Helsinki, 25 September 2018

Addressee: [redacted]

Decision number: CCH-D-2114445510-59-01
Substance name: TALL OIL, COMPD. WITH DIETHANOLAMINE
EC number: 268-452-3
CAS number: 68092-28-4
Registration number: [redacted]
Submission number: [redacted]
Submission date: 18.04.2018
Registered tonnage band: 10-100T (submission number [redacted] with latest tonnage band)

**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. **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**

2. **Long-term toxicity testing on aquatic invertebrates (Annex VII, Section 9.1.1., column 2; test method: Daphnia magna reproduction test, EU C.20./OECD TG 211) with the registered substance**

3. **Long-term toxicity testing on fish (Annex VIII, Section 9.1.3., column 2; test method: Fish, early-life stage (FELS) toxicity test, OECD TG 210) with the registered substance**

You may adapt the testing requested above according to the specific rules outlined in Annexes VI to X and/or according to the general rules contained in Annex XI 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.

You have to submit the requested information in an updated registration dossier by **02 October 2019**. You also have to update the chemical safety report, where relevant.

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.

**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[1] by Ofelia Bercaru, Head of Unit, Evaluation E3

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

**Appendix 1: Reasons**

## 1. Ready biodegradability (Annex VII, Section 9.2.1.1.)

In accordance with Articles 10(a) and 12(1) of the REACH Regulation, a technical dossier registered at 100 to 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.

"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.

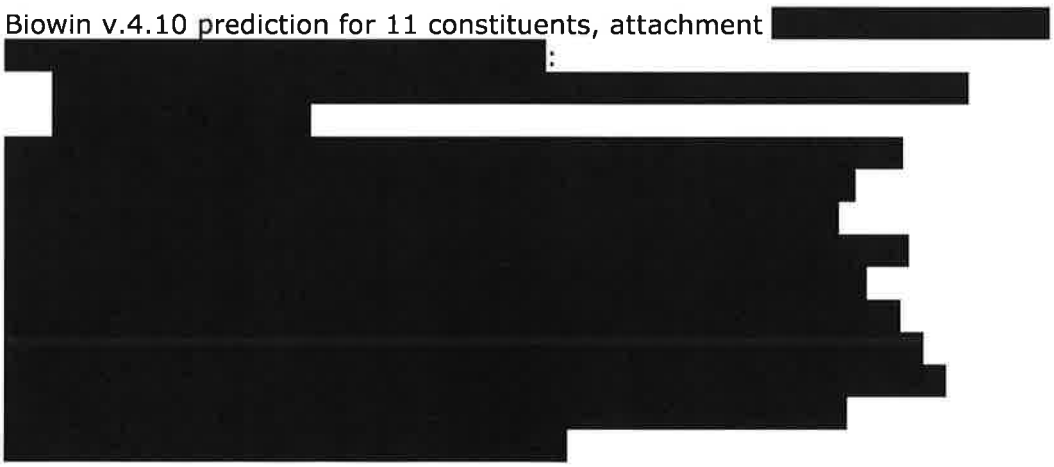
*Information provided*

In the technical dossier you have provided the following four study records to fulfil the standard information requirement of Annex VII, section 9.2.1.1.:

a) Key study, QSAR predictions: "*Biodegradation prediction for CAS 68092-28-4 by read-across using the OECD QSAR Toolbox*" [redacted]. (2016).

- QSAR toolbox prediction: Analogue 1: 67.8 % biodegradation %, Analogue 2: 76.9 % biodegradation, Analogue 3: 88.1% biodegradation, Analogue 4: 74.4 % biodegradation.

- Biowin v.4.10 prediction for 11 constituents, attachment [redacted]:



b) Supporting study on analogue substance distilled tall oil (DTO; CAS No 924-020-2): "*Biodegradation of Distilled Tall Oil*", [redacted] (1993), experimental study according to OECD Guideline 301 D (Ready Biodegradability: Closed Bottle Test), (reliability 2, GLP), composition of test material: "*the test material is* [redacted]", result: 60 % degradation in 28 d, conclusion: "*readily biodegradable, but failing 10-day window*".

c) Supporting study on analogue substance 2,2'-iminodiethanol (DEA; CAS No 111-42-2, EC No 203-868-0): "[redacted]", [redacted] (1992), (reliability 2, GLP) OECD Guideline 301 F (Ready Biodegradability: Manometric Respirometry Test), test material analytical purity 98 %, impurities < 1%

monoethanolamine, < 1 % triethanolamine, result: 93 % biodegradation, readily biodegradable.

d) Supporting study, QSAR prediction on constituent "*Resin acids and Rosin acids*" (CAS No 73138-82-6, EC No 277-299-1): "*01.03.2016 17:27 [R]: 59.9 %; Estimation for CO2 evolution, DOC removal, O2 consumption for CAS 73138-82-6*"

ECHA notes that you have sought to adapt this information requirement according to Annex XI, Section 1.3. of the REACH regulation by providing results obtained from the application of quantitative structure activity relationship models ((Q)SARs) and according to Annex XI, Section 1.5. by providing data on proposed analogue substances. ECHA has evaluated the acceptability of these adaptations below.

*ECHA's assessment of the information provided*

*Study record a)*

ECHA notes that for a QSAR prediction to be accepted it needs to fulfil the requirements set for acceptance of QSAR models in Annex XI, Section 1.3:

- Adequate and reliable documentation of the applied method is provided
- Results are derived from a (Q)SAR model whose scientific validity has been established
- The substance falls within the applicability domain of the (Q)SAR model.
- Results are adequate for the purpose of classification and labelling and/or risk assessment.

In the following, ECHA assesses whether the QSAR predictions submitted fulfil the above requirements.

In the Endpoint Study Record (ESR) marked as the key study (a) (above) you have submitted two QSAR toolbox and BIOWIN predictions. For the QSAR toolbox prediction you have indicated that you have used the profiler for "*Acute aquatic toxicity ECOSAR*" and chosen "*surfactants-anionic and surfactants-cationic*" as basis for the grouping. ECHA notes that the substances used as basis for this prediction differ from the registered substance in that they all are quaternary ammonium compounds and the majority of them contain sulfonates whilst the registered substance consists of organic acids and a secondary amine. Due to these differences ECHA considers these substances as not appropriate to be used as a starting point for predicting the biodegradation of the registered substance. Consequently the results are not adequate for the purpose of classification and labelling and/or risk assessment and the prediction cannot be accepted.

With regards to the BIOWIN predictions, ECHA notes that you have not provided any documentation of the applied method but have summarised the results in the [redacted] document attached to the ESR. Whilst the BIOWIN model can be considered as scientifically valid and acceptable the predictions are not valid for the registered substance due to the following reasons. Firstly, you have not identified whether the constituents of the registered substance fall within the applicability domain of the model. Furthermore, you have used an incorrect SMILES as a starting point as a dot in the SMILES structure which in the model creates a covalent bond between the O and N atom has been deleted. Instead, in the model used the fatty acids and the amine are connected via an ionic bond. Furthermore, whilst the fragments are covered by the training set, the training set does not contain any chemicals that are very similar in structure to the

registered substance. For these reasons ECHA considers the predictions not adequate for the purpose of classification and labelling and/or risk assessment. As a conclusion, the BIOWIN predictions are not acceptable.

ECHA notes further that the BIOWIN QSAR approach did not cover the "*unassigned components in Tall oil, compound with diethanolamine*" (CAS Nos not available). In the [redacted] document you conclude that these are "*not expected to be P or vP, based on read-across to identified constituents*".

Furthermore, in the [redacted] attachment in study record a) listed above, you have stated that the constituent "resin& rosin acids" (CAS No 73138-82-6) is "*highly biodegradable, based on RA to Rosin, CASRN 8050-09-7 (71% degradation), and Rosin acids & resin acids, Ca Zn salt CASRN 68334-35-0 (80%) and resin acids & rosin acids, K salts (73.3 - 89.5%) in REACH dossiers*", however, you provide no further justification nor data to support this claim. ECHA notes that in absence of any supporting information it is not possible for ECHA to assess whether the read-across proposed to the constituent "*resin& rosin acids*" only would be acceptable. Therefore ECHA considers that this analogue approach does not fulfil the requirements of REACH Annex XI, section 1.5. set for acceptability of read-across approaches.

In summary, the QSAR predictions submitted in the ESR of the key study, do not fulfil the requirements of Annex XI section 1.3. and cannot be accepted.

*Study record d)*

Concerning study record d) listed above ECHA notes the following. You have submitted a QSAR prediction using the QSAR Toolbox to assess the ready biodegradation of the constituent "*resin& rosin acids*" (percentage composition in registered substance circa [redacted] % (range between [redacted] %)). You have indicated that you used the "*Organic Functional groups*" profiler. As basis of the prediction you have used (1) structurally related compounds (salts), (2) a rosin, (3) fatty acids, tall-oil low boiling and (4) resin acids and rosin acids, methyl esters. While the salts (1) show high biodegradability, (2) to (4) have degradation values between 41 to 52 %. Based on this QSAR prediction you have concluded that the "*resin& rosin acids*" constituent has a biodegradation of 59.9 % and have acknowledged that the prediction may fail the ready biodegradation threshold of 60 %. ECHA notes that the prediction is based on only four experimental studies, the acceptability of which ECHA cannot assess in absence of study summaries. Therefore, ECHA considers that the prediction is not reliable and cannot be accepted for the purpose of classification and labelling and/or risk assessment. Furthermore, the prediction does not support the conclusion of ready biodegradation of the registered substance made by you.
In conclusion, the QSAR information submitted for the biodegradation of the constituent "*resin& rosin acids*" constituent is not sufficient to fulfil the requirements of Annex XI, Section 1.3.

*Study records b) and c)*

In addition to the QSAR predictions you have sought to adapt this information requirement according to Annex XI, Section 1.5. of the REACH Regulation and have submitted data on analogue substances distilled tall oil (DTO; CAS No 924-020-2) and 2,2'-iminodiethanol (DEA; CAS No 111-42-2, EC No 203-868-0) as supporting studies (study records b) and c) listed earlier).

Concerning the proposed analogue approach with DTO and DEA as source substances ECHA notes the following. In the Endpoint summary of Biodegradation in water: screening tests, section 5.2.1. of IUCLID, and in the CSR section 4.1.2. Biodegradation (p. 25) you have provided the following arguments to justify the read-across approach used for the present endpoint: "*Two key studies are provided, one on tall oil and one on diethanolamine. The justification of choosing these two analogues is provided in detail in the document "Tall oil compound with diethanolamine -- read across justification based on the Read-Across Assessment Framework (RAAF) document", attached in section 13 of this dossier.*" In the read-across justification document you have indicated that you have used the Read-Across Assessment Framework (RAAF) and considered that "*Scenario 1, (Bio) transformation to common compound(s) is the most appropriate scenario to use for the target substance taking into account the available data*". You indicate that "*although there is no toxicokinetic data in the literature, the OECD Toolbox and associate software programme, TIMES is able to model the expected metabolites of this substance*" and that "*it is clear the target substance is hydrolysed to two primary metabolites, Tall Oil (CAS # 8002-26-4, represented by SMILES notation CCCCCCCCC=CCCCCCCCC(O)=O for oleic acid, CAS # 112-80-1) and DEA (CAS # 111-42-2, SMILES Notation OCCNCCO)".* You consider that these two, i.e. tall oil and DEA are the most suitable source substances. ECHA considers this as your hypothesis for the proposed read-across.

ECHA notes further that in IUCLID section 13 you have attached a read-across justification document "[redacted]". However, ECHA observes that this document does not cover the read-across submitted for environmental endpoints in general nor for the present endpoint of ready biodegradation specifically.

ECHA understands from the information submitted that you considered that the substance subject to this decision dissociates in water into two transformation products, tall oil (a UVCB in itself) and DEA, and that you concluded that the properties of the substance subject to this decision can be predicted from data obtained on these dissociation products. Even though no supporting evidence characterising the rate and extent of this dissociation and specifically how this process takes place in the environment has been provided, ECHA considers that this read-across hypothesis based on dissociation is an acceptable approach.

Furthermore, ECHA considers the OECD 301 F study on DEA (study c) listed above) as suitable to conclude that DEA is readily biodegradable.

However, ECHA notes that there are deficiencies in reporting of composition and identity of the tall oil in the OECD Guideline 301 D study (study b) listed above). ECHA considers that for a read-across approach to be acceptable, the substance characterisation of the source substance(s) and the actual test material need to be sufficiently detailed in order to assess whether the attempted prediction is not compromised by the composition and/or impurities. In the ECHA practical guide 6 "How to report on Read-Across" it is recommended to follow the ECHA Guidance for identification and naming of substances under REACH and CLP (version 2.1, May 2017) also for the source substances. This ensures that the identity of the source substance and its impurity profile allows an assessment of the suitability of the substances for read-across purposes.

In the RA justification document you have indicated that tall oil with CAS No 8002-26-4 is "*a UVCB that is primarily composed on* [redacted] In the ESR for study b) in the IUCLID technical dossier (section 5.2.1.) you have indicated that the tested material is distilled tall oil with CAS No 924-020-2 and given the composition as "*the test material is a* [redacted]". ECHA notes that with the information

provided it is not possible for ECHA to verify whether the tested material, i.e. the composition of the UVCB source material tested, is representative of the registered UVCB substance. More specifically, as you have not provided any information on the concentration ranges of the constituents in the material tested in the tall oil ready biodegradation study. It is not possible for ECHA to verify that the tested material represents worst case in terms of ready biodegradability of the registered substance.

ECHA notes also that information on the fate of the substance in the environment is one of the key parameters to be considered for the PBT/vPvB assessment. Regarding this ECHA notes that pursuant to Annex XIII of the REACH Regulation "*the identification* [of PBT and vPvB substances] *shall also take account of the PBT/vPvB-properties of relevant constituents of a substance*". ECHA Guidance on information requirements and chemical safety assessment (version 3.0, June 2017), Chapter R.11.4.1. further specifies that "*constituents, impurities and additives are relevant for the PBT/vPvB assessment when they are present in concentration of ≥ 0.1% (w/w). This limit of 0.1% (w/w) is set based on a well-established practice rooted in a principle recognised in European Union legislation.* ECHA therefore notes that information on the composition of the substance tested in a ready biodegradation study is essential.

Therefore ECHA considers that the supporting study conducted with tall oil and included in your dossier cannot be used to fulfil the requirement of Annex XI, Section 1.5 of the REACH Regulation. Consequently it cannot fulfil the information requirement of Ready biodegradability (Annex VII, Section 9.2.1.1.).

Therefore, even though ECHA accepts your read-across hypothesis based on dissociation, your adaptation according to Annex XI 1.5 of the information requirement is rejected due to the unacceptability of the QSAR data (studies a) and d) listed above) and the tall oil ready biodegradation data (study c) listed above) the data provided on ready biodegradation does not cover the whole registered substance. Consequently there is an information gap and it is necessary to provide information for this endpoint.

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

*Conclusion*

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, 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, July 2017) and in the paragraph below. The test guidelines include the description of their applicability domain.

In your comment on the Draft Decision (DD) you indicated that the tall oil used for read-across (study b. as listed above) and the tall oil used in the manufacturing of the registered substance "*are one and same*". You note that you will clarify the EC number of tall oil and that the correct EC No is 232-304-6 as that is the identifier of the tall oil used in the manufacturing of the registered substance. You intend to update your dossier with this information together with updated read-across documentation. You will also delete the QSAR predictions due to the questions raised by ECHA.

ECHA acknowledges your intentions to update this endpoint to address the shortcomings addressed by ECHA above. ECHA agrees that clarification of the tall oil used in study b. and its relation to the registered substance will improve the read-across for this endpoint. ECHA notes that at the follow-up stage ECHA will assess the updated dossier and any adaptations therein.

Therefore, pursuant to Article 41(1) and (3) of the REACH Regulation, you are requested to perform one of the following tests with 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*

ECHA notes that for the purpose of the risk assessment of the registered substance you have considered that "*as a precautionary measure, the overall determination that will be carried forward for risk assessment of the registered substance will be readily biodegradable but failing the 10 day window.*" However, as discussed above, based on the data provided ECHA considers it not justified to conclude that the registered substance is readily biodegradable but failing 10-day window. Therefore, once results of the ready biodegradation test are available, you shall revise the chemical safety assessment as necessary according to Annex I of the REACH Regulation.

Furthermore, if based on the new ready biodegradation data to be generated the registered substance would not be shown to be readily biodegradable and further information on its degradation would be required for example for the purpose of the PBT/vPvB assessment you are to submit testing proposal(s) for further degradation studies according to the relevant information requirements of Annex VII to IX.

## 2. Long-term toxicity testing on aquatic invertebrates (Annex VII, Section 9.1.1., column 2

In accordance with Articles 10(a) and 12(1) of the REACH Regulation, a technical dossier registered at 10 to 100 tonnes per year must contain, as a minimum, the information specified in Annexes VII to VIII 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 "*guidance note on fulfilling the requirement of Annexes VI to XI*" laid down in Annex VI to the REACH Regulation, explicitly indicates that "*in some cases, the rules set out in Annexes VII to XI may require certain tests to be undertaken earlier than or in addition to the standard requirements*". More specifically, column 2 entries in Annexes VII-X of the REACH Regulation provide that the standard information required in Column 1 of those Annexes may in some cases be adapted, *i.e.* waived or augmented, when appropriately justified. In particular, Column 2 of Annex VII, Section 9.1.1. of the REACH Regulation ('Short-term toxicity testing on invertebrates') indicates that:

"*The long-term aquatic toxicity study on* Daphnia *(Annex IX, section 9.1.5) shall be considered if the substance is poorly water soluble.*"

ECHA considers that some of the constituents of the registered substance are poorly water soluble, with a water solubility of <1 mg/L, as fully discussed further below. Poorly soluble substances require longer time to be taken up by the test organisms and so steady-state conditions are likely not to be reached within the duration of a short-term toxicity test. For this reason, short-term tests may not give a true measure of toxicity for poorly soluble substances and toxicity may actually not even occur at the water solubility limit of the substance if the test duration is too short.

Information on long-term toxicity testing on aquatic invertebrates shall be considered for the risk assessment and for the classification and labelling of the substance. ECHA notes that no reliable PNEC can currently be derived for the registered substance. Information on on long-term toxicity to *Daphnia* and fish need to be generated in order to derive reliable PNECs. Furthermore, if toxicity is to be observed in these studies, the classification of the substance might have to revised. Therefore, as the hazard and risk assessments provided in your dossier are not conclusive, ECHA considers that the available information in your chemical safety assessment does not rule out the need to investigate further long-term effects to aquatic invertebrates.

Therefore, pursuant to Column 2 of Annex VII, Section 9.1.1. of the REACH Regulation, it is considered that a long-term aquatic toxicity study on invertebrates (Annex IX, Section 9.1.5) is warranted.

You have sought to adapt this information requirement according to Annex IX, Section 9.1., column 2. You provided the following justification for the adaptation: "*In accordance with the Column 2 adaptation of Annex IX of Regulation (EC) 1907/2006 (REACH), point 9.1, long-term testing on aquatic invertebrates will only be proposed if the CSR indicates the need to investigate further effects on aquatic organisms. Although the substance is classified with regards to chronic effects, it is not classified as PBT or vPvB and the results of the CSR did not trigger any concern for long-term exposure; it is therefore considered that a study is scientifically unjustified. As such the registrant proposes to waive the long term toxicity test on aquatic invertebrates required under Section 9.1.5 of Annex IX.*"

However, ECHA notes that your adaptation does not meet the general rules for adaptation of Annex IX, Section 9.1., column 2 due to the following.

Firstly, in several exposure scenarios (ES) of your CSR you have reported Risk Characterisation Ratios (RCRs) of almost one for the aquatic environment (both freshwater and marine). ECHA considers that due to the uncertainty arising from having only acute aquatic data for a UVCB substance with also poorly water soluble constituents (as discussed further in the following paragraph) and the fact that the ready biodegradation status of the registered substance is unclear (as discussed in section 1 above), it is not justified to conclude that the CSR did not trigger any concern for long-term exposure.

In IUCLID section 4.8, water solubility you explain that you have attempted to investigate the water solubility of the substance. However, due to technical difficulties the study was not possible and you have consequently adapted the standard information requirement of a water solubility study (Annex VII, section 7.7.) according to Annex XI, section 2 governing 'testing is not technically not possible'. In the adaptation you explain that in the attempted water solubility study sample solutions saturated in the range of 0.11 to 4.77 % w/w resulted in the formation of stable, uniform dispersions at 20.0 ± 0.5 °C which could not be removed by centrifugation or filtration. You also note that assessing the water solubility of the registered substance is outside the scope of available prediction (QSAR) methods.

ECHA notes that based on the information in the dossier, the water solubility of the registered substance cannot be confirmed. However, ECHA notes that long chain fatty acids, such as some of the constituents of the registered substance, are known to have low water solubility values. In your CSR, you also discuss that specific sample preparation, the Water Accommodated Fraction (WAF) method, was required in the existing aquatic studies "*due to the low aqueous solubility and complex nature of the test material*". Therefore, based on the information provided in your technical dossier, ECHA considers that some constituents of your substance are likely to be poorly soluble.

Also, ECHA considers that it is not possible to fully assess the toxicity of a low water solubility substance even if using the WAF approach for sample preparation due to the issues such as the time taken for the effects to be observed described in ECHA *Guidance on information requirements and chemical safety assessment, Chapter R.7b* (version 4.0, June 2017) and as outlined above in this decision. Please also refer to the *Note for consideration* at the end of request 4. (below) regarding ECHAs overall considerations on the use of the WAF approach. ECHA also notes that it is unclear how the WAF represents the registered substance as a whole since you have reported that "*the test material gave a chromatographic profile consisting of a single peak*".

For the reasons stated above, ECHA also considers that the aquatic ITS (*ECHA Guidance on information requirements and chemical safety assessment*, Chapter R.7b, Section R.7.8.5.3. (version 4.0, June 2017), is not applicable and it is necessary to provide long-term data on both aquatic invertebrates and on fish.

ECHA therefore considers that the available information in your CSA does not allow to omit long-term testing.

In your comments on the Draft Decision (DD) you reiterate that long-term testing is not needed due to "*high-reliability short-term aquatic test data*", "*Substance is readily biodegradable (by read across)*" and "*is not expected to be bioaccumulative*". You also note

that "*there is adequate information for classifying the substance*" and that you intent to downgrade the tonnage to the 10-100 MT range. ECHA refers to its reasoning above as to why the current data and CSA does not allow to waive long-term testing, even at the current Annex VII level. ECHA also notes that the substance is currently self classified as aquatic chronic 2 and therefore the data to be generated may lead to a more stringent classification. As the data is needed for the derivation of the PNECaquatic substances bioaccumulation potential is not an acceptable adaptation. Furthermore, ECHA notes that the ready biodegradation status of the registered substance is still unclear and also notes that even if the registered substance is biodegradable, its concentration might still be locally significant if there are continuous releases into the environment. Furthermore, even if the registered substance, a UVCB, would be found to be readily biodegradable in a standard ready biodegradation study, the ready biodegradation status of the low water soluble constituents may be different.

Therefore, your adaptation of the information requirement cannot be accepted and long-term testing is indicated.

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, July 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.

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: Daphnia magna reproduction test (test method: EU C.20./OECD TG 211).

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

In accordance with Articles 10(a) and 12(1) of the REACH Regulation, a technical dossier registered at 10 to 100 tonnes per year must contain, as a minimum, the information specified in Annexes VII to VIII 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 "*guidance note on fulfilling the requirement of Annexes VI to XI*" laid down in Annex VI to the REACH Regulation, explicitly indicates that "*in some cases, the rules set out in Annexes VII to XI may require certain tests to be undertaken earlier than or in addition to the standard requirements*". More specifically, column 2 entries in Annexes VII-X of the REACH Regulation provide that the standard information required in Column 1 of those Annexes may in some cases be adapted, *i.e.* waived or augmented, when appropriately justified. In particular, Column 2 of Annex VIII, Section 9.1.3. of the REACH Regulation ('Short-term toxicity testing on fish') indicates that:

"*Long-term aquatic toxicity testing as described in Annex IX* [of the REACH Regulation] *shall be considered if the chemical safety assessment according to Annex I* [of the REACH Regulation] *indicates the need to investigate further effects on aquatic organisms. The choice of the appropriate test(s) will depend on the results of the chemical safety assessment.*

*The long-term aquatic toxicity study on fish (Annex IX, Section 9.1.6) shall be considered if the substance is poorly water soluble".*

ECHA considers that some of the constituents of the registered substance are poorly water soluble, with a water solubility of <1 mg/L, as fully discussed below. Poorly soluble substances require longer time to be taken up by the test organisms and so steady-state conditions are likely not to be reached within the duration of a short-term toxicity test. For this reason, short-term tests may not give a true measure of toxicity for poorly soluble substances and toxicity may actually not even occur at the water solubility limit of the substance if the test duration is too short.

Information on long-term toxicity testing on fish shall be considered for the risk assessment and for the classification and labelling of the substance. ECHA notes that no reliable PNEC can currently be derived for the registered substance. Information on on long-term toxicity to *Daphnia* and fish need to be generated in order to derive reliable PNECs. Furthermore, if toxicity is to be observed in these studies, the classification of the substance might have to revised. Therefore, as the hazard and risk assessments provided in your dossier are not conclusive, ECHA considers that the available information in your chemical safety assessment does not rule out the need to investigate further long-term effects to aquatic invertebrates.

Therefore, pursuant to Column 2 of Annex VIII, Section 9.1.3. of the REACH Regulation, it is considered that a long-term aquatic toxicity study on fish (Annex IX, Section 9.1.6) is warranted.

You have sought to adapt this information requirement according to Annex XI, Section 9.1, column 2. You provided the following justification for the adaptation: "*In accordance with the Column 2 adaptation of Annex IX of Regulation (EC)1907/2006 (REACH), point 9.1, long-term testing will only be proposed if the CSR indicates the need to investigate further effects on aquatic organisms. The substance is not classified for acute toxicity, nor is it classified as PBT or vPvB. The CSR did not trigger any concern for long-term exposure and it is therefore considered that a study is scientifically unjustified.*"

However, ECHA notes that your adaptation does not meet the general rules for adaptation of Annex IX, Section 9.1., column 2. since as fully discussed above in section 3, it is not justified to conclude that the CSR did not trigger any concern for long-term exposure.

Furthermore, as also discussed in section 2 above, there are indications that some of the constituents of the registered substance are poorly water soluble, hence acute aquatic data alone cannot be used to conclude the aquatic toxicity potential of the registered substance.

Nevertheless, ECHA notes the following concerning the short-term fish data provided in the technical dossier. In the technical dossier you have provided data on short-term fish on the analogue substances tall oil (CAS No 8002-26-4, EC No 232-304-6) and DEA. As discussed in section 2 above ECHA considers the read-across hypothesis based on dissociation acceptable for the endpoint of ready biodegradation for which you have applied a read-across approach based on Annex XI section 1.5. However, as also discussed in that section due to the lack of information on the composition of the tested material of tall oil it is not possible to verify whether the tested material is representative of the registered substance. This issue also applies to the data provided on tall oil in section 6.1.1. Short-term toxicity to fish of IUCLID technical dossier. In the study "*Fish, Acute Toxicity Test, Limit-Test*" ([redacted] 2006) conducted on tall oil you have not provided any information on the composition of

the tested tall oil material. As no concentration ranges of the material tested are provided, it is not possible for ECHA to verify that the tested material represents a worse case in terms of toxicity to fish of the registered substance. It is therefore not possible for ECHA to assess how the material tested represents the registered substance.

In your comments on the DD you have reiterated that you consider the long-term fish study not necessary due to the same reasons that have been addressed by ECHA under section 2. above. In addition, you note that if ECHA still considers long-term aquatic testing necessary you will carry out the *Daphnia* study "*as daphnia seem to be most sensitive organism for the Target Substance and diethanolamine (DEA) and fish the least sensitive, from acute studies*". As discussed in section 2. and in the *Notes for your consideration* at the end of this section, the aquatic ITS relying on acceptable acute data is not applicable in this case as the species sensitivity cannot be determined due to low water solubility of some of the constituents of the registered substance making comparison based on acute data alone not acceptable.

Furthermore, ECHA acknowledges that for diethanolamine (DEA) fish appear to be less sensitive than daphnids. However, for the registered substance as a whole only acute data on daphnids is available while read-across data for acute fish has been provided. ECHA has identified the deficiencies of this read-across acute fish study above. As discussed in section 1. above, in your general comment on the DD you indicate that the tall oil used for read-across and the tall oil used in the manufacturing of the registered substance are identical and that you will clarify this in a dossier update. ECHA acknowledges your intention, however notes that clarifying the composition of the tall oil used in the read-across short-term fish study does not alone remove the necessity to carry out a long-term toxicity test on fish. Since the need for long-term testing arises from the need to accurately assess the toxicity of the registered UVCB substance with also low water soluble constituents, for a read-across approach to be acceptable for aquatic standard information requirements it would need to address how the toxicity of these low water solubility constituents is also covered by the approach provided.

In summary, ECHA considers that the currently available information in your CSA does not allow to omit long-term testing.

Therefore, your adaptation of the information requirement cannot be accepted and long-term testing on fish is indicated.

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, July 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, July 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, July 2017).

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: Fish, early-life stage (FELS) toxicity test (test method: OECD TG 210).

*Notes for your consideration concerning requests 2 and 3*

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

Before conducting the above test you are advised to consult the ECHA Guidance on information requirements and chemical safety assessment, Chapters R.4 (v.1.1, December 2011), R.5 (v.2.1, December 2011), R.6 (May 2008), R.7b (v 4.0, June 2017) and R.7c (v 3.0, June 2017). If you decide to adapt the testing requested according to the specific rules outlined in Annexes VI to X and/or according to general rules contained in Annex XI of the REACH Regulation, you are referred to the advice provided in practical guides on "How to use alternatives to animal testing to fulfil your information requirements for REACH registration.

As further explained in Appendix 3, it is important to ensure that the particular sample of substance selected to be tested in the study is appropriate to assess the properties of the registered substance. Hence, it is critical that those constituents which are most relevant shall be present at appropriate concentrations in any sample tested.

ECHA notes that due to low water solubility of some of the constituents of the registered substance and lack of data on short-term fish on the overall registered substance, 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*, Chapter R7b (version 4.0, July 2017; 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 also discussed in section 3. above.

Due to the low solubility of the substance in water and high water-octanol partitioning coefficient of the substance in water 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, July 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).

In addition, regarding the use of the Water Accommodated Fraction (WAF) approach, please note that the WAF approach is problematic when used with a test substance containing several constituents, as in the case of the registered substance. In such cases the toxicity cannot be allocated to specific constituents directly and interpretation of the results in the

risk assessment requires careful consideration taking into account differences in fate of the constituents in the environment. When constituents of varying solubility are present there can be partitioning effects which limit dissolution in the water. These effects should be minimised and appropriate loadings selected accordingly to allow an appropriate determination of the toxicity of the different constituents. In that respect, it is critical that a robust chemical analysis is carried out to identify those constituents present in the water to which the test organisms are exposed. Additionally, chemical analysis to demonstrate attainment of equilibrium in WAF preparation and stability during the conduct of the test is required. Methods capable of identifying gross changes in the composition of WAFs with time are required, such as ultra-violet spectroscopy or total peak area, have been used successfully for this purpose. The method used to prepare the WAF should be fully described in the test report and evidence of its compositional stability over time should be provided.

**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. However, following your comments on the draft decision indicating a tonnage band downgrade, only, ECHA has taken into account the updated tonnage band (submission number [redacted] and date 19 April 2018), only. No assessment of the updated registration has occurred. Based on the average production and/or import volumes for the three preceding calendar years, ECHA has changed the tonnage band as basis for the draft decision from 100 - 1000 tonnes per year (submission number: [redacted] from 14 March 2016) to 10 - 100 tonnes per year (submission number: [redacted]).

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

The compliance check was initiated on 16 January 2017.

ECHA notified you of the draft decision and invited you to provide comments. ECHA took into account your comments and your information about tonnage band downgrade. This has resulted in the removal of the following decision request: Extended one-generation reproductive toxicity study (Annex IX, Section 8.7.3.).

As a consequence the deadline for providing the information to meet the requests remaining in the draft decision has been set to 12 months.

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

As no amendments were proposed, ECHA took the decision according to Article 51(3) 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 carrying out the tests required by the present decision, it is important to ensure that the particular sample of substance tested 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. If the registration of the substance covers different grades, the sample used for the new tests must be suitable to assess these.

   Furthermore, 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.

4. If the required information is derived from tests conducted with an analogue substance in the context of a read-across approach, the identity of the test material used to perform the test should be specified in line with ECHA's Practical Guide on "How to use alternatives to animal testing to fulfil your information requirements" (chapter 4.4). This is required to show that the test material is representative of the analogue substance identified in the read-across approach and used to predict the properties of the registered substance.