EUROPEAN CHEMICALS AGENCY

Helsinki, 20 November 2018

Addressee: [redacted]

Decision number: CCH-D-2114447799-27-01/F
Substance name: Hydrogenated rosin alcohols
EC number: 701-057-0
CAS number: NS
Registration number: [redacted]
Submission number: [redacted]
Submission date: 30/10/2017
Registered tonnage band: 10-100

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. **Water solubility (Annex VII, Section 7.7.; test method: OECD TG 105) with the registered substance;**

2., 3. **Combined repeated dose toxicity study with the reproduction/developmental toxicity screening study (Annex VIII, Section 8.6.1. and Section 8.7.1.; test method: OECD TG 422) in rats, oral route with the registered substance;**

4. **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;**

5. **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;**

6. **Identification of the degradation products of the registered substance for the purpose of PBT and vPvB Assessment (Annex I, section 4; test method: OECD TG 309, suspended sediment test with higher concentration of the test material as defined in the respective TG or any appropriate and suitable test method, as further defined in the Appendix I);**

7. **Exposure assessment and risk characterisation (Annex I, Sections 5. and 6.) for environment as further specified in Appendix 1, Section 7 of the present decision.**

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 **27 November 2020**. 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. Water solubility (Annex VII, Section 7.7.)

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.

"Water solubility" is a standard information requirement as laid down in Annex VII, Section 7.7 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.

To fulfil the information requirement for water solubility (Annex VII, Section 7.7) you have provided a key study for the registered substance using EU Method A.6 ([redacted], 2011) resulting a water solubility of 0.1999 mg/L at 20 C , pH 7.0.

ECHA notes that you have provided a single value to represent the registered UVCB substance. However, a range of water solubility should be provided for a UVCB. This information is needed for the design of for example aquatic toxicity testing (ECHA Guidance on information requirements and chemical safety assessment (version 4.0, June 2017), Chapter R.7b, Appendix R.7.8-1 for Sections R.7.8.1. to R.7.8.6 and related Table R.7.8-3). The registered substance consist of four constituent/constituent groups;

- Tetrahydroabietyl alcohol / (7-isopropyl-1,4a-dimethyltetradecahydrophenanthren-1-yl)methanol / 855618-62-1, [redacted]% (w/w)
- Dehydroabietylalcohol /(7-isopropyl-1,4a-dimethyl-1,2,3,4,4a,9,10,10a-octahydrophenanthren-1-yl)methanol / 102314-98-7, [redacted]% (w/w)
- Dihydroabietyl alcohol /(7-isopropyl-1,4a-dimethyl-1,2,3,4,4a,4b,5,6,7,9,10,10a-dodecahydrophenanthren-1-yl)methanol / 127-36-6 / 204-836-9, [redacted]% (w/w)
- Rosin, hydrogenated, methyl ester / Resin acids and Rosin acids, hydrogenated, Methyl esters / 8050-15-5 / 232-476-2, [redacted] % (w/w)

ECHA notes that there is a significant fraction of Rosin, hydrogenated, methyl ester / Resin acids and Rosin acids, hydrogenated, Methyl esters in the composition which could have significantly lower water solubility than the value obtained from the study in the dossier and no information has been provided on these.

In your comments to the draft decision, you acknowledge that the constituents of the UVCB may have different water solubilities that may not be accurately represented by a single water solubility value. You describe that in the study by [redacted] (2011) (cited above) multiple peaks where observed when the substance was dissolved in the solvent but only one peak was observed in the solution used in the water solubility study. You considered that the value from the single peak represents the water solubility of the whole test item and at the same time indicate that the other constituents would be much less water soluble.

You proposed to provide additional information on the water solubility of the individual constituents, from QSAR predictions rather than conducting a new water solubility study on the whole UVCB substance. ECHA considers this to be a reasonable approach. However, the information provided needs to cover the whole substance and the results obtained from a QSAR model need to fulfil the criteria set in Annex XI, section 1.3. of the REACH Regulation. In particular, ECHA highlights that the substance(s) need to fall into the applicability domain of the QSAR model used.

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 concludes that further information is needed to describe the range of water solubility of the registered substance to cover the water solubility of all the constituents of the registered UVCB substance.

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: Water solubility (test method: OECD TG 105).

Guidance for determining the water solubility is available in the ECHA Guidance on information requirements and chemical safety assessment (version 6.0, July 2017), Chapter R.7a, Section R.7.1.7.

2. Short-term repeated dose toxicity (28 day), one species (Annex VIII, Section 8.6.1.)

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.

A "short-term repeated dose toxicity study (28 days)" is a standard information requirement as laid down in Annex VIII, Section 8.6.1. 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.

You have not provided any study record of a short-term repeated dose toxicity study (28 days) in the dossier that would meet the information requirement of Annex VIII, Section 8.6.1.

The technical dossier does not contain an adaptation in accordance with column 2 of Annex VIII, Section 8.6.1. or with the general rules of Annex XI for this standard information requirement.

In the technical dossier under the toxicity to reproduction endpoint (IUCLID section 7.8.1.) you indicated that "*the LR is starting an OECD 422 in order to meet the requirements for repeat dose and reproductive toxicity under Annex VIII immediately*". ECHA notes your intention to conduct the OECD TG 422 study. However, since the study is currently not available in the technical dossier there is still a data gap.

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.

When there is no information available neither for the 28-day repeated dose toxicity endpoint (EU B.7, OECD TG 407), nor for the screening study for

reproductive/developmental toxicity (OECD TG 421 or TG 422) as explained below under point 3.), the conduct of a combined repeated dose toxicity study with the reproduction/developmental toxicity screening test (OECD TG 422) is preferred to ensure that unnecessary animal testing is avoided. Such an approach offers the possibility to avoid carrying out a 28-day study according to OECD TG 407, because the OECD TG 422 can at the same time fulfil the information requirement of REACH Annex VIII, 8.6.1 and that of REACH Annex VIII, 8.7.1.[2]

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* (version 6.0, July 2017) Chapter R.7a, Section R.7.5.4.3 - is the most appropriate route of administration. More specifically, the substance has a concern for potential inhalation exposure due to uses of the registered substance with industrial and professional spray application (PROC 7 and 11), as reported in the chemical safety report. However, the substance is a viscous, tacky semi-liquid of very low vapour pressure (0.0019 Pa at 25°C) and a very high boiling point (394°C). Hence, the test shall be performed by the oral route.

According to the test method OECD TG 422, the test is designed for use with rats. On the basis of this default assumption ECHA considers testing should be performed with rats.

A member state proposed an amendment to request only OECD 422 study as the repeated dose toxicity endpoint was not initially addressed under the compliance check process because there was an ongoing 90-day testing proposal examination. After a dossier update in October 2017 you downgraded the tonnage band to Annex VIII (10-100tpa) hence the 90-day testing proposal was removed. In the technical dossier you indicated that you intend to conduct an OECD TG 422 study to meet the repeated dose toxicity and reproductive toxicity standard information requirements.

As a response, you were informing ECHA that you had already started the OECD 422 combined repeat dose toxicity/reproductive screening study in July 2018. ECHA will assess the latest dossier update in the follow-up process according to Art 42 of the REACH Regulation whether the provisions of Annex VIII, Section 8.6.1 are met.

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: Combined repeated dose toxicity study with the reproduction/developmental toxicity screening test (test method: OECD TG 422) in rats by the oral route.

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

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.

"Screening for reproductive/developmental toxicity" (test method OECD TG 421 or 422) is a

[2] ECHA Guidance, Section R.7.6.2.3.2., pages 484 to 485 of version 6.0 – July 2017. (https://echa.europa.eu/documents/10162/13632/information_requirements_r7a_en.pdf)

standard information requirement as laid down in Annex VIII, Section 8.7.1. of the REACH Regulation if there is no evidence from available information on structurally related substances, from (Q)SAR estimates or from *in vitro* methods that the substance may be a developmental toxicant. No such evidence is presented in the dossier. 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 not provided any study record of a screening for reproductive/developmental toxicity in the dossier that would meet the information requirement of Annex VIII, Section 8.7.1.

In the technical dossier you have provided the following statement under justification for data waiving: "*This information will be submitted later based on ECHA communication SUB-C-2114363415-50-01/F for submission* [redacted]". However, ECHA notes that this communication was only to inform you that the registration update for the previous tonnage band (with submission no. [redacted]) was considered as incomplete, due to missing information. Moreover, you indicated that "*the LR is starting an OECD 422 in order to meet the requirements for repeat dose and reproductive toxicity under Annex VIII immediately*". ECHA notes your intention to conduct the OECD TG 422 study. However, since the study is currently not available in the technical dossier there is still a data gap.

As explained above, currently 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.

When there is no information available neither for the 28-day repeated dose toxicity endpoint (EU B.7, OECD TG 407) (as explained above under point 2.), nor for the screening study for reproductive/developmental toxicity (OECD TG 421 or TG 422), the conduct of a combined repeated dose toxicity study with the reproduction/developmental toxicity screening test (OECD TG 422) is preferred to ensure that unnecessary animal testing is avoided. Such an approach offers the possibility to avoid carrying out a 28-day study according to OECD TG 407, because the OECD TG 422 can at the same time fulfil the information requirement of REACH Annex VIII, 8.6.1 and that of REACH Annex VIII, 8.7.1.[3] According to the test method OECD TG 422, the test is designed for use with rats. On the basis of this default assumption ECHA considers testing should be performed with 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* (version 6.0, July 2017) Chapter R.7a, Section R.7.6.2.3.2. Since the substance to be tested is a viscous, tacky, semi-liquid, ECHA concludes that testing should be performed by the oral route.

In your comments on the draft decision, you agree to perform the test.

A member state proposed an amendment to request only OECD 422 study as the repeated dose toxicity endpoint was not initially addressed under the compliance check process because there was an ongoing 90-day testing proposal examination. After a dossier update in October 2017 you downgraded the tonnage band to Annex VIII (10-100tpa) hence the 90-day testing proposal was removed. In the technical dossier you indicated that you intend

[3] ECHA Guidance, Section R.7.6.2.3.2., pages 484 to 485 of version 6.0 – July 2017. (https://echa.europa.eu/documents/10162/13632/information_requirements_r7a_en.pdf)

to conduct an OECD TG 422 study to meet the repeated dose toxicity and reproductive toxicity standard information requirements.

ECHA notes that following the proposal for amendments submitted by one of the Member States Competent Authories, to request only the OECD TG 422 under this section, you informed ECHA that you had already started the OECD 422 combined repeat dose toxicity/reproductive screening study in July 2018. ECHA will assess the latest dossier update in the follow-up process according to Art 42 of the REACH Regulation whether the provisions of Annex VIII, Section 8.7.1 are met.

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:
- Combined repeated dose toxicity study with the reproduction/developmental toxicity screening test (test method: OECD TG 422) in rats by the oral route.

4. 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.

"Short term toxicity testing on aquatic invertebrates" is a standard information requirement as laid down in Annex VII, Section 9.1.1. of the REACH Regulation. Furthermore, pursuant to Annex VII, section 9.1.1, column 2 the long-term aquatic toxicity study on Daphnia (Annex IX, section 9.1.5) shall be considered when the substance is poorly water soluble. Adequate information on this endpoint needs to be present in the technical dossier for the registered substance to meet this information requirement. The choice of the appropriate test(s) will depend on the results of the chemical safety assessment.

ECHA considers that substances that are poorly soluble in water require longer time to be significantly 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 such substances and toxicity may actually not even occur at the water solubility limit of the substance if the test duration is too short. ECHA notes that the registered substance is poorly water soluble (WS<1mg/l) and the request under section 1 is not expected to change that conclusion. The uncertainties of the provided water solubility value is further discussed in this Appendix section 1. Concerning the reported low water solubility of the substance (0.1999 mg/L), ECHA Guidance on information requirements and chemical safety assessment Chapter R7b (Version 4.0, June 2017) explains that short-term tests may not give a true measure of toxicity for poorly soluble substances. Annex VIII 9.1.3. and Annex VII 9.1.1. of the REACH Regulation also explicitly recommend that long-term aquatic toxicity tests are considered if the substance is poorly water soluble. Therefore, long-term toxicity needs to be investigated already at the tonnage band currently applicable for the substance subject to the present decision.

ECHA notes that no information on long-term toxicity on aquatic invertebrates is reported in the dossier. ECHA acknowledged that you have provided a key study for a short term toxicity study with aquatic invertebrates (OECD TG 202, Daphnia sp. Acute Immobilisation test) using the Water Accommodated Fraction (WAF) method. You did not find any effects

on *Daphnia magna* in the short term definitive or confirmatory test with the used loading rates up 100 mg/L (measured concentrations in definitive study 0.017 mg/L and confirmatory study 0.0203 mg/L). In the range finding study you reported significant effects with the WAF loading rates of 10 and 100 mg/L corresponding to measured concentrations of 0.00679 and 0.111 mg/L (48 hours). ECHA notes that the measured concentrations in the above described studies were up to 1000 times lower than the WAF loading rate of 100 mg/L used in PNEC derivation and about 10 times lower than reported water solubility of the substance. This study does not provide the information required by Annex VII, Section 9.1.1., column 2 because as described above the registered substance is poorly soluble and short-term toxicity may not give a true measure of the toxicity of the substance.

ECHA observes that you have provided the following justification for data waiving for information requirement for long term toxicity testing on aquatic invertebrates (Annex IX, Section 9.1.5.): *"In Annex IX of Regulation (EC) No 1907/2006, it is laid down that long-term toxicity testing shall be proposed by the registrant if the chemical safety assessment indicates the need to investigate further the effects on aquatic organisms. Based upon the chemical safety assessment for this substance, adequate information has been provided to determine that the substance is not a PBT or vPvB and the risk assessment has shown that RCRs for the aquatic environment are less than 1demonstrating a lack of risk and negating the need for long-term toxicity testing".*

However, ECHA notes that, as your substance is registered under Annex VIII, the information requirements under Annex IX, and the related adaptations, do not apply for this registration. In addition the provided adaptations does not meet the specific rules of adaptation of Annex VII, Section 9.1.1., Column 2 because of the substance being poorly soluble and it is not justified to conclude that the CSR did not trigger any concern for long-term exposure as described below.

ECHA notes that the risk characterisation ratios (RCRs) you provided in the chemical safety assessment are based on PNEC derived with the highest loading rate of 100 mg/L that is above both the measured test concentrations and the reported water solubility of the registered substance.

ECHA considers that due to the uncertainty arising from having only acute aquatic data for a UVCB with potentially poorly water soluble constituents (as discussed above), it is not justified to conclude that the CSR did not trigger any concern for long-term exposure.

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

In the technical dossier you have provided evidence that the parent substance is not PBT/vPvB. The PBT properties are further discussed in this decision under issue 5. Degradation. However, adequate information on aquatic toxicity is also needed for the purpose of classification and labelling and/or risk assessment.

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 VII, Section 9.1.1, column 2.

Regarding the use of the WAF approach, please note that this 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. If WAF method is used 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.

In your comments on the draft decision you agree to perform the long-term toxicity test on aquatic invertebrates. Related comments on the testing strategy for long-term aquatic toxicity are addressed under section 5. below.

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).

5. Long-term toxicity testing on fish (Annex VIII, Section 9.1.3., column 2)

Analysis of your dossier

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.

"Short-term toxicity testing on fish" is a standard information requirement as laid down in Annex VIII, Section 9.1.3. of the REACH Regulation. Furthermore, pursuant to Annex VIII, Section 9.1.3, Column 2 the long-term aquatic toxicity study on fish (Annex IX, Section 9.1.6.) shall be considered if the substance is poorly water soluble. Adequate information on this endpoint needs to be present in the technical dossier for the registered substance to meet this information requirement. The choice of the appropriate test(s) will depend on the results of the chemical safety assessment.

As described in detail in section 3 of this Appendix, ECHA considers that short-term tests may not give a true measure of toxicity for such substances and toxicity may actually not even occur at the water solubility limit of the substance if the test duration is too short. Therefore, long-term toxicity needs to be investigated already at the tonnage band currently applicable for the substance subject to the present decision.

ECHA notes that no information on long-term toxicity on fish is reported in the dossier. ECHA acknowledged that you have provided a study record for a short term toxicity study with fish (OECD TG 203, Fish Acute Toxicity Test) were no toxicity was observed with maximum loading rates of 100 mg/L. Based on the range finding test you reported results on a "limit test" with a single loading rate of 100 mg/L to confirm that no mortalities or sub-lethal effects of exposure were observed. You provided results of the chemical analysis of the test preparations with measured values ranging from less than the limit of quantitation 0.0016 mg/L to 0.022 mg/L. This study does not provide the information required by Annex VIII, Section 9.1.3., column 2 because as described above and in section 3 of this Appendix the registered substance is poorly soluble and the request under section 1 is not expected to change that conclusion and short-term toxicity may not give a true measure of the toxicity of the substance.

ECHA observes that you have provided the following justification for data waiving for information requirement for long-term toxicity testing on fish (Annex IX, Section 9.1.6.): "*In Annex IX of Regulation (EC) No 1907/2006, it is laid down that long-term toxicity testing shall be proposed by the registrant if the chemical safety assessment indicates the need to investigate further the effects on aquatic organisms. Based upon the chemical safety assessment for this substance, adequate information has been provided to determine that the substance is not a PBT or vPvB and the risk assessment has shown that RCRs for the aquatic environment are less than 1 demonstrating a lack of risk and negating the need for long-term toxicity testing*".

However, ECHA notes that, as your substance is registered under Annex VIII, the information requirements under Annex IX, and the related adaptations, do not apply for this registration. In addition the provided adaptations does not meet the specific rules of adaptation of Annex VIII, Section 9.1.3., Column 2 because of the substance being poorly soluble and it is not justified to conclude that the CSR did not trigger any concern for long-term exposure as described below.

ECHA notes that the RCRs you provide in the chemical safety assessment are based on PNEC derived with the highest loading rate of 100 mg/L that is above both the measured test concentrations and the reported water solubility of the registered substance.

ECHA considers that due to the uncertainty arising from having only acute aquatic data for a UVCB with potentially poorly water soluble constituents, it is not justified to conclude that the CSR did not trigger any concern for long-term exposure.

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

In the technical dossier you have provided evidence that the parent substance is not PBT/vPvB. The PBT properties are further discussed in this decision under issue 5. Identification of the degradation products of the registered substance for the purpose of PBT and vPvB Assessment. However, adequate information on aquatic toxicity is also needed for the for the purpose of classification and labelling and/or risk assessment.

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 VIII, Section 9.1.3., Column 2.

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 3.0, February 2016), *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).

Regarding the use of the WAF approach, please note that this 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. If WAF method is used 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.

Your comments

In your comments on the draft decision, you agreed that a chronic Daphnia study (section 3. above) is needed to assess long-term toxicity of the substance, but that a long-term toxicity to fish study is not additionally needed. You indicate that additional short term data to that which is in the technical dossier is available and on the basis of this data consider Daphnia to be the most sensitive species. The studies in question were conducted with Resin acid and rosin acid, hydrogenated, methyl esters which is a constituent of the registered substance ([redacted]% w/w). In the Daphnia study an EL50 of 27 mg/L (nominal) was determined, whereas in the fish study no mortality was observed at a nominal loading rate of 1000 mg/L. You note that the other main constituents within the registered substance are

structurally similar to the constituent tested and therefore consider it likely that Daphnia would also be the most sensitive species when exposed to these constituents.

ECHA acknowledges that you intend to use the data available on one of the constituents (Resin acid and rosin acid, hydrogenated, methyl esters) to describe the species sensitivity in aquatic organisms for the registered UVCB substance as a whole. You base your argument solely on structural similarity of the constituents. Firstly, ECHA notes that this constituent is likely to be of low solubility and hence the adequacy of short-term data is questionable. According to ECHA Guidance on information requirements and chemical safety assessment, Chapter R.7b (version 4.0, June 2017) poorly water soluble substances have a water solubility below 1 mg/L or below the detection limit of the analytical method of the test substance. ECHA considers that substances that are poorly soluble in water require a longer time to be significantly 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 such substances and toxicity may actually not even occur at the water solubility limit of the substance if the test duration is too short. For such substances long-term aquatic testing is required to accurately assess the risks to the aquatic environment.

Secondly, in the context of structural similarity, ECHA considers that you have not explained how the differences in the structures and their physical-chemical properties e.g. water solubility (as described in Section 1 of this Appendix) could affect the level of aquatic toxicity in different organisms. In general, structural similarity does not necessarily lead to predictable or similar environmental properties. Thus, structural similarity per se is not sufficient to enable the prediction of aquatic toxicity of a substance.

Finally, ECHA notes that this information is currently not in the technical dossier and the validity of the studies referred to cannot be evaluated.

Additionally, bearing in mind the deficiencies outlined above, ECHA notes the following general principles with regard to UVCBs:

- Due to the properties of the complex UVCB substances with variable water solubilities, it would be difficult to conclude on the species sensitivity based solely on one set of acute aquatic data for one of the constituents..
- Effect values based on the nominal concentration in the test system lead to uncertainty on the level of exposure to the test organisms due to the varying physicochemical properties. Results from reliable analytical monitoring are needed for the tests to be considered valid.

You also indicate a wish to support your assessment on the species sensitivity by QSAR. However, you provide no information on the predictions you intend to use. ECHA notes that any QSAR prediction need to fulfil the conditions set in Annex XI, section 1.3. of the REACH Regulation and you need to provide a scientific justification as to why the information provided relates to the whole substance as registered, including the constituents present in ≥ 0.1%.

Therefore, at present, the Integrated testing strategy (ITS) is not applicable and consequently, long-term studies on both, invertebrate and fish, are needed to derive a PNEC aquatic.

In your comments, you also indicate that due to the complex nature of the registered UVCB substance you would like to ensure that any new testing is carried out and reported in a

way that is acceptable to ECHA and the Member States. More specifically, you seek advice on 1) the recommended solution preparation method, acceptability of a study conducted with the WAF method or flow-through method with the highest test concentration approximating the water solubility limit and 2) reporting of results of the study conducted.

With regards to 1), ECHA notes that there are multiple ways to conduct aquatic toxicity test(s) with UVCB substances. For detailed instructions, please refer to ECHA Guidance on information requirements and chemical safety assessment, Chapter R.11, Section R.11.4.2.2 Assessment of substances containing multiple constituents, impurities and/or additives (version 3.0 June 2017) and to the recently updated OECD GD 23. In addition, guidance on special considerations for toxicity testing and risk assessment of multi-constituent and UVCB substances is provided in the ECHA Guidance on information requirements and chemical safety assessment, Chapter R7b (version 4.0, June 2017) and Chapter R.7.13 (version 3.0, June 2017), where principles of risk assessment for such substances are discussed (example of use of Hydrocarbon Block method for risk assessment of petroleum substances is provided).

In the ECHA Guidance R.11, the following assessment approaches could be considered for UVCB substances: The "known constituents" approach, The "fraction profiling" (or "block profiling") approach, The whole substance approach, or any combination of these approaches. As already indicated above, the use of the WAF approach can be problematic for substances, such as the registered substance, containing several different poorly water soluble components with varying solubility. As indicated in the updated OECD Guidance Document (GD) 23, results obtained with the WAF method may be considered acceptable only when attainment of equilibrium in the WAF preparation and stability during exposure in the toxicity tests is demonstrated. If stability of the WAF during a test cannot be achieved, it is recommended to consider performing the test on the relevant worst-case fractions/constituents of the substance. In case you apply the worst-case fraction approach you should fully justify the selection of the fraction and explained how the results would applies to the whole substance as registered.

With regards to reporting of results (2), ECHA recommends you to follow the requirements given in ECHA Practical Guide 3: 'How to report robust study summaries' and the specific OECD guideline used for testing. If you would still consider it feasible to conduct the study using a WAF method, the details on reporting are given in the OECD GD 23.
ECHA considers it particularly important to express all test results in terms of measured concentrations. If you use the "loading rate" for expressing exposures of mixtures that neither fully dissolve nor completely form a stable dispersion or emulsion over the required test range, WAFs can be considered analogous to the term "nominal concentration". As indicated in the OECD TG 210 and OECD GD 23, when the measured concentrations do not remain within 80-120% of the nominal concentration, the effect concentrations need to be analytically determined and expressed relative to the arithmetic or geometric mean of the measured concentrations. Therefore, it is recommended that before applying a WAF method, you should first consider conducting a preliminary stability test as per OECD GD 23. If based on that test you consider that the WAF is the only option to prepare the test solution, you should report the potential effect concentrations from the WAF test based on mean measured concentrations.

If you decide however to use the fraction or constituent approach, in your robust study summary you need to sufficiently justify the reasons for selection of the relevant fraction/constituent and explain why testing of this selected fraction/constituent would be

appropriate to fulfil the purposes of the chemical safety assessment (PBT assessment, or risk characterization, classification) of the registered substance as a whole. When testing fractions or representative constituents you also need to consider the interactions between the constituents of the registered substance and to explain how any (potential) combined effects are covered.

Conclusion

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 for requests 4. and 5. above

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.

ECHA notes that due to lack of effects in short-term studies available in the registration dossier 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 adsorptive properties and low solubility 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, 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).

6. Identification of the degradation products of the registered substance for the purpose of PBT and vPvB Assessment (Annex I, Section 4.)

Analysis of your dossier

In accordance with Articles 10(b) and 14(1) of the REACH Regulation, the registration must contain a chemical safety report (CSR) which documents the chemical safety assessment (CSA) conducted in accordance with Article 14(2) to (7) and with Annex I to the REACH Regulation.

Annex I, Section 4 of the REACH Regulation requires to generate separate PBT and vPvB assessment for the registered substance. Annex XIII lays down the criteria for the identification of persistent, bioaccumulative and toxic substances (PBT substances), and very persistent and very bioaccumulative substances (vPvB substances) as well as the information that must be considered for the purpose of assessing the P, B, and T properties of a substance. The identification shall also take account of the PBT/vPvB properties of relevant constituents of a substance and relevant transformation and/or degradation products.

The PBT and vPvB assessment (Annex XIII) shall consider the information as described in Annex I and in Section 3 of Annex XIII. If the technical dossier contains for one or more endpoints only information as required in Annexes VII and VIII, you should consider information relevant for screening for P, B, or T properties in accordance with Section 3.1 of Annex XIII. If the result from the screening tests or other information indicate that the substance may have PBT or vPvB properties, you should generate relevant additional information as set out in Section 3.2 of Annex XIII. The choice of the appropriate test(s) will be depend on the results of the chemical safety assessment.

ECHA observes that in the CSR you have provided an assessment of PBT/vPvB properties of the registered substance. ECHA notes that based on the information in the Chemical Safety Report, in the simulation test in water (OECD TG 309), you have observed primary degradation of the registered substance. You have concluded based on these results in the OECD TG 309 test that the registered substance is not persistent. The initial concentrations of the test substance in the pelagic OECD TG 309 test, reported in the technical dossier, were [redacted] µg/L and [redacted] µg/L. The degradation of the parent substance was ca. 95% and half-life 4.5 days at 22 °C. You have also provided information on degradation products as a part of the OECD TG 309 study. During the aerobic mineralization in surface water you identified two unknown degradation products, M1 and M3. These degradation products were reported to be formed at levels above 10% of the applied radioactivity. LC-MS analysis for further characterization of these transformation products were conducted but, due to the low concentration of the sample investigated the degradation products, could not be identified. Therefore, the results remained inconclusive.

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

As your CSA shows the need to investigate further the degradation of the substance (see above), the request to identify the degradation products is, therefore, also justified under Annex VIII, section 9.2, column 2 of the REACH Regulation.

The appropriate and suitable test method for this request is discussed below. The Aerobic mineralisation in surface water – simulation biodegradation (test method EU C.25. / OECD TG 309) you applied to determine the degradation rate of the parent substance is a validated standard international test laid down in the Test Methods Regulation (EC) No 440/2008 and therefore meets the requirements of Article 13(3) of the REACH Regulation. This test is appropriate, in addition to obtain information on the primary degradation, to assess the formation of major transformation products in water.

Regarding the appropriate and suitable test method to provide further information on degradation/transformation products, you may obtain this information from the OECD TG 309 "pathway part" or by some other measures. ECHA considers that in this case you are recommended to perform the "pathway part" of the OECD TG 309 test with water amended with suspended solids/sediment of 0.01 to 1 g/L dry weight ("suspended sediment test") to simulate a water body with suspended solids or re-suspended sediment and to increase the amount of degraders in the test system. ECHA also notes that to overcome the potential analytical limitations in the identification and quantification of major transformation products you may use higher concentrations of the test substance (e.g. >100 µg/L) as specified in the OECD 309 test guideline. Furthermore, when reporting the role of 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.

You may also use other appropriate and suitable test methods to provide information on the identity of the degradation products for example by enhanced screening level degradation test or modelling tools. You will need to provide a scientifically valid justification for the chosen method. The provided information should include, identification, stability, behaviour, molar quantity of metabolites relative to the parent compound. In addition, degradation half-life, log Kow and potential toxicity of the metabolites may be investigated.

Your comments

In your comments on the draft decision you confirm that in the OECD 309 study included in the registration dossier, and discussed above, two metabolites (M1 and M3) were formed at >10% of the applied radioactivity. You indicate that "*despite significant efforts to identify the metabolites, this was not possible*". You identify several difficulties hampering the identification related to the available analytical methods and to the nature of the UVCB substance having several structurally similar constituents with slightly different isotopic masses as well as the low concentration of degradation products formed.

In your comments, you further describe that conducting the recommended pathway part of an OECD 309 study with higher test concentrations would likely be analytically very challenging, and perhaps technically unfeasible. You indicate that concentrations required to facilitate identification of degradation products would be very close to the limit of solubility of the test item. You note that even if the reported overall solubility is 0.199 mg/L, the least soluble constituents are likely to have water solubility around the concentration suggested to be used in OECD TG 309 (i.e. 100 µg/L), leading to difficulties in determining the identity of the degradation products. In the available OECD TG 309 were you faced with difficulties in identification of the degradation products, the starting concentrations you used ([redacted] µg/L and [redacted] µg/L) were more than 100 times lower than your estimation on the solubility of the least soluble constituents. In addition, you indicate that the optimum concentration of the analytical method you used for the structure identification was 1 µg/L which is above the starting concentrations in the available OECD TG 309 and equals to about 1 % of your estimation of the solubility of the least soluble constituent.

ECHA considers that it would be possible for you to conduct another OECD 309 study with concentration >1 µg/L and < 100 µg/L which would enhance the potential of identifying the degradation products. Currently there is no information available on the water solubility of all of the constituents (please see request 1).

In your comments, you also provide the following considerations on the potential degradation products and their PBT/vPvB properties:

- Potential degradation products can be predicted based on the structures of the constituents.
- Rosin alcohol constituents; degradation of the -OH group is likely to occur
- Methyl ester constituents; the ester bond is likely to degrade first with removal of the methyl group.
- Both rosin alcohol and rosin methyl ester constituents; initial degradation products are likely to be resin acids, which are the same constituents that are present in the rosin starting material.
- Resin acids (abietic, dehydroabietic, chlorodehydroabietic, dichlorodehydroabietic,

neoabietic, pimaric, isopimaric, sandaracopimaric and palustric acids) (Niimi and Lee,1992); Oncorhynchus mykis were exposed to mean waterborne concentrations of 0.7 to 3.6 µg/L for 20 days, followed by a 10-day depuration period resulting bioconcentration factors ranging from <25 to 130. No detectable levels of free or conjugated acids found in fish sampled 4 to 10 days into the depuration period, therefore no half-lives could be calculated. However, based on initial chemical concentrations, it was suggested that the half-lives of these acids were <4 days.

- Effluent from a pulp and paper mill containing resin acids (pimaric acid, isopimaric acid, dehydroabietic acid, abietic acid and 14-chlorodehydroabietic acid) (Burggraaf et al.,1996); Mussels (Hyridella menziesi), BCF values for the individual resin acids ranged from 110 to 330 L/kg (28-day exposure phase, followed by a 21-day depuration phase).
- Both of the above studies determined BCF values were below the PBT threshold for bioaccumulation.

You also note that in the bioaccumulation study (OECD TG 305) with the registered substance included in the technical dossier ([redacted], 2013) all of the BCF values were below 2000, and therefore you concluded that the parent substance is not bioaccumulative and not PBT/vPvB. ECHA has taken into account this study during the evaluation of the available information and considers that is has no impact on the request for identification of the observed degradation products.

ECHA recognises that, instead of performing the OECD 309 pathway part study recommended above, you propose to use the available considerations described above on the degradation of the constituents and in addition to update the dossier to include prediction of the primary degradation products (e.g. using the EAWAG-BBD Pathway prediction system http://eawag-bbd.ethz.ch/predict/) and consider the bioaccumulation potential of the predicted degradation products. Based on the above you state that you have sufficiently demonstrated that the primary degradation products formed by degradation of Hydrogenated rosin alcohols are not bioaccumulative and thus the substance is not PBT/vPvB. Therefore you consider that further detailed investigation of the degradation pathways is not considered to be necessary and conducting the preferred study by ECHA-S, OECD 309 "pathway part" unnecessary.

ECHA considers that while obtaining information on the degradation products and their PBT/vPvB properties by conducting a OECD TG 309 "pathway part" is ECHA's preferred approach you may also use other appropriate and suitable test methods to provide information on the identity of the degradation products, as fully described above.

Your proposed Weight-of-Evidence (WoE) type approach whereby you would combine predictions of the potential degradation products with information on the specific constituents may in principle be acceptable. However, the information to be provided needs to consider the identity and fate of the degradation products formed from the whole registered substance (including all constituents present ≥ 0.1%) and be reported in the technical dossier according to the relevant sections of the REACH Regulation, such as Annex XI, section 1.2. for WoE and Annex XI, section 1.3 for QSAR. ECHA notes the predictions may be challenging or yet impossible in case the defined structures of the constituents of this complex UVCB are not available.

Conclusion

Based on the above, ECHA has noted incompliances in the PBT and vPvB assessment and therefore pursuant to Article 41(1)(c) and (3) requires a revision of the PBT and vPvB assessment (Annex I, Section 4) and you are requested to submit the following information derived with the registered substance subject to the present decision:

Identification of the degradation products of the registered substance: EU.C.25/ OECD TG 309, suspended sediment test with higher concentration of the test material as defined in the respective TG or any appropriate and suitable test method, as described above. ECHA recommends to use OECD TG 309, as specified above.

Notes for your consideration

Before providing the above information you are advised to consult the ECHA *Guidance on information requirements and chemical safety assessment* (version 4.0, June 2017), Chapter R.7b., Sections R.7.9.2.3 and R.7.9.4. These guidance documents explain that the data on degradation products is only required if information on the degradation products following primary degradation is required in order to complete the chemical safety assessment. Section R.7.9.4. further states that when substance is not fully degraded or mineralised, degradation products may be determined by chemical analysis

7. Exposure assessment and risk characterisation (Annex I, Sections 5. and 6.) for environment

In accordance with Articles 10(b) and 14(1) of the REACH Regulation, the registration must contain a chemical safety report (CSR) which documents the chemical safety assessment (CSA) conducted in accordance with Article 14(2) to (7) and with Annex I to the REACH Regulation.

Annex I, Section 5 of the REACH Regulation requires to generate exposure scenarios and exposure estimations for the registered substance. The exposure assessment shall consider all stages of the life-cycle of the substance resulting from the manufacture and identified uses and shall cover any exposure that may relate to the identified hazards. The life-cycle stages resulting from the manufacture of the substance cover, where relevant, the waste stage. The life-cycle stages resulting from identified uses cover, where relevant, the service-life of articles and the waste stage. The emission estimation shall be performed under the assumption that the risk management measures and operational conditions described in the exposure scenario have been implemented. In addition, Annex I, Section 6 of the REACH Regulation requires that the overall environmental risk caused by the substance shall be reviewed by integrating the results for the overall releases, emissions and losses from all sources to all environmental compartments.

ECHA observes that in the CSR you have provided quantitative environmental exposure assessment for eight Exposure Scenarios (ESs) reported. ECHA, however, has noted incompliances in the environmental exposure assessment and therefore, pursuant to Article 41(1)(c) and (3), requires a revision of the assessment (Annex I, Section 5) and the risk characterisation (Annex I, Section 6.) which takes into account the following:

a) Identification of the missing life-cycle stages

According to ECHA's Guidance on Information Requirements and Chemical Safety Assessment, Chapter R.12 (version 3.0, December 2015) "*the use description includes therefore any use of the substance as such and in mixtures and any subsequent service life in articles resulting from a use*".

ECHA observes that in the registration dossier you identified industrial and professional uses of the substance in adhesives, sealants, coatings and inks which lead to the inclusion of the substance into/onto articles (e.g. you indicated as relevant to these uses process category 13: Treatment of articles by dipping and pouring etc.). The service life of the substance in such articles is not addressed and is thus missing from the use description of the substance in the registration dossier.

Thus, you are requested in the registration dossier to:
- identify missing life-cycle stages of the substance in the registration dossier;
- consider these life-cycle stages of the substance for the exposure assessment and risk characterisation steps in the CSA of the substance.

b) Waste management measures and the exposure estimation of the waste life-cycle stage

Annex VI, section 3.6 of REACH Regulation requires the registrants to collect "*Information on waste quantities and composition of waste resulting from manufacture of the substance, the use in articles and identified uses".* Additionally, section 5.8 of the same Annex requires "*disposal considerations"* to be included in the registration dossier if no CSR is required. Pursuant to Annex I, section 5.1.1 of the REACH Regulation the exposure scenario includes, where relevant, a description of the risk management measures including the waste management measures to reduce or avoid exposure of humans and the environment to the substance during waste disposal and/or recycling. Section 5.2.2 provides that the emission estimation shall consider the emissions during all relevant parts of the life-cycle of the substance resulting from the manufacture and each of the identified uses. The life-cycle stages resulting from the manufacture and identified uses cover, where relevant, the waste stage.

Moreover, according to ECHA's Guidance on Information Requirements and Chemical Safety Assessment, Chapter R.18 (version 2.1, October 2012) "*M/I are required to specify the types of wastes generated at each step in the supply chain (identified uses) and indicate its composition with regard to the content of the registered substance (and potential degradation products related to the registered substance).* "

ECHA notes that information about waste quantities, composition and its treatment/disposal during whole life-cycle stages of the substance is not provided in the registration dossier. Furthermore, there is no information in the exposure scenarios reported in the CSR on waste originating from each identified use and waste management measures necessary. Finally, there is no quantification of exposure of humans and the environment arising due to the emissions of the substance from waste containing the substance provided in the CSR.

Therefore, you are requested in the registration dossier to:
- provide information on waste quantities, types and composition of waste resulting from manufacture of the substance, the use in articles and identified uses;
- consider and quantify exposure of humans and the environment arising due to the emissions of the substance from waste containing the substance; and

- describe in the CSR the waste management measures to reduce or avoid exposure of humans and the environment to the substance during waste disposal and/or recycling.

c) Combined environmental risk caused by the substance

ECHA's Guidance on Information Requirements and Chemical Safety Assessment, Chapter R.16 (version 3.0, February 2016) notes that "*When information is available to registrants that a combination of several activities (being either several techniques for the same use or various uses taking place at the same site) are often taking place within one site, they are advised to cover the combination of those activities in their assessment. In this case, the registrant would combine those assessments in the "combined risk" section of the CSR.*" Furthermore, this Guidance notes that "*Since the releases to water from all the widespread uses can, by default, be assumed to enter into the same sewage system, combined risk from all the widespread uses should be considered."*

ECHA notes that there is no combined environmental risk assessment provided by you in the CSR. However, ECHA notes that number of widespread uses are identified by you in the registration dossier and combined environmental risk assessment is relevant for these uses.

Thus, you are requested in the registration dossier to provide combined environmental risk assessment for widespread uses and, if relevant, for industrial uses unless you provide valid justification why this information may not be provided.

d) Use of default fraction of main local source for exposure estimation for Exposure Scenario 1

ECHA's Guidance on Information Requirements and Chemical Safety Assessment, Chapter R.16 (version 3.0, February 2016) notes that "*The "tonnage per use" plays a key role in environmental assessment.*"

ECHA notes that in the exposure estimation for ES 1 (manufacture) to the EU tonnage assigned for this use you apply fraction of main local source of 0.2. ECHA notes that there is no justification provided for such value of fraction of main local source used for the exposure estimation. Thus, the number of the sites where the registered (tonnage of) substance is manufactured is not clear.

Therefore, ECHA requests to use default fraction of main local source of 1 for exposure estimation for the manufacture life-cycle stage. Alternatively, sufficient justification for the use of non-default fraction of main local source should be provided in the CSR.

e) Risk management measures to reduce or avoid direct and indirect exposure of the different environmental compartments to the substance

According to the ECHA *Guidance on information requirements and chemical safety assessment* Chapter R.16 (version 3.0, February 2016) the exposure scenario should contain information about operational conditions (OC) and risk management measures (RMM) based on which the assumed release factors can be justified. Furthermore, the Guidance indicates that sector specific environmental release categories (SPERCs) developed by industrial sector organisations can be used in place of the conservative default

environmental release categories (ERCs) of ECHA guidance. As far as possible, SPERCs have to be linked to the applied RMM and OC driving the release estimation.

ECHA observes that release factors used by you for the environmental exposure estimation are taken from various SPERCs developed by industry. ECHA notes that for a number of ESs (e.g. ES1, ES3 etc.) you indicated in the CSR that value of release factor to air is estimated after RMM is applied. ECHA observes that these values are lower than respective release factor values indicated in the respective factsheets (versions from February 2013) of SPERCs publically available on the European Solvents Industry Group (who developed respective SPERCs) website. This confirms that specific RMMs are necessary to reduce release factors indicated in the SPERCs factsheets. However, ECHA notes that there are no RMMs specified in ESs in the CSR which would justify reduction of the release factors indicated in the SPERCs factsheets.

Furthermore, ECHA notes that in some of SPERC factsheets referred by you in the CSR, obligatory OC/RMM are listed to support indicated values of the release factors (e.g. SPERC ESVOC 4.3a.v1 notes following: "*Processing conditions:* Dry process"). However, ECHA notes that these conditions supporting the use of indicated release factors are not reported by you in respective ESs.

In your comments to the draft decision, you have indicated that you would conduct the requested chronic Daphnia study prior to derivation of PNEC values and update of the exposure assessment. ECHA has replied to your comments on the long-term aquatic toxicity to invertebrates and fish testing above under section 4, where it is considered that both long-term tests are required. ECHA agrees with the proposed approach to derive the PNEC values based on new information from the requested long-term aquatic studies prior to an exposure assessment update.

Therefore, you are requested to provide, in the respective ESs, a detailed justification (e.g. based on RMMs, including efficiencies of these, and/or OCs and/or substance properties) for using SPERC (or reduced SPERC) release factors for estimation of environmental exposure. Alternatively, you should use default ERC release factors and other recommendations of ECHA Guidance R.16 for environmental exposure estimation and revise the risk characterisation accordingly.

Deadline to submit the requested information in this decision

In the draft decision communicated to you the time indicated to provide the requested information was 18 months from the date of adoption of the decision. In your comments on the proposals for amendments, you requested an extension of the timeline to 24 months. Based on your justification relating to the complex nature of the test substance and the complex analytical work that will be required, ECHA has granted the request and set the deadline to 24 months.

Appendix 2: Procedural history

For the purpose of the decision-making, this decision does not take into account any updates of your registration after the date when the draft decision was notified to you under Article 50(1) of the REACH Regulation.

The compliance check was initiated on 12 September 2017.

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

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

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

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

ECHA received proposals for amendment and modified the draft decision.

ECHA invited you to comment on the proposed amendments.

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.

In addition, you provided comments on the draft decision. These comments were not taken into account by the Member State Committee as they were considered to be outside of the scope of Article 51(5).

The Member State Committee reached a unanimous agreement on the draft decision in its MSC-61 written procedure and ECHA took the decision according to Article 51(6) of the REACH Regulation.

Appendix 3: Further information, observations and technical guidance

1. The substance subject to the present decision is provisionally listed in the Community rolling action plan (CoRAP) for the start of substance evaluation in 2020.

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

3. Failure to comply with the 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.

4. 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.