performing the test, in particular with regard to the test design; including the exposure system, test solution preparation, and sampling. OECD GD 23 (Table 1) describes testing difficulties related to a specific property of the substance. You may use the approaches described in OECD GD 23 or other approaches if more appropriate for your substance. The approach selected must be justified and documented. Due to the substance properties it may be difficult to achieve and maintain the exposure concentrations. Therefore, you have to demonstrate that the concentration of the substance is stable throughout the test (i.e. measured concentrations remains within 80-120% of the nominal concentration). If it is not possible to demonstrate the stability, you must express the effect concentration based on measured values as described in the applicable test guideline. In case the dose-response relationship cannot established (no observed effects), you must demonstrate that the test solution preparation method applied was sufficient to maximise the concentration of the Substance in the test solution.

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

Effects on terrestrial organisms is a standard information requirement in Annex IX, Section 9.4. to REACH. The requirement must be addressed for different taxonomic groups: invertebrates, soil micro-organisms and terrestrial plants. Column 2 of section 9.4 of Annex IX specifies that long-term toxicity testing must be considered instead of short-term, in particular for substances that have a high potential to adsorb to soil or that are very persistent.

You have submitted a testing proposal for a long-term toxicity test to terrestrial invertebrates (Earthworm reproduction test (*Eisenia fetida/Eisenia andrei*), OECD TG 222) with the Substance.

According to the provided information, the Substance has a high potential to adsorb to soil (logPow = 4.969, log = Koc 2.95) and is potentially very persistent (default setting for non-readily biodegradable substances when half-life in soil is not available, Section R.7.11.5.3 of ECHA Guidance R.7c).

Therefore, ECHA agrees that a long-term testing is required and the proposed test is appropriate to fulfil the information requirement of Annex IX, Section 9.4.1.

Under Article 40(3)(a) of the REACH Regulation, you are requested to carry out the proposed test.

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

The effects on terrestrial organisms is a standard information requirement in Annex IX, Section 9.4. to REACH. The requirement must be addressed for different taxonomic groups: invertebrates, soil micro-organisms and terrestrial plants. Column 2 of section 9.4 of Annex IX specifies that long-term toxicity testing must be considered instead of short-term, in particular for substances that have a high potential to adsorb to soil or that are very persistent.

You have submitted a testing proposal for a long-term toxicity test to terrestrial plants (Terrestrial Plants Test: Seedling Emergence and Seedling Growth Test, OECD TG 208) with the Substance.

According to the provided information, the Substance has a high potential to adsorb to soil and is potentially very persistent, as explained in section 6 above.

Therefore, ECHA agrees a long-term testing is required and the proposed test is appropriate to fulfil the information requirement.

Under Article 40(3)(a) of the REACH Regulation, you are requested to carry out the proposed test.

Test design

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

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

Effects on terrestrial organisms is a standard information requirement in Annex IX, Section 9.4. to REACH. The requirement must be addressed for different taxonomic groups: invertebrates, soil micro-organisms and terrestrial plants.

You have submitted a testing proposal for soil micro-organisms test (Soil Microorganisms: Nitrogen Transformation Test, OECD TG 216) with the Substance. Because your dossier does not contain the required information, ECHA agrees with your proposal.

Under Article 40(3)(a) of the REACH Regulation, you are requested to carry out the proposed test.

Appendix B: Procedural history

ECHA started the testing proposal evaluation in accordance with Article 40(1) on 27 April 2018.

ECHA held a third party consultation for the testing proposals from 4 October 2018 until 19 November 2018. ECHA did not receive information from third parties.

For the purpose of the decision-making, this decision does not take into account any updates of registration dossiers after the date on which you were notified the draft decision according to Article 50(1) of the REACH.

ECHA notified you of the draft decision and invited you to provide comments within 30 days of the notification.

ECHA did not receive any comments within the 30-day notification period.

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

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

Appendix C: Observations and technical guidance

1. This testing proposal examination decision does not prevent ECHA from initiating compliance checks at a later stage on the registrations present.

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(s).

3. Test guidelines, GLP requirements and reporting

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

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

Under Article 10 (a) (vi) and (vii) of REACH, all new data generated as a result of this decision must be reported as study summaries, or as robust study summaries, if required under Annex I of REACH. See ECHA Practical Guide: 'How to report robust study summaries[2]'

4. Test material

Selection of the test material(s) for UVCB substances

While selecting the test material you must take into account the impact of each constituent/impurity is known to have or could have on the test results for the endpoint to be assessed. For example, if a constituent/impurity of the Substance is known to have an impact on (eco)toxicity, the selected test material must contain that constituent/ impurity. Any constituents that have harmonised classification and labelling according to the CLP Regulation (Regulation (EC) No 1272/2008) must be identified and quantified using the appropriate analytical methods.

The OECD Series on Principles of Good Laboratory Practice and Compliance Monitoring, Number 11 [ENV/MC/CHEM(98)16] requires a careful identification of the test material and description of its characteristics. In addition, the Test Methods Regulation (EU) 440/2008, as amended by Regulation (EU) 2016/266, requires that "*if the test method is used for the testing of a* [...] *UVCB* [...] *sufficient information on its composition should be made available, as far as possible, e.g. by the chemical identity of its constituents, their quantitative occurrence, and relevant properties of the constituents*".

In order to meet this requirement, all the constituents of the test material used for each test must be identified as far as possible. For each constituent the concentration value in the test material must be reported in the Test material section of the endpoint study record.

Technical Reporting of the test material for UVCB substances

[2] https://echa.europa.eu/practical-guides

The composition of the selected test material must be reported in the respective endpoint study record, under the Test material section. The composition must include all constituents of the test material and their concentration values. Without such detailed reporting, ECHA may not be able to confirm that the test material is relevant for the Substance and to all the registrants of the Substance.

Technical instructions are available in the manual "How to prepare registration and PPORD dossiers" on the ECHA website (https://echa.europa.eu/manuals).

5. Strategy for the PBT/vPvB assessment

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

You are advised to first conclude whether the Substance may fulfil the Annex XIII criteria of being P or vP, and then continue with the assessment for bioaccumulation. The sequence of the simulation tests also needs to consider the intrinsic properties of the Substance, its identified use and release patterns as these could significantly influence the environmental fate of the Substance. You shall revise the PBT assessment when the new information is available.

6. Environmental testing on UVCB substances

The purpose of the environmental hazard assessment under REACH is to perform the PBT assessment, to determine classification and labelling of the Substance and to perform the risk assessment (e.g. for PNEC derivation).
Your Substance is a complex UVCB and, as indicated in the ECHA Guidance R.11, to fulfil information requirements for persistency, bioaccumulation and aquatic toxicity, you need to consider the following approaches:

- The "known constituents approach" (by assessing specific constituents), or
- The "fraction/block approach, (performed on the basis of fractions/blocks of constituents), or
- The "whole substance approach," or various combinations of the approaches described above.

The selection of the proper approach depends on the purpose of the study and the ability to characterise the Substance i.e. knowledge of constituents and/or fractions of the Substance and differences in the properties amongst them.

7. Use of Water Accommodated Fraction (WAF) approach for ecotoxicity testing

Before conducting the requested test[s] (x-z) you must consult ECHA Guidance R.11 (Section R.11.4.2.2), R7b (Table R.7.8-3 and Appendix R.7.9-4) and the OECD GD 23 on conducting and reporting the results of ecotoxicity test(s) on difficult to test substances.
If you use the Water Accommodated Fraction (WAF) approach in your ecotoxicity tests, you must:

- Choose/develop the analytical methods relevant for your substance.
- Prepare the WAF in a consistent manner with the applied test conditions (including e.g. the use of co-solvents or the stirring methods).

- Conduct chemical analyses of the WAF and the test medium.

The following key information must be reported:

- Full description of the method used to prepare the WAF.
- Identity of those constituents to which the test organisms are exposed.
- A demonstration that equilibrium has been obtained in the WAF.
- A demonstration of stability in the exposure concentrations during the conduct of the test.
- Test results expressed in terms of measured concentrations, unless you can demonstrate that exposure concentrations remain within ±20% of the initial loading rate.

If it is not possible to provide the above information when using the WAF approach you should consider the use of newer techniques (e.g. passive dosing) as noted in OECD GD 23 that may be better suited for your Substance.

8. List of references for Guidance documents[3]

Environmental toxicology and fate

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

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

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

PBT assessment

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

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

Guidance document on aqueous-phase aquatic toxicity testing of difficult test chemicals, OECD 23 (ENV/JM/MONO(2000)6/REV1).

[3] https://echa.europa.eu/guidance-documents/guidance-on-information-requirements-and-chemical-safety-assessment

Appendix D: List of the registrants to which the decision is addressed and the corresponding information requirements applicable to them

Registrant Name	Registration number	(Highest) Data requirements to be fulfilled
[redacted]	[redacted]	[redacted]