EUROPEAN CHEMICALS AGENCY

Helsinki, 5 July 2019

Addressee: [redacted]

Decision number: CCH-D-2114465576-37-01/F
Substance name: Paraffin oils, sulfochlorinated, saponified
EC number: 269-144-1
CAS number: 68188-18-1
Registration number: [redacted]
Submission number: [redacted]
Submission date: 17/08/2017
Registered tonnage band: Over 1000

DECISION ON A COMPLIANCE CHECK

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

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

2. **Revision of robust study summaries for short-term toxicity testing in aquatic invertebrates (Annex VII Section 9.1.1., in conjunction with Annex I, Section 3.1.5.) as specified in Appendix 1, section 2; OR**

   Short-term toxicity testing in aquatic invertebrates (Annex VII, Section 9.1.1.; test method: *Daphnia* sp. Acute immobilisation test, EU C.2./OECD TG 202) with the registered substance;

3. **Revision of robust study summaries for short-term toxicity testing in fish (Annex VIII Section 9.1.3., in conjunction with Annex I, Section 3.1.5.) as specified in Appendix 1, section 2;**

4. **Revision of robust study summaries for Long-term toxicity testing on aquatic invertebrates (Annex IX, Section 9.1.5., in conjunction with Annex I, Section 3.1.5.) as specified in Appendix 1, section 2; OR**

   Long-term toxicity testing on aquatic invertebrates (Annex IX, Section 9.1.5.; test method: Daphnia magna reproduction test, EU C.20./OECD TG 211) with the registered substance;

5. **Long-term toxicity testing on fish (Annex IX, Section 9.1.6.1.; test method: Fish, early-life stage (FELS) toxicity test, OECD TG 210) with the registered substance.**

You have to submit the requested information in an updated registration dossier by ***12 January 2021***. You shall also 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 **Wim De Coen**, Head of Unit, Hazard Assessment.

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

Appendix 1: Reasons

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

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

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

The technical dossier contains information on a pre-natal developmental toxicity study in rats by the oral route. The study did not follow a guideline and it is not GLP compliant. It was performed with the analogous substance Hostapur SAS 93 (CAS no 97489-15-1) as test material.

However, there is no information provided for a pre-natal developmental toxicity study in a second species with the registered substance.

You have sought to adapt this information requirement by providing the following justfication: *The toxicological information available for paraffin oils, sulfochlorinated, saponified confirms that the primary hazard for the substance is not systemic toxicity. After chronic (1 year) exposure to the substance rats reveal only non-specific effects at the LOAEL of 1000 mg/kg, no functional or structural changes were observed (effects observed were impaired grooming activity and retarded body weight gain). This was confirmed in a study upon reproductive function and developmental toxicity. Studies on skin and eye irritation and on dermal toxicity demonstrate on the other hand an irritant potential for the substance. Overall, no clear signs of systemic toxicity were observed in any of the available toxicological information. Thus it is not expected that a second study on developmental toxicity in another species would change the hazard assessment. This study should therefore be ommitted, also for reasons of animal welfare."*

To support you adaptation, you provide two study records with an analogous substance in rats:

- End-point study record 1: Read-across study: chronic toxicity study, rat, oral (study equivalent or similar to OECD TG 452; not GLP compliant) with analogous substance Hostapur SAS 93 (CAS no 97489-15-1), [redacted], 1977 (study report), rel 2.

- End-point study record 2: Read-across study: two-generation reproductive toxicity study, rat, oral (no guideline; not GLP compliant) with analogous substance Hostapur SAS 93 (CAS no 97489-15-1), [redacted] 1978 (study report), rel 2.

You did not specifically refer to a legal basis in your adaptation. However, ECHA has evaluated your adaptation according to Annex XI Section 1.2., weight of evidence.

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EUROPEAN CHEMICALS AGENCY

An adaptation pursuant to Annex XI, Section 1.2. requires sufficient weight of evidence from several independent sources of information leading to the assumption/conclusion that a substance has or has not a particular dangerous property with respect to the information requirement in question including an adequate and reliable documentation while the information from each single source alone is regarded insufficient to support this notion.

Your weight of evidence adaptation needs to address the specific dangerous (hazardous) properties of the registered substance with respect to pre-natal developmental toxicity study in a second species as requested in this decision, i.e. information on species differences regarding to prenatal developmental toxicity.

The available pre-natal developmetal toxicity study with the analogous substance Hostapur SAS 93 substance covers only the information requirement of pre-natal developmental toxicity study in the first species. The submitted chronic toxicity study and the two-generation reproductive toxicity study with the analogous analogous substance Hostapur SAS 93 does not provide the information covered by a pre-natal developmetal toxicity study, because they do not cover key parameters of a pre-natal developmental toxicity study, such as examinations of foetuses for skeletal and visceral alterations. In addition, all of the provided information was obtained from studies in rat. Hence, there is no information from studies in a second species, such as the rabbit. Therefore, your adaptation of the information requirement is rejected.

Hence, the individual sources of information you provided, together with your justification for the adaptation, do not allow to assume/conclude that the substance does not have a particular dangerous (hazardous) property with respect to the information requirement for Pre-natal developmental toxicity study (Annex X, Section 8.7.2.) in a second species.

Therefore, the general rules for adaptation laid down in Annex XI, Section 1.2. of the REACH Regulation are not met and your adaptation of the information requirement is rejected.

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.

The test in the first species was carried out by using a rodent species (rat). According to the test method OECD 414, the rabbit is the preferred non-rodent species. On the basis of this default assumption, ECHA considers that the test should be performed with rabbit as a second species.

ECHA considers that the oral route is the most appropriate route of administration for substances except gases to focus on the detection of hazardous properties on reproduction as indicated in ECHA *Guidance on information requirements and chemical safety assessment* (version 5.0, December 2016) Chapter R.7a, Section R.7.6.2.3.2. Since the substance to be tested is a liquid, ECHA concludes that testing should be performed by the oral route.

In your comments on the draft decision according to Article 50(1) of the REACH Regulation you agree to perform the requested test.

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

2. Revision of robust study summaries for short-term toxicity testing in aquatic invertebrates (Annex VII Section 9.1.1., in conjunction with Annex I, Section 3.1.5.) as specified in Appendix 1, section 2; OR

Short-term toxicity testing in aquatic invertebrates (Annex VII, Section 9.1.1.; test method: *Daphnia* sp. Acute immobilisation test, EU C.2./OECD TG 202) with the registered substance;

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

Pursuant to Article 10(a)(vii) of the REACH Regulation, the information set out in Annex VII to XI must be provided in the form of a robust study summary, if required under Annex I. Article 3(28) of the REACH Regulation defines a robust study summary as a detailed summary of the objectives, methods, results and conclusions of a full study report providing sufficient information to make an independent assessment of the study minimising the need to consult the full study report. Guidance on the preparation of the robust study summaries is provided in the ECHA Practical Guide 3: 'How to report robust study summaries'.

Short-term toxicity on invertebrates is an standard information requirement as laid down in Annex VII, Section 9.1.1. 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. Furthermore, pursuant to Article 10(a)(vii) and Annex I, Section 3.1.5. where there is more than one study addressing the same effect, then the study or studies giving rise to the highest concern shall be used to draw a conclusion and a robust study summary shall be prepared for that study or studies and included as part of the technical dossier. Robust study summaries will be required of all key data used in the hazard assessment.

In the technical dossier you have provided the following study record to fulfil the standard information requirement of Annex VII, Section 9.1.1., short-term toxicity to aquatic invertebrates: Key study, reliability 1, by [redacted] 1992a, GLP compliance: yes, test method: equivalent or similar to OECD Guideline 202 (Daphnia sp., Acute Immobilisation Test and Reproduction Test) with the registered substance.

ECHA notes that, contrary to Article 3(28) of the REACH Regulation, the documentation of this study is insufficient and does not allow an independent assessment of the adequacy of this study, its results and their use for hazard assessment. In particular, ECHA notes that no analytical monitoring during the test has been included in the technical dossier. This does not provide sufficient information to enable the relevance of the tests to be assessed. The registered substance has a hydrophobic moiety and a charged hydrophylic moiety, so that the potential for adsorption is high. ECHA notes that for adsorbing substances, effect concentrations should be expressed based on measured values at the start and end of the test (OECD Guidance Document on Aquatic Toxicity Testing of Difficult Substances and Mixtures, ENV/JM/MONO (2000)6 ; ECHA *Guidance on information requirements and chemical safety assessment* (v.4.0, June 2017), Chapter R7b, Table R.7.8-3 and Appendix R.7.8-1).

ECHA notes that in the technical dossier, the information requirement on adsorption was also adapted based on the rapid degradability of the substance (column 2). In addition to the adaptation, a supporting study endpoint, a QSAR, was provided. ECHA notes that the provided QSAR is based on calculations using PCKOC Program v1.66 of EPI-Suite software as well as according to [redacted] (1995) and [redacted] (1990). These calculations are based on a statistical relationship between Koc and the octanol/water partition coefficient. Since the registered substance has surface active properties, it is possible that the measured Kow data would not be reliable. Besides, the estimates from Episuite would most surely not be reliable, since the data set of Episuite does not include surface active substances, and therefore, these type of substance are typically out of the domain.

In additon, the technical dossier includes an static short-term fish OECD 203 test ([redacted] 1992b), where >20% of the registered substance was lost from the water column during the test duration . This is indicated by you as a key study record. ECHA finds this information relevant for the reported key study for the short-term Daphnia endpoint. Being this test, also an static test, >20% loss of the registered substance from the water column cannot be discarded.

The technical dossier includes one further supporting endpoint study record [redacted] which includes secondary literature experimental data on Paraffin oils, sulfoxidized, saponified test material (24 h respectively 48 h EC50/ EC0 = 1.8 - 275 mg/L).

ECHA considers you may have wanted to include an adaptation as per Annex XI, section 1.5 of the REACH Regulation. You did not specifically refer to this legal basis in your adaptation. However, ECHA has evaluated your adaptation according to Annex XI, section 1.5., read-across.

You have labelled the [redacted] as reliability score of 4 in the technical dossier. ECHA finds that the reliability and validity of this supporting endpoint study record cannot be established, based on the submitted information.

Therefore, the general rules for adaptation laid down in Annex XI, Section 1.5. of the REACH Regulation are not met and your adaptation of the information requirement is rejected.

Hence, 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.

In your comments on the draft decision according to Article 50(1) of the REACH Regulation you agree to update the robust study summary by including additional information about the analytical monitoring with a detailed description of the applied measurement methodology as well as the analytical findings at the beginning and at the end of the experiment, and update the CSA accordingly. You also state that considering these changes, there will be no necessity to perform a new study with aquatic invertebrates.

In your comments on the draft decision according to Article 50(1) of the REACH Regulation yu indicate that you submitted on 08 October 2018 a dossier update concerning addressed robust study summaries and new PNEC derivations in section 6 of the dossier. ECHA will review the latest dossier update only at the follow up stage once the deadline set in the decision has passed.

Therefore, pursuant to Article 41(1) and (3) of the REACH Regulation, you are requested to submit the following information: complete robust study summary where, if the analytical monitoring shows a decrease of >20% of the registered substance from the water column, the effect values will be provided related to mean measured concentrations for:

- Robust study summary for the Short-term toxicity testing in aquatic invertebrates ([redacted]1992a).

Alternatively, if you cannot submit a complete RSS or the RSS indicates that the study is not reliable as per the criteria indicated above and/or not adequate to fulfil the information requirement, 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 sp. Acute immobilisation test, (EU C.2./OECD TG 202) with the registered substance.

3. Revision of robust study summaries for short-term toxicity testing in fish (Annex VIII Section 9.1.3., in conjunction with Annex I, Section 3.1.5.) as specified in Appendix 1, section 2;

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

Pursuant to Articles 10(a)(vii) of the REACH Regulation, the information set out in Annexes VII to XI must be provided in the form of a robust study summary, if required under Annex I. Article 3(28) of the REACH Regulation defines a robust study summary as a detailed summary of the objectives, methods, results and conclusions of a full study report providing sufficient information to make an independent assessment of the study minimising the need to consult the full study report. Guidance on the preparation of the robust study summaries is provided in the ECHA Practical Guide 3: 'How to report robust study summaries'.

A 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. Adequate information on this endpoint needs to be present in the technical dossier for the registered substance to meet this information requirement. Furthermore, pursuant to Article 10 (a)(vii) and Annex I, Section 3.1.5. where there is more than one study addressing the same effect, then the study or studies giving rise to the highest concern shall be used to draw a conclusion, and a robust study summary shall be prepared for that study or studies and included as part of the technical dossier. Robust summaries will be required of all key data used in the hazard assessment.

In the technical dossier you have provided the following study record to fulfil the standard information requirement of Annex IX, Section 9.1.3., Short-term toxicity on fish: Key study, reliability 1, by [redacted] 1992b, GLP compliance: yes, test method: equivalent or similar to OECD Guideline 203 (Fish, acute toxicity test) with the registered substance.

ECHA notes that, contrary to Article 3(28) of the REACH Regulation, the documentation of this study is insufficient and does not allow an independent assessment of the adequacy of this study, its results and its use for hazard assessment.

In particular, ECHA notes that your reporting of the effects identified (e.g. LC50) is based on nominal concentrations, although analytical measurements during the test have been

done in the same study and significant loss from the water column has been observed, as it states in the technical dossier: " *The analytically determined stability of the test material in the test solutions after 96 hours of exposure was found to be within the range of 13 % and 42 % of the nominal values with an average of 26.5 %.*"

This does not provide sufficient information to enable the relevance of the tests to be assessed.

ECHA notes that for substances that are likely to be lost from the water column, like the registered substance, effect concentrations should be expressed based on measured values at the start and the end of the test (OECD Guidance Document on Aquatic Toxicity Testing of Difficult Substances and Mixtures, ENV/JM/MONO (2000)6 ; ECHA *Guidance on information requirements and chemical safety assessment* (v.4.0, June 2017), Chapter R7b, Table R.7.8-3 and Appendix R.7.8-1).

The technical dossier also includes four further supporting endpoint study records:

- [redacted], which includes secondary literature experimental data on Paraffin oils, sulfoxidized, saponified test material (48 h respectively 96 h LC50/LC0/EC0 = 0.5 - 12 mg/L)
- [redacted] (1995), which includes secondary literature experimental data on Paraffin oils, sulfoxidized, saponified test material (LC 100 = 1.97 mg/L for AE3S, LC 100 = 12.1 mg/L for AE2S and LC 100 = 12.2 mg/L for SAS)
- [redacted] (1995), which includes data on noninoic tensids test material (LC100 at 24 and 48 h, for AE7, AE8, iso-C13-AE8, AE9 and fatty acid-diethanolamide, with values between 0.03 - 1 mg/L)
- [redacted] (1995), which includes secondary literature experimental data on amphoteric tensid (coco amido betaine) test material (LC100=1.61 mg/L)

ECHA considers you may have wanted to include an adaptation as per Annex XI 1.5, read-across.

You have labelled the four endpoint study records as reliability 4 in the technical dossier. ECHA finds that the reliability and validity of these study records cannot be established, based on the little detail of the submitted information (e.g. study design, test conditions or discussion sections are missing).

In addition, ECHA notes that the two latter studies have been performed on another test material than the registered substance (i.e. noninoic tensids and amphoteric tensid (coco amido betaine) and that a read-across justification on these have not been submitted in the technical dossier. As described above (request 2), in order to evaluate the reliability of the read-acrosses a justification for these specific source substances should be provided. However, no read-across justification was provided in the technical dossier for noninoic tensids and amphoteric tensids. Therefore, ECHA cannot assess your adaptations.

Therefore, the general rules for adaptation laid down in Annex XI, Section 1.5. of the REACH Regulation are not met and your adaptation of the information requirement is rejected.

Hence, 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.

In your comments on the draft decision according to Article 50(1) of the REACH Regulation you agree to update the robust study summary by providing a more detailed description of the analytical procedure as well as the analytical findings at the beginning and at the end of the experiment, and update the CSA accordingly.

In your comments on the draft decision according to Article 50(1) of the REACH Regulation yu indicate that you submitted on 08 October 2018 a dossier update concerning addressed robust study summaries and new PNEC derivations in section 6 of the dossier. ECHA will review the latest dossier update only at the follow up stage once the deadline set in the decision has passed.

Therefore, pursuant to Article 41(1) and (3) of the REACH Regulation, you are requested to submit the following information: complete robust study summary where effect values are related to mean measured concentrations for:

- Short-term toxicity on fish (OECD TG 203, [redacted] 1992b).

4. Revision of robust study summaries for Long-term toxicity testing on aquatic invertebrates (Annex IX, Section 9.1.5., in conjunction with Annex I, Section 3.1.5.) as specified in Appendix 1, section 2; OR

Long-term toxicity testing on aquatic invertebrates (Annex IX, Section 9.1.5.) with the registered substance;

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

Pursuant to Articles 10(a)(vii) of the REACH Regulation, the information set out in Annexes VII to XI must be provided in the form of a robust study summary, if required under Annex I. Article 3(28) of the REACH Regulation defines a robust study summary as a detailed summary of the objectives, methods, results and conclusions of a full study report providing sufficient information to make an independent assessment of the study minimising the need to consult the full study report. Guidance on the preparation of the robust study summaries is provided in the ECHA Practical Guide 3: 'How to report robust study summaries'.

"Long-term toxicity testing on aquatic invertebrates" is a standard information requirement as laid down in Annex IX, Section 9.1.5. of the REACH Regulation. Adequate information on this endpoint needs to be present in the technical dossier for the registered substance to meet this information requirement. Furthermore, pursuant to Article 10(a)(vii) and Annex I, Section 3.1.5. where there is more than one study addressing the same effect, then the study or studies giving rise to the highest concern shall be used to draw a conclusion and a robust study summary shall be prepared for that study or studies and included as part of the technical dossier. Robust study summaries will be required of all key data used in the hazard assessment.

In the technical dossier you have provided the following study record to fulfil the standard information requirement of Annex IX, Section 9.1.5.: Key study, reliability 1, by [redacted] (1995), GLP compliance: yes, test method: equivalent or similar to OECD Guideline 202 (Prolonged Toxicity Study with Daphnia magna: Effects an Reproduction) with the analogue substance Paraffin oils, sulfoxidized, saponified (EC no 307-055-2).

ECHA notes that, contrary to Article 3(28) of the REACH Regulation, the documentation of this study is insufficient and does not allow an independent assessment of the adequacy of this study, its results and its use for hazard assessment.

In particular, ECHA notes that the robust study includes analytical data of the test freshly done test concentrations: "*The analytically determined test substance concentrations in the samples from the freshly prepared stock solutions amounted from 97 % to 106 % of the nominal concentration.*", but no analytical monitorig during the test has been included in the technical dossier. This does not provide sufficient information to enable the relevance of the tests to be assessed.

The tested substance has a hydrophobic moiety and a charged hydrophylic moiety, so that the potential for adsorption is high. ECHA notes that for adsorbing substances, effect concentrations should be expressed based on measured values at the start and end of the test (OECD Guidance Document on Aquatic Toxicity Testing of Difficult Substances and Mixtures, ENV/JM/MONO (2000)6 ; ECHA *Guidance on information requirements and chemical safety assessment* (v.4.0, June 2017), Chapter R7b, Table R.7.8-3 and Appendix R.7.8-1).

Besides, the technical dossier includes an static OECD 203 test ([redacted] 1992b), where >20% of the registered substance was lost from the water column during the test time. Although the current reported Daphnia test, is a semi-static test, >20% loss of the registered substance from the water column cannot be discarded.

The technical dossier includes 11 further supporting endpoint study records:

- [redacted], which includes secondary literature experimental data on Paraffin oils, sulfoxidized, saponified test material (NOEC (21d): 0.12-550 mg/L provided in range)
- [redacted] (1992), which includes secondary literature experimental data on Nonionic tensids (NOEC (21d): 0.3 mg/L nominal for Alkyl (14-C15)-polyethylene glycol ether (8 EO)),
- [redacted] (1994), which includes secondary literature experimental data on Nonionic tensids (NOEC (21d): 1 mg/L nominal for Isotridecyl-polyethylene glycol ether (8 EO) and Iso-C13-AE8; and NOEC (21d): 0.3 mg/L nominal for Alkyl (14-C15)-polyethylene glycol ether (8 EO)),
- [redacted] (1991), which includes secondary literature experimental data on Amphoteric tensid (Coco Amido Betaine) (NOEC (21d): 0.03 mg/L nominal for Fatty acid (12-C18)-amidopropylbetain (CAPB)),
- [redacted] (1995), which includes secondary literature experimental data on Anionic tensids (NOEC (21d): 0.72 mg/L nominal for Alkyl (12-C18)-polyethylene glycol ether (9 EO), AE9 and Alkyl (c12-C14)-polyethylene glycol ether (AE2S); and NOEC (21d): 2.9 mg/L nominal for Alkyl (c12-C14)-polyethylene glycol ether (AE2S)),
- [redacted] (1992), which includes secondary literature experimental data on Nonionic tensids (NOEC (21d): 0.3 mg/L nominal for Alkyl (14-C15)-polyethylene glycol ether (8 EO)),
- [redacted] (1992), which includes secondary literature experimental data on Nonionic tensids (NOEC (21d): 0.3 mg/L nominal for Alkyl (14-C15)-polyethylene glycol ether (8 EO)),
- [redacted] (1995), which includes secondary literature experimental data on Nonionic tensids (NOEC (21d): 0.3 mg/L nominal for Isotridecyl-polyethylene glycol ether (8

EO), Iso-C13-AE8),
- [redacted] (1995), which includes secondary literature experimental data on Paraffin oils, sulfoxidized, saponified (NOEC (21d): 0.61 mg/L nominal for sek. Alkansulfonat C14-17; and NOEC (21d): 0.68 mg/L nominal for Alkyl (12-C15)-polyethylene glycol ether (3 EO)-sulfate (AE3S)),
- [redacted] (1995), which includes secondary literature experimental data on Nonionic tensids (NOEC (21d): 0.06 mg/L nominal for Isotridecyl-polyethylene glycol ether (8 EO), Iso-C13-AE8; and NOEC (21d): 0.1 mg/L nominal for Alkyl (c13-C15)-polyethylene glycol ether (7O), AE7),
- [redacted] (1995), which includes secondary literature experimental data on Amphoteric tensid (Coco Amido Betaine) (NOEC (21d): 0.03 mg/L nominal on fatty acid (C12-C18)amidopropylbetain, CAPB).

ECHA considers you may have wanted to include an adaptation as per Annex XI, section 1.5, read-across.

You have labelled the eleven endpoint study records as reliability 4 in the technical dossier. ECHA finds that the reliability and validity of these study records cannot be established, based on the little submitted information (e.g. study design, test conditions or discussion sections are missing). Moreover, as described above (in the statement of reasons for request 2), in order to evaluate the reliability of the read-acrosses, a justification for these specific source substances should be provided. However, no read-across justification was provided in the technical dossier for anionic tensids, noninoic tensids and amphoteric tensid.

Therefore, ECHA cannot assess your adaptation.

Therefore, the general rules for adaptation laid down in Annex XI, Section 1.5. of the REACH Regulation are not met and your adaptation of the information requirement is rejected.

Hence, 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.

Moreover, reliable results from a long-term toxicity test to Daphnia are important for the CSR and particularly to the environmental hazard assessment (Annex I).

ECHA notes that the provided results in the current technical dossier seem to lead the registered subtance to be classified. This classification is not currently addressed in the technical dossier. Therefore, pursuant to Annex I, once you have the final results, you should classify the registered substance for aquatic toxicity in line with the newly obtained results from the long term Daphnia studies, and eventually from the other newly obtained aquatic toxicity results, and adapt your RMMs accordingly; or provide a justification for not classifying.

In your comments on the draft decision according to Article 50(1) of the REACH Regulation you agree to adapt the robust study summary by providing a more detailed description of the analytical method including analytical findings at the beginning and at the end of the experiment, and update the CSA accordingly.

In your comments on the draft decision according to Article 50(1) of the REACH Regulation yu indicate that you submitted on 08 October 2018 a dossier update concerning addressed

robust study summaries and new PNEC derivations in section 6 of the dossier. ECHA will review the latest dossier update only at the follow up stage once the deadline set in the decision has passed.

Therefore, pursuant to Article 41(1) and (3) of the REACH Regulation, you are requested to submit the following information: complete robust study summary where the analytical monitoring shows a decrease of >20% of the registered substance from the water column, the effect values will be provide related to mean measured concentrations for:

- Prolonged Toxicity Study with Daphnia magna: Effects an Reproduction (OECD TG 202, Part II; [redacted], 1995).

Alternatively, if you cannot submit a complete RSS or the RSS indicates that the study is not reliable as per the criteria indicated above and/or not adequate to fulfil the information requirement, 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) with the registered substance.

5. 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 more than 1000 tonnes per year must contain, as a minimum, the information specified in Annexes VII to X to the REACH Regulation. The information to be generated for the dossier must fulfil the criteria in Article 13(4) of the same regulation.

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

You have sought to adapt this information requirement according to Annex IX, Section 9.1.6., column 2. You provided the following justification for the adaptation "*According to column 2 of REACH Annex IX, long-term toxicity tests should be proposed by the registrant if the chemical safety assessment indicates the need to further investigate effects on aquatic organisms as indicated by a PEC/PNEC ratio > 1. Having a PEC/PNEC ratio < 1 for all exposure scenarios, there is no need to perform a long-term assay as the risk towards aquatic organisms is sufficiently controlled based on the already available information.*"

However, ECHA notes that your adaptation does not meet the specific rules for adaptation of Annex IX, Section 9.1.6., column 2, because the current technical dossier includes at least one RCR above 1. The PEC/PNEC for freshwater at the Scenario 4 "Industrial use; formulation of plastic preparations; production of articles" shows to be [redacted]. ECHA notes that this value might have been miscalculated. ECHA would like to point out that once the information on short-term fish and Daphnia, and long-term Daphnia are updated, if all RCRs are below 1, you may adapt the information requirement on long-term fish toxicity (See Notes for your consideration for points 2-5, below).

Besides, several RCRs are close to one, such as the agricultural soil RCR from Scenario 5 "Industrial use of formulation in textile and leather production" and Scenario 6 "Industrial

use of formulation", where the RCR is [redacted]; or the agricultural soil RCR from Scenario 7 "Professional use of formulations", where the RCR equals to [redacted]; or the RCRs from the aquatic compartment at the Scenario 5 "Industrial use of formulation in textile and leather production" where RCRs are [redacted]

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) can be performed to cover the standard information requirement of Annex IX, Section 9.1.6.

However, the FELS toxicity test according to OECD TG 210 is more sensitive than the fish, short-term toxicity test on embryo and sac-fry stages (test method EU C.15 / OECD TG 212), or the fish, juvenile growth test (test method EU C.14. / OECD TG 215), as it covers several life stages of the fish from the newly fertilized egg, through hatch to early stages of growth (see ECHA *Guidance on information requirements and chemical safety assessment* (version 4.0, June 2017), *Chapter R7b, Section R.7.8.4.1.*

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).

In your comments on the draft decision according to Article 50(1) of the REACH Regulation you argue that the RCR value of [redacted] was miscalculated, and should have stated [redacted]. Besides, you agree that if the outcome of the updated risk assessment after the reevaluation of the requests 2-4 would show risk (i.e. RCR>1) you would perform the test, and otherwise you would adapt it.

In your comments on the draft decision according to Article 50(1) of the REACH Regulation yu indicate that you submitted on 08 October 2018 a dossier update concerning addressed robust study summaries and new PNEC derivations in section 6 of the dossier. ECHA will review the latest dossier update only at the follow up stage once the deadline set in the decision has passed.

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 points 2-5

Before conducting any of the tests mentioned above in points 2-5 you should consult the ECHA *Guidance on information requirements and chemical safety assessment (*version 4.0, June 2017*)*, Chapter R7b, Section R.7.8.5 to determine the sequence in which the aquatic

long-term toxicity tests are to be conducted and the necessity to conduct long-term toxicity testing on fish.

For example, according to 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), if based on acute aquatic toxicity data neither fish nor invertebrates are shown to be substantially more sensitive, long-term studies may be required on both. In such case, according to the integrated testing strategy, the *Daphnia* study is to be conducted first. If based on the results of the long-term *Daphnia* study and the application of a relevant assessment factor, no risks are observed (PEC/PNEC<1), no long-term fish testing may need to be conducted. However, if a risk is indicated, the long-term fish study needs to be conducted.

Due to the surface activity of the substance 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).

Once reviewed results and/or results of the tests on requests 2-5 are available, you should revise the chemical safety assessment as necessary according to Annex I of the REACH Regulation.

Appendix 2: Procedural history

ECHA notes that the tonnage band for several members of the joint submission is 1 000 tonnes or more per year.

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 23 August 2018.

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.

In your comments you agreed to the draft decision. ECHA took your comments into account and did not amend the request(s).

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 will result in a notification to the enforcement authorities of your Member State.

3. In relation to the information required by the present decision, the sample of the substance used for the new tests must be suitable for use by all the joint registrants. Hence, the sample should have a composition that is suitable to fulfil the information requirement for the range of substance compositions manufactured or imported by the joint registrants.

   It is the responsibility of all joint registrants who manufacture or import the same substance to agree on the appropriate composition of the test material and to document the necessary information on their substance composition. In addition, it is important to ensure that the particular sample of the substance tested in the new tests is appropriate to assess the properties of the registered substance, taking into account any variation in the composition of the technical grade of the substance as actually manufactured or imported by each registrant.

   If the registration of the substance by any registrant covers different grades, the sample used for the new tests must be suitable to assess these grades. Finally there must be adequate information on substance identity for the sample tested and the grades registered to enable the relevance of the tests to be assessed.

4. If the required tests are 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.