ECHA
EUROPEAN CHEMICALS AGENCY

Helsinki, 10 December 2019

Addressee: [redacted]

Decision number: CCH-D-2114493654-37-01/F
Substance name: (xylenes and 4-ethylbenzene) sulfonic acids
EC number: 701-247-3
CAS number: NS
Registration number: [redacted]
Submission number: [redacted]
Submission date: 10/05/2018
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. **In vitro gene mutation study in bacteria (Annex VII, Section 8.4.1.; test method: Bacterial reverse mutation test, EU B.13/14. / OECD TG 471) with the registered substance or its corresponding salts;**

2. **In vitro gene mutation study in mammalian cells (Annex VIII, Section 8.4.3.; test method: OECD TG 476 or TG 490) with the registered substance or its corresponding salts provided that the study requested under 1. has negative results;**

3. **Pre-natal developmental toxicity study (Annex X, Section 8.7.2.; test method: OECD TG 414) in a second species (rabbit), oral route with sodium (xylenes and 4-ethylbenzene) sulphonates (EC no 701-037-1);**

4. **Extended one-generation reproductive toxicity study (Annex X, Section 8.7.3.; test method OECD TG 443) in rats, oral route with sodium (xylenes and 4-ethylbenzene) sulphonates (EC no 701-037-1) specified as follows:**
   - **Ten weeks premating exposure duration for the parental (P0) generation;**
   - **Dose level setting shall aim to induce systemic toxicity at the highest dose level;**
   - **Cohort 1A (Reproductive toxicity);**
   - **Cohort 1B (Reproductive toxicity) without extension to mate the Cohort 1B animals to produce the F2 generation;**

5. **Short-term toxicity testing on aquatic invertebrates (Annex VII, Section 9.1.1.; test method: Daphnia sp. Acute immobilisation test, EU C.2./OECD TG 202) with sodium (xylenes and 4-ethylbenzene) sulphonates (EC no 701-037-1);**

6. **Short-term toxicity testing on fish (Annex VIII, Section 9.1.3.; test method:**

Fish, acute toxicity test, OECD TG 203) with sodium (xylenes and 4-ethylbenzene) sulphonates (EC no 701-037-1);

7. **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 or the corresponding salt ;**

8. **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 or the corresponding salt ;**

9. **Robust study summary (RSS) for [redacted], ready biodegradability (Annex VII, Section 9.2.1.1.);**

   OR

   Ready biodegradability (Annex VII, Section 9.2.1.1.; test method: DOC die-away test, OECD TG 301A) or

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

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

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

   Ready biodegradability (Annex VII, Section 9.2.1.1.; test method: Modified OECD screening test, OECD TG 301E) or

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

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

You have to submit the requested information in an updated registration dossier by ***15 September 2022***. You shall also update the chemical safety report, where relevant. The deadline has been set to allow for sequential testing.

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

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Appeal

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

Authorised[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

INFORMATION ON TOXICOLOGY AND ECOTOXICOLOGY

I. Grouping and read-across approach for (eco)toxicological information

Your registration dossier contains adaptation arguments which are based on a grouping and read-across approach in accordance with Annex XI, Section 1.5. of the REACH Regulation. You have grouped registered substances and formed a group (category) of 'aromatic sulphonic acid' to predict from data for reference substance(s) missing (eco)toxicological properties for other substances within this group (read-across approach).

You seek to adapt the information requirements for the following standard information requirements by grouping substances in the category and applying a read-across approach in accordance with Annex XI, Section 1.5:

i. *in vitro* gene mutation study in bacteria (Annex VII, Section 8.4.1.);
ii. *in vitro* cytogenicity study in mammalian cells (Annex VIII, Section 8.4.2.);
iii. sub-chronic toxicity study (90-days; Annex IX, Section 8.6.2.);
iv. pre-natal developmental toxicity study (Annex IX, Section 8.7.2.); and
v. pre-natal developmental toxicity study (Annex X, Section 8.7.2.).
vi. Short-term toxicity testing on invertebrates (Annex VII, Section 9.1.1);
vii. Growth inhibition study aquatic plants (Annex VII, Section 9.1.2);
viii. Short-term toxicity testing on fish (Annex VIII, Section 9.1.3);
ix. Ready biodegradability (Annex VII, Section 9.2.1.1);.

ECHA has considered the scientific and regulatory validity of your grouping and read-across approach in general before assessing the individual properties of the substance in section II of this appendix.

According to Annex XI, Section 1.5., two conditions shall be necessarily fulfilled. Firstly, there needs to be structural similarity between substances which results in a likelihood that the substances have similar physicochemical, toxicological and ecotoxicological properties so that the substances may be considered as a group or category.

Secondly, it is required that the relevant properties of a substance within the group may be predicted from data for reference substance(s) within the group (read-across approach). ECHA considers that the generation of information by such alternative means should offer equivalence to prescribed tests or test methods.

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

Due to the different nature of each endpoint and consequent difference in scientific considerations (e.g. key parameters, biological targets), a read-across must be specific to the endpoint or property under consideration. Key physicochemical properties may determine the

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

The ECHA Read-across assessment framework foresees that there are two options which may form the basis of the read-across hypothesis[2, 3] - (1) (Bio)transformation to common compound(s)- the read-across hypothesis is that different substances give rise to (the same) common compounds to which the organism is exposed and (2) Different compounds have the same type of effect(s)- the read-across hypothesis is that the organism is exposed to different compounds which have similar (eco)toxicological and fate properties as a result of structural similarity (and not as a result of exposure to common compounds).

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

A. Scope of the category

You have provided a read-across justification document in the CSR (sections 0.1 and 0.2).

You have defined the structural basis for the category/grouping as "*sulphonic acids, a class of organic acids with the general formula R-S(=O)$_2$-OH, where* R "

You have identified the following substances as the 'Aromatic Sulphonic Acids (ASA)' category members:

[1] Toluene-4-sulphonic acid (EC No. 203-180-0, CAS No. 104-15-4);
[2] 2 (or 4)-toluene sulphonic acid (EC No. 274-893-2, CAS No. 70788-37-3);
[3] (Xylenes and 4-ethylbenzene) sulphonic acid (EC No. 701-247-3, CAS No. NS);
[4] Benzene sulphonic acid (EC No. 202-638-7, CAS No. 98-11-3);
[5] p-cumene sulphonic acid (EC No. 240-210-1, CAS No. 16066-35-6);
[6] Cumene sulphonic acid (EC No. 253-730-9, CAS No. 37953-05-2);
[7] Hydroxybenzensulphonic acid (EC No. 215-587-0, CAS No. 1333-39-7) and
[8] 4-hydroxybenzene sulphonic acid (EC No. 202-691-6, CAS No. 98-67-9).

The substances are hereafter refered to as substance [1] to [8].

In your comments to the draft decision you discuss in further detail the similarity between the members of your category. You state, for example, that

- it has been concluded in different reports that sulfonic acids behave in a toxicologically similar manner and that para-TSA (toluene sulphonic acid) can be used as a toxicological surrogate for BSA (benzene sulphonic acid).

[2] Read-Across Assessment Framework (RAAF). 2017 (March) ECHA, Helsinki. 60 pp. Available online: Read-Across Assessment Framework (https://echa.europa.eu/support/registration/how-to-avoid-unnecessary-testing-on-animals/grouping-of-substances-and-read-across)
[3] Read-across assessment framework (RAAF) - considerations on multi-constituent substances and UVCBs. 2017 (March) ECHA, Helsinki. 40 pp. Available online: https://echa.europa.eu/publications/technical-scientific-reports

- you acknowledge a slight increase of activity from BSA to CSA (cumene sulphonic acid) due to the alkyl substituents, which can increase the nucleophilicity of the benzene ring. However, you consider it negligible.
- the increase in carbon atoms from toluene to xylene and to cumene improve solubility in apolar solvents and reduce solubility in polar solvents like water. You state that the substances are highly water-soluble and expected to be rapidly excreted and minimally absorbed into systemic circulation.
- the substances have low octanol-water partitioning coefficients (Kow). Therefore, you indicate that they have similar behaviour in the environment due to their affinity for water phase and that bioaccumulation is not expected.
- the reactivity increases from the substance with the lowest acidity (HBSA; hydroxybenzene sulphonic acid) to the one with highest acidity (CSA) and therefore you consider that CSA and HBSA could be considered as the most representative substances of the group for the evaluation of human health effects and environmental distribution properties.
- HBSA could be considered one of the metabolites of BSA since usually the aromatic hydroxylation is the first reaction in the microbial and human metabolism (confirmed by the available data on TSA). Therefore, you say that HBSA has the highest water solubility and is the lowest bioavailable and CSA has the highest number of methyl groups with the most activated benzene ring.

You further provide information from the QSAR Toolbox, showing for example that there are no alerts for genotoxicity for any of the members of the category (or any of their corresponding salts), and that alerts for reprotoxicity are similar for the aromatic sulphonic acids and the hydrotropes.

i. Characterisation of the composition of the category members

The characterisation of the substances identified as members of a category needs to be as detailed as possible in order to confirm category membership and to assess whether the attempted predictions are not compromised by the composition and/or impurities. The information provided on the substance characterisation of the category members must establish a clear picture of the chemical structures of their constituents to establish the extent of qualitative and quantitative differences and similarities in the structure and in the composition of these substances. ECHA recommends to follow its Guidance for identification and naming of substances under REACH and CLP for all source substances within the category.

You have not addressed the composition of the category members in your read-across justification. However, information on composition for substances [1], [3], [4], [5] and [8] can be found in the IUCLID dossiers for the respective registrations.

The toluene-4, benzene, 4-hydroxybenzene and p-cumene sulphonic acids are mono-constituent substances whereas the (xylenes and 4-ethylbenzene) sulphonic acid is an UVCB substance.

Toluene-4, p-cumene- and 4-ethyl-benzene sulphonic acids are mainly in the form of [redacted] For xylene-sulphonic acid the alkyl groups are mainly in the [redacted]

ECHA considers the information provided in the technical dossiers with regard to the composition of the category members [1], [3], [4], [5] and [8] as sufficient to establish

structural similarity (and structural differences) between the category members.

However, substances [2], [6] and [7] are not registered under REACH. Therefore, no information on their composition is available. As a consequence, ECHA considers that there is no adequate information available to establish the extent of the similarity and of the differences in the structure and in the composition of these three substances.

ii. Applicability domain of the category

According to the ECHA Guidance on information requirements and chemical safety assessment Chapter R.6.2, Section R.6.2.4.1, (version 1.0, May 2008) a category hypothesis should address "*the set of inclusion and/or exclusion rules that identify the ranges of values within which reliable estimations can be made for category members for the given endpoint. These rules, can be described as the applicability domain for an endpoint and provide a means of extending the category membership to chemicals not explicitly included in the current definition of a category.*"

Furthermore, according to the ECHA Guidance on information requirements and chemical safety assessment Chapter R.6.2, Section R.6.2.1.2, (version 1.0, May 2008) "*a category evaluation does not necessarily result in all the individual substances included in the category evaluation being registered to the Agency, although the data from these substances will be included in the category report in support of the registration.*"

Based on your description of the structural basis of your grouping/category approach, ECHA understands that all category members share a common 'core structure' and that they vary only in terms of their alkyl- substitutions on the benzene ring. Furthermore, ECHA understands that the allowed substituents to the 'core structure' define the inclusion critera for the category membership. You have defined the structural basis for the category/grouping as "*sulphonic acids, a class of organic acids with the general formula R-S(=O)$_2$-OH, where R is usually a hydrocarbon (aromatic) side chain*".

Considering the UVCB nature of the (xylene and 4-ethylbenzene) sulphonic acid, ECHA considers that the the applicability domain of the category to be: sulphonic acids of benzene, hydroxybenzene, cumene, toluene, and xylene (containing up to [redacted] 4-ethylbenzene). The structural variation within the category is defined by the alkyl- (or hydroxy-) substituents on the core structure, i.e. benzene sulphonic acid. ECHA assessed your proposed predictions on this basis.

B. Prediction of toxicological properties

You have provided the following reasoning for the prediction of toxicological properties:

"*.....the acidity of the sulphonic acid group is not expected to change significantly among the five aromatic sulphonic acids.[.....] Thus the reactivity of the sulphonic acids are very similar and they can each be used as a surrogate for the others. A full set of 2010 guideline physical-chemical studies demonstrates the similar chemical and physical properties and behavior of the 5 sulphonic acids in the category. The sulphonic acid moiety is the primary driver for mammalian toxicity and any difference between the benzene, xylene, cumene, and toluene moieties would be insignificant given the relatively high level of corrosivity of all five substances in the category.*"

ECHA understands that you base your predictions on the assumption that different compounds

have similar toxicological properties as a result of structural similarity. You assume that all substances will show the same type of effects for toxicological properties. ECHA notes the following shortcomings with regards to prediction of toxicological properties:

i. *Insufficient information to support the claim of the* same type of effects *for toxicological properties*

According to Annex XI, Section 1.5., '*Application of the group concept requires that [...] human health effects [...] may be predicted from data for reference substance(s) within the group by interpolation to other substances in the group (read-across approach).*'

A number of factors contributes to the robustness of the predictions made within a group. According to the ECHA Guidance on information requirements and chemical safety assessment Chapter R.6.2, Section R.6.2.1.5. (version 1.0, May 2008), one of these factors is the density and distribution of the available data across the category. In order to derive reliable prediction of the properties of the members of the category, adequate and reliable information covering the range of structural variations identified among the category members needs to be available.

In the read-across hypothesis, you assume, based on the available information, the same type of effects across the category. You provided:

- Repeated dose toxicity studies conducted with a (xylenes and 4-ethylbenzene) sulphonate and p-toluene sulfonic acid
- pre-natal developmental toxicity studies conducted with a (xylenes and 4-ethylbenzene) sulphonates in rats and rabbits;
- Reproductive and developmenal toxicity screening test conducted with p-toluene sulfonic acid as well as supporting toxicokinetic information available on toluene sulphonate; and
- In vivo micronucleus test with cumene sulphonate and calcium xylenesulphonate
- In vitro micronucleus tests with p-toluenesulfonic acid
- In vitro gene mutation study in bacteria with benzenesulfonic acid and p-toluenesulfonic acid (both studies not acceptable due to quality issues as described in section II)

ECHA notes that you predict (or propose to predict) the properties of the members of the category from data available mainly on (xylenes and 4-ethylbenzene) sulphonates and its salts, and to a lesser extent on toluene-4 sulphonic acid and its corresponding salt and on p-cumene sulphonate. Prediction is based on structural similarity and appears plausible if the available data allows for a side-by-side comparison of the toxicity profiles of the source and target substance.

However, there is very little data available on the target substances benzene, p-cumene and hydroxybenzene sulphonic acids to support such a prediction for the endpoints of mutagenicity, repeated dose toxicity, developmental toxicity and toxicity to reproduction. Therefore, ECHA considers that the available information does not cover the range of structural variations for those substances and hence there is no support for your claim of a regular pattern of similar ecotoxicological properties.

With regard to reading across from (xylenes and 4-ethylbenzene) sulphonic acid or sulphonate to toluene 4-sulphonic acid (and *vice versa*), ECHA notes that the results from the available reproductive and developmental toxicity screening test conducted with toluene sulphonic acid is consistent with the available repeated dose toxicity and pre-natal developmental toxicity

studies conducted with (xylenes and 4-ethylbenzene) sulphonates. In both cases a lack of toxicity have been demonstated up to the limit dose. In addition, there is supporting toxicokinetic information available on toluene sulphonate which demonstrates that this substance is excreted unchanged in urine.

Therefore, ECHA considers it likely that the repeated dose, developmental toxicity and the toxicity to reproduction effects of toluene sulphonates may be predicted from (xylenes and 4-ethylbenzene) sulphonates. This conclusion is further supported by a 28-day repeated dose toxicity study on toluene 4-sulphonic acid. However, for mutagenicity there is not a sufficient database to allow for a side-by-side comparison of the effects. Therefore, ECHA considers that, in the absence of any relevant mutagenicity data on toluene sulphonic acid, the available information does not support your claim of a regular pattern of same type of effects for with regard to mutagenicity. This issue is further discussed below and under the respective endpoints for genotoxicity.

With regard to reading across from a (xylenes and 4-ethylbenzene) sulphonate or toluene sulphonic acid to the p-cumene, benzene, and hydroxybenzene sulphonic acids (and *vice versa*) first for human health endpoints other than mutagenicity, ECHA notes that there is no relevant information to allow a side-by-side comparison of effects related to repeated dose toxicity, reproductive or developmental toxicity wich supports the read-across approach. Furthermore, there is no toxicokinetic information available on the substances that could have helped supporting the read-across approach.

Therefore, in the absence of any relevant repeated dose, reproductive or developmental data on p-cumene, benzene, and hydroxybenzene sulphonic acids, ECHA considers that there is no support for the read-across for these endpoints. A reproductive and developmental toxicity screening test (OECD TG 422) allows a screening level assessment of such effects and could potentially be used to support read-across for these endpoints, provided that the results obtained are consistent with those obtained with the source substances.

Secondly, for mutagenicity, ECHA notes that for p-toluenesulfonic acid, a xylenesulphonate, and a cumene sulphonate, that there are *In vitro* and *In vivo* micronucleus tests available. However, the *In vitro* tests for mutagenicity cover two aspects, chromosome aberration and gene mutation. There is no acceptable information available which would allow comparison of the gene mutation potential between these category members. In the absence of such data, ECHA considers that there is no support for your claim of a regular pattern of same type of effects with regard to potential to induce gene mutation for any of the category members.

Furthermore, for benzene sulphonic acid and hydroxybenzene sulphonic acid, there is no acceptable data available on chromosome aberration. In the absence of suitable "bridging information", ECHA considers that there is no support for your claim of a regular pattern of same type of effects with regard to that endpoint for benzene sulphonic acid and hydroxybenzene sulphonic acid.

ECHA has evaluated the information from QSAR Toolbox provided by you. We note that the lack of experimental results for many endpoints is a concern in this case. Generally, the purpose of QSAR Toolbox is to group substances with similar structures and profiling outcome to fill the data gaps with available experimental data. In this particular case, it appears this group of substances was grouped mainly on the basis of similar physical, structural and chemical properties, and consistent outcome from the QSAR Toolbox profilers within the group. The profilers are only indicative additional 'similarity measures'. Therefore the consistency within the profiling outcome have to be confirm by the consistency of the data

from toxicological studies, and consequently reliable experimental data for category members must be available. Taking these considerations into account, this QSAR Toolbox category can be considered as a good starting point for category formation, but the available information is not sufficient to predict consistent toxicological behaviour of the category members.

In conclusion, ECHA considers that there is still no support for your claim of a regular pattern of same type of effects for the endpoints discussed above due to missing "bridging" information. In your endpoint-specific comments generation of such information is discussed, and ECHA has responded to those comments below under the respective endpoint requests.

C. Prediction of ecotoxicological and ready biodegradability properties

You have provided the following reasoning for the prediction of ecotoxicological properties and ready biodegradability properties: *"……the acidity of the sulphonic acid group is not expected to change significantly among the five aromatic sulphonic acids. [……] Thus the reactivity of the sulphonic acids are very similar and they can each be used as a surrogate for the others. A full set of 2010 guideline physical-chemical studies demonstrates the similar chemical and physical properties and behavior of the 5 sulphonic acids in the category.[…] The aromatic sulphonic acids are almost completely ionized in watery environments."*

Specifically for ready biodegradability, you claim in section 4.1.2.1.2 of the CSR that *"…seven biodegradation studies are performed with the closely related hydrotropes (the salts) for which was concluded that these are readily biodegradable. As the cation has limited affect on the biodegradation potential, and in principle the salts gets dissociated when in contact with water thus forming the acid, it is considered justified to conclude that these substances are readily biodegradable, taking into account all the available information."*

ECHA understands that you base your predictions on the assumption that different compounds have similar ecotoxicological and ready biodegradability properties as a result of structural similarity. ECHA notes the following shortcomings:

i. Insufficient information to support a claim of similar ecotoxicological and ready biodegradability properties

According to Annex XI, Section 1.5., *'Application of the group concept requires that […] environmental effects or environmental fate may be predicted from data for reference substance(s) within the group by interpolation to other substances in the group (read-across approach).'*

A number of factors contributes to the robustness of the predictions made within a group. According to the ECHA Guidance on information requirements and chemical safety assessment Chapter R.6.2, Section R.6.2.1.5. (version 1.0, May 2008), one of these factors is the density and distribution of the available data across the category. In order to derive reliable prediction of the properties of the members of the category, adequate and reliable information covering the range of structural variations identified among the category members needs to be available.

Ecotoxicological properties

In the read-across hypothesis, you assume similar ecotoxicity properties across the category.

ECHA notes that you propose to predict the properties of the members of the category from data available mainly on toluene-4-sulphonic acid, on salts of (xylenes and 4-ethylbenzene) sulphonic acid, and on benzene sulphonic acid. However, based on the information provided in the technical dossier of category members, there is very little data available on the category members to support such a prediction for the aquatic toxicity endpoints of algae growth inhibition, short-term toxicity testing on aquatic invertebrates, and short-term toxicity testing on fish, as explained below:

- short-term toxicity testing on fish: data is only available for one member of the category, toluene-4-sulphonic acid.

- short-term toxicity testing on aquatic invertebrates: one reliable study is available for one member of the category, benzene sulphonic acid (key study). A study is available also on toluene-4-sulphonic acid, but with an exposure duration of 24h ('weight of evidence' study). According to the ECHA guidance R7b (Section R.7.8.4.1), 24 hour values can have considerable variability in the repeatability of results and should not be compared to 48 hour values. Therefore ECHA considers that this study on toluene sulphonic acid cannot be used to compare with the study on benzene sulphonic acid.

- algae growth inhibition: meaningful data for comparison are available only on two category members, i.e. toluene-4-sulphonic acid and (xylenes and 4-ethylbenzene) sulphonic acid. There is also an algae study available for benzene sulphonic acid (key study), but the study has not been performed in optimal pH conditions (i.e. pH of 3 and 5 at the two highest test concentrations, which might have influenced the results), hence its results cannot be compared to those of studies with the other two category members.

Consequently, the data density across the category members is limited in the aquatic toxicity endpoints. In particular, for 4-hydroxybenzene sulphonic acid and p-cumene sulphonic acid, no aquatic toxicity data is available. With such limited reliable information available on the aquatic toxicity, no quantitative trend between the category members can be established for these endpoints.

Therefore, ECHA considers that the available information does not cover the range of structural variations and hence there is no support for your claim of a regular pattern of similar ecotoxicological properties.

In response to the additional information provided in your comments on the draft decision, you acknowledge that no tests are available for 4-hydroxybenzene sulphonic acid and you indicate that new tests will be performed in order to strengthen the validity of the category. In your endpoint-specific comments generation of such information is discussed.

Furthermore, you consider that the read-across between toluene-4-sulphonic acid and benzene sulphonic acid is acceptable and you claim that the presence of methyl group on the benzene rind does not significantly impact the ecotoxicological profile of the substance. However, ECHA notes that you do not provide any evidence to support your claim.

In particular, ECHA considers that there is still no support for your claim of a regular pattern of same type of effects for the endpoints discussed above due to missing "bridging" information. As a consequence, ECHA notes that the read-across between 4-hydroxybenzene sulphonic acid and benzene sulphonic acid, as well as, benzene sulphonic acid and toluene-4-

sulphonic acid is not acceptable based on the information currently available.

ECHA acknowledges that in your comments on the draft decision you indicate your intention to strengthen the read-across approach after new data for the registered substance (or its corresponding salt) become available. However, you do not specify which substance you want to test in the long-term studies. Since this information and an updated read-across justification for the long-term aquatic toxicity endpoints is not yet available, ECHA cannot currently assess whether your choice of appropriate tests and use read-across adaptations for the long-term aquatic toxicity endpoints would be acceptable.

ECHA will evaluate your information after the deadline of this decision according to the specific rules of column 2 adaptations in Annex IX/X, and in support of an adaptation according to Annex XI, section 1.5.

For your consideration, ECHA notes there may be information available on these substances that has not been included in the technical dossier nor in the data matrix for ecotoxicity even though such data may be relevant. For instance, in your read-across justification you propose read-across between each individual sulphonic acid and the corresponding ammonium, calcium, potassium and sodium salts (defined as "hydrotropes" or "sulphonates" in your read-across justification document). However, ECHA notes that there are aquatic toxicity studies available in the technical dossiers of the corresponding salts that have not been considered and reported in the technical dossier of the acid (e.g. short-term fish and short-term *Daphnia* studies on (xylenes and 4-ethylbenzene) sulphonate, short-term *Daphnia* study on sodium toluene sulphonate). Since these additional studies on salts have not been included in the technical dossiers of the registered substance, they could not be taken into account when assessing the scientific and regulatory validity of your grouping and read-across approach of the 'aromatic sulphonic acid (ASA) ' category.

Ready biodegradability property

In the read-across hypothesis, you assume the same ready biodegradability properties across the category. You further argue that this is supported by the available studies on the various category members and their salts which demonstrate the ready biodegradability of the substances.

ECHA notes that you propose to predict the ready biodegradability properties of the "aromatic sulphonic acid" category members based on the available data on the category members and their corresponding salts.

ECHA accepts read-across between the "aromatic sulphonic acids" and their corresponding ammonium, calcium, potassium and sodium salts provided that the source study is adequate and reliable for the endpoint concerned.

ECHA notes that the source study on sodium salt of toluene 4-sulphonic acid is valid and shows that this substance is ready biodegradable. You use this study in order to conclude on this endpoint for all category members. However, ECHA notes that, for the reasons explained in request 9 below, all the other studies available on the category members and their corresponding salts are either not adequate (in total twelve studies) or the information provided is insufficient to make an independent assessment of the study (three studies).

Since adequate information on ready biodegradability is currently available only for one

category member, ECHA considers that the available information does not cover the range of structural variations and hence there is no support for your claim of a regular pattern of similar ready biodegradability properties.

ii. Inconsistency between the read-across hypothesis and the experimental results for ready biodegradability endpoint

Annex XI, Section 1.5 of the REACH Regulation requires that "Substances whose [..] ecotoxicological properties are likely to be similar or follow a regular pattern as a result of structural similarity may be considered as a group". According to the ECHA Guidance on information requirements and chemical safety assessment Chapter R.6.2, Section R.6.2.2.2, (version 1.0, May 2008) "a demonstration of consistent trends in the behaviour of a group of chemicals is one of the desirable attributes of a chemical category and one of the indicators that a common mechanism for all chemicals is involved". The observation of a deviation in a trend among some members of a category is a warning sign. An explanation for this deviation in the trend resulting in a contradiction between the similarities in properties claimed in the read-across hypothesis and the observation of different properties needs to be provided and supported by scientific evidence.

In the read-across hypothesis, you assume the same ready biodegradability properties across the category. You further argue that this is supported by the available studies on the various category members and their salts which demonstrate the ready biodegradability of the substances.

ECHA notes that the source study on sodium salt of Toluene-4-sulphonic acid is valid and shows that this substance is ready biodegradable. Regarding the other source studies available for this endpoint, for the reasons explained in request 9 below ECHA considers that twelve of them are not adequate, while three of them (OECD 301D studies) are insufficiently reported hence their reliability cannot be currently assessed.

In addition, ECHA notes that the results of the three OECD 301D studies show that salts of cumene-, (xylenes and 4-ethylbenzene) sulphonic acids as well as benzene sulphonic acid are not ready biodegradable. Although ECHA cannot currently establish the reliability of these three OECD 301D studies, you consider them reliable since you have assigned Klimisch score 2. The results of these three OECD 301D studies contradict your hypothesis that the category members are ready biodegradable. Therefore, ECHA considers that you have not demonstrated that the read-across is supported.

D. Conclusion

ECHA accepts read-across between the "aromatic sulphonic acids" and their corresponding ammonium, calcium, potassium and sodium salts provided that the source study is adequate and reliable for the endpoint concerned.

- *Read-across for toxicological endpoints*

Reading across form (xylene and 4-ethyl benzene) sulphonates to toluene sulphonic acid (and *vice versa*), for repeated dose toxicity, developmental toxicity and toxicity to reproduction "bridging infromation" is available and as a result ECHA accept the proposed read-across. However, ECHA considers that due to missing "bridging infromation" it is not possible to establish a scientifically credible link between the target and source substances which would

allow to predict the outcome of the *in vitro* mutagenicity tests. Concequently, read-across is rejected for mutagenicity.

Reading across form (xylene and 4-ethyl benzene) sulphonates and toluene sulphonic acid to p-cumene, benzene, and hydroxybenzene sulphonic acids (and *vice versa*), ECHA considers that due to missing "bridging information" it is not possible establish a scientifically credible link between the target and source substances which would allow to predict the outcome of the *in vitro* mutagenicity tests, repeated dose toxicity, developmental toxicity studies, and toxicity to reproduction studies. Concequently, read-across is rejected for these endpoints.

For benzene sulphonic acid and hydroxybenzene sulphonic acid, read-across for chromosome aberration is furthermore rejected in the absence of suitable "bridging information".

- *Read-across for ecotoxicological and ready biodegradability endpoints*

ECHA considers that due to missing "bridging information" it is not possible to establish a scientifically credible link between the category members which would allow to predict the outcome of the algae growth inhibition, short-term fish and short-term *Daphnia* studies. Consequently, the proposed read-across is rejected.

ECHA concludes that, due to insufficient reliable information and contradicting information, your proposed prediction for ready biodegradability is not supported. Consequently, the proposed read-across is rejected.

II. SPECIFIC CONSIDERATIONS ON THE INFORMATION REQUIREMENTS

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.

1. In vitro gene mutation study in bacteria (Annex VII, Section 8.4.1.)

An "*In vitro* gene mutation study in bacteria" is a standard information requirement as laid down in Annex VII, Section 8.4.1. 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 sought to adapt this information requirement according to Annex XI, Section 1.5. of the REACH Regulation by providing studies conducted with other category members, however, for reasons explained below none of these studies (alone or combined) meet the standard information requirement of Annex VIII, Section 8.4.1. Concequently, your adaptation of this information requirement according to Annex XI, Section 1.5. is rejected.

According to Article 13(3) of the REACH Regulation, tests required to generate information on intrinsic properties of substances shall be conducted in accordance with the test methods recognised by the Commission or ECHA.

Other tests may be used if the conditions of Annex XI are met. More specifically, Section 1.1.2 of Annex XI provides that existing data on human health properties from experiments not

carried out according to GLP or the test methods referred to in Article 13(3) may be used if the following conditions are met:

(1) Adequacy for the purpose of classification and labelling and/or risk assessment;
(2) Adequate and reliable coverage of the key parameters foreseen to be investigated in the corresponding test methods referred to in Article 13(3);
(3) Exposure duration comparable to or longer than the corresponding test methods referred to in Article 13(3) if exposure duration is a relevant parameter; and
(4) adequate and reliable documentation of the study is provided.

You have provided the following study records:

i. [redacted](1988), key study, Reliability 2, according to GLP, *in vitro* gene mutation study in bacteria (similar to OECD TG 471), p-toluenesulfonic acid (EC no 203-180-0) was tested in five strains of *S. typhimurium* (TA 1535, TA 1537, TA 1538 TA 98 and TA 100), metabolic activation; and according to OECD TG 471, (*in vitro* gene mutation study in bacteria rel. 2, GLP compliant, 1988, [redacted]); Metabolic activation missing for the positive controls (strains TA100, TA1535 and TA 1537).

ii. [redacted] (1988), supporting study, Reliability 2, not according to GLP, *in vitro* gene mutation study in bacteria (non-guideline), [redacted] was tested in four strains of *S. typhimurium* (TA97, TA98, TA100, and TA1535), metabolic activation only for the highest dose.

According to paragraph 13 of the current OECD TG 471 test guideline (updated 1997) at least five strains of bacteria should be used: S. typhimurium TA1535; TA1537 or TA97a or TA97; TA98; TA100; S. typhimurium TA102 or E. coli WP2 uvrA or E. coli WP2 uvrA (pKM101). This includes four strains of *S. typhimurium* (TA1535; TA1537 or TA97a or TA97; TA98; and TA100) that have been shown to be reliable and reproducibly responsive between laboratories. These four *S. typhimurium* strains have GC base pairs at the primary reversion site and it is known that they may not detect certain oxidising mutagens, cross-linking agents and hydrazines. Such substances may be detected by *E.coli* WP2 strains or *S. typhimurium* TA102 which have an AT base pair at the primary reversion site.

You have provided studies none of which included tests with strains *S. typhimurium* TA102 or *E. coli* WP2 uvrA or *E. coli* WP2 uvrA (pKM101). In addition, both tests deviate form the OECD TG 471 in terms of the required positive controls.

Therefore, the provided studies do not provide the information required by Annex VIII, Section 8.4.1., nor can it be considered as providing equivalent data according to the criteria in Annex XI, 1.1.2. of the REACH Regulation.Consequently there is an information gap and it is necessary to provide information for this endpoint.

ECHA considers that the bacterial reverse mutation test (test method EU B.13/14. / OECD TG 471) is appropriate to address the standard information requirement of Annex VII, Section 8.4.1. of the REACH Regulation.

In your comments to the draft decision you propose to cover this endpoint with available test on sodium and calcium xylene sulphonate, and with new test on benzene and cumene sulphonic acid. ECHA agrees to this approach provided that read-across can be sufficiently justified. ECHA further notes that the quality of the available test will be evaluated during follow-up according to Article 42.

Therefore, pursuant to Article 41(1) and (3) of the REACH Regulation, you are requested to submit following information derived with the registered substance subject to the present decision or its corresponding salts: Bacterial reverse mutation test (test method: EU B.13/14. / OECD TG 471).

2. In vitro gene mutation study in mammalian cells (Annex VIII, Section 8.4.3.)

An "*In vitro* gene mutation study in mammalian cells" is an information requirement as laid down in Annex VIII, Section 8.4.3. of the REACH Regulation, "if a negative result in Annex VII, Section 8.4.1. and Annex VIII, Section 8.4.2." is obtained.

ECHA notes that the registration dossier does not contain study records or adaptataions according to Column 2 of Annex VIII, Section 8.4.3. or according to Annex XI for this endpoint. Adequate information *on in vitro* gene mutation in mammalian cells will however need to be present in the technical dossier for the registered substance to meet this information requirement provided that the study requested under [1] has a negative result. ECHA set the deadline for provision of the information to allow for sequential testing.

Consequently there is an information gap and it is necessary to provide information for this endpoint.

ECHA considers that the *in vitro* mammalian cell gene mutation tests using the *Hprt* and *xprt* genes (OECD TG 476) and the *in vitro* mammalian cell gene mutation tests using the thymidine kinase gene (OECD TG 490) are appropriate to address the standard information requirement of Annex VIII, Section 8.4.3.

In your comments to the draft decision you propose to use read-across from an existing OECD 476 study on sodium xylene sulphonate to cover this endpoint. ECHA agrees to this approach but notes that the quality of the available test will be evaluated during follow-up according to Article 42.

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 or its corresponding salts, provided that the study requested under [1] has a negative result: *In vitro* mammalian cell gene mutation test (test method: OECD TG 476 *or* OECD TG 490).

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

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 using the the analogue substance [redacted] as test material.

However, there is no information provided for a pre-natal developmental toxicity study in a second species. You have attempted to adapt this information requirement by submitting the following justification:

"The study does not need to be conducted because the substance is of low toxicological activity (no evidence of toxicity seen in any of the tests available), it can be proven from toxicokinetic data that no systemic absorption occurs via relevant routes of exposure (e.g. plasma/blood concentrations below detection limit using a sensitive method and absence of the substance and of metabolites of the substance in urine, bile or exhaled air) and there is no or no significant human exposure – [exposure considerations; study scientifically not necessary/other information available]" and

"The test substance did not induce developmental or teratogenic effects at doses up to 3000 mg/kg/day in the rat (first species) so on the grounds of animal welfare, testing on a 2nd species is waived."

ECHA interprets your adaptation as an adaptation according to Annex X, Section 8.7. Column 2. However, even if the substance may be of low toxicological activity you have not provided any toxicokinetic data to demonstrate that no systemic absorption occurs via relevant routes of exposure. Furthermore, ECHA notes that in the CSR, human exposure levels resulting in RCRs at or above 0.6 are reported. Such information does not support that no significant exposure takes place. Hence, your adaptation 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 6.0, July 2017) Chapter R.7a, Section R.7.6.2.3.2. Since the substance to be tested is a liquid, ECHA concludes that testing should be performed by the oral route.

In your comments to the draft decision you propose to use read-across from an OECD 414 study on sodium xylene sulphonate in rabbits to cover this endpoint. ECHA agrees to this approach.

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

Notes for your consideration

ECHA notes that a pre-natal developmental study (test method: OECD 414) in rabbit, oral route, is available for the analogous substance 1300-72-7_sodium xylenesulphonate (EC no. 701-037-1).

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

The basic test design of an extended one-generation reproductive toxicity study (test method OECD TG 443 with Cohorts 1A and 1B, without extension of Cohort 1B to include a F2 generation, and without Cohorts 2A, 2B and 3) is a standard information requirement as laid down in column 1 of 8.7.3., Annex X. If the conditions described in column 2 of Annex X are met, the study design needs to be expanded to include the extension of Cohort 1B, Cohorts 2A/2B, and/or Cohort 3. Further detailed guidance on study design and triggers is provided in the ECHA *Guidance on information requirements and chemical safety assessment* Chapter R.7a, Section R.7.6 (version 6.0, July 2017).

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

a) The information provided

You have not provided any study record of an extended one-generation reproductive toxicity study in the dossier that would meet the information requirement of Annex X, Section 8.7.3.

Instead you have sought to adapt the information requirements for this endpoint by providing the following justification:

"Studies from the chemically related hydrotropes category are being recommended as read across for this endpoint. Hydrotropes are the salt form of the sulphonic acids. The corrosive nature of the sulphonic acids with regard to animal welfare further support this waiver. The 90-day oral rat and oral mouse studies and the 2-year chronic dermal rat and mouse studies with the closely related hydrotropes included examination of sex organs of both sexes. No treatment related effects were observed on reproductive organs."

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

Evaluation approach/criteria

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 an extended one-generation reproductive toxicity study (EU B.56./OECD TG 443) as requested in this decision. ECHA considers that this study provides, in addition to information to general toxicity, information in particular on two aspects, namely on sexual function and fertility in P0 and F1 generations

(further referred to as 'sexual function and fertility') and on development and toxicity of the offspring from birth until adulthood due to pre- and postnatal and adult exposure in the F1 generation (further referred to as 'effects on offspring').

Relevant elements for 'sexual function and fertility' are in particular functional fertility (oestrous cycle, sperm parameters, mating behaviour, conception, pregnancy, parturition, and lactation) in the parental generation after sufficient pre-mating exposure duration and histopathological examinations of reproductive organs in both P and F1 generations. Relevant elements for 'effects on offspring' are in particular peri- and post-natal investigations of the F1 generation up to adulthood including investigations to detect certain endocrine modes of action, and sexual development. Also the sensitivity and depth of investigations to detect effects on 'sexual function and fertility' and 'effects on offspring' needs to be considered.

Evaluation of the provided information

ECHA notes that the studies referred to in your adaptation may provide information on systemic toxicity. However, none of the studies are studies intended to investigate "sexual function and fertility" or "developmental toxicity". Thus, the studies do not provide sufficient information to conclude on these aspects of an extended one-generation reproductive toxicity study.

ECHA concludes that 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 Annex X, Section 8.7.3. 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. Thus, an extended one-generation reproductive toxicity study according Annex X, Section 8.7.3. is required. The following refers to the specifications of this required study.

b) The specifications for the study design

Premating exposure duration and dose-level setting

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

Ten weeks premating exposure duration is required because there is no substance specific information in the dossier supporting shorter premating exposure duration as advised in the ECHA *Guidance on information requirements and chemical safety assessment* Chapter R.7a, Section R.7.6 (version 6.0, July 2017).

The highest dose level shall aim to induce systemic toxicity, but not death or severe suffering of the animals, to allow comparison of reproductive toxicity and systemic toxicity. The dose

level selection should be based upon the fertility effects with the other cohorts being tested at the same dose levels.

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

Species and route selection

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

ECHA considers that the oral route is the most appropriate route of administration for substances except gases to focus on the detection of hazardous properties on reproduction as indicated in ECHA *Guidance on information requirements and chemical safety assessment* (version 6.0, July 2017) Chapter R.7a, Section R.7.6.2.3.2. Since the substance to be tested is a liquid, ECHA concludes that testing should be performed by the oral route.

In your comments to the draft decision you propose to use read-across from the new OECD 443 test on sodium xylene sulphonate to cover this endpoint. ECHA agrees to this approach.

c) Outcome

Therefore, pursuant to Article 41(1) and (3) of the REACH Regulation, you are requested to submit the following information derived with sodium xylene sulphonate: Extended one-generation reproductive toxicity study (test method OECD TG 443), in rats, oral route, according to the following study-design specifications:

- Ten weeks premating exposure duration for the parental (P0) generation;
- Dose level setting shall aim to induce systemic toxicity at the highest dose level;
- Cohort 1A (Reproductive toxicity);
- Cohort 1B (Reproductive toxicity) without extension to mate the Cohort 1B animals to produce the F2 generation;

While the specifications for the study design are given above, you shall also submit with the new endpoint study record a scientific justification on each of the following aspects: 1) length of the premating exposure duration and dose level selection, 2) reasons for why or why not Cohort 1B was extended, 3) termination time for F2 generation, and 4) reasons for why or why not Cohorts 2A/2B and/or Cohort 3 were included.

Notes for your consideration

The conditions to include the extension of Cohort 1B are currently not met. Furthermore, no triggers for the inclusion of Cohorts 2A and 2B (developmental neurotoxicity) and Cohort 3 (developmental immunotoxicity) were identified. However, you may expand the study by including the extension of Cohort 1B, Cohorts 2A and 2B and/or Cohort 3 if new information becomes available after this decision is issued to justify such an inclusion. Inclusion is justified if the available information, together with the new information shows triggers which are described in column 2 of Section 8.7.3., Annex X and further elaborated in ECHA *Guidance on information requirements and chemical safety assessment* Chapter R.7a, Section R.7.6 (version 6.0, July 2017). You may also expand the study to address a concern identified

during the conduct of the extended one-generation reproduction toxicity study and also due to other scientific reasons in order to avoid a conduct of a new study. The justification for the expansion must be documented.

5. Short-term toxicity testing on aquatic invertebrates (Annex VII, Section 9.1.1.)

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

You have sought to adapt this information requirement according to Annex XI, Section 1.5. of the REACH Regulation by providing the following three study records on analogue substances:

1. Key study on the analogue substance benzene sulphonic acid according to OECD TG 202, (*Daphnia sp.* Acute Immobilisation Test): [redacted], reliability 2, GLP compliance: yes,
2. Supporting study on the analogue substance benzene sulphonic acid according to OECD TG 202, (*Daphnia sp.* Acute Immobilisation Test): [redacted], reliability 2, GLP compliance: not specified,
3. Supporting study on the analogue substance toluene sulphonic acid according to OECD TG 202, (*Daphnia sp.* Acute Immobilisation Test): [redacted] reliability 2, GLP compliance: not specified.

However, as explained above, your adaptation of the information requirement according to Annex XI, Section 1.5. is rejected.

ECHA notes further that the read-across study no 2 is not adequate to conclude on this endpoint because, contrary to what is given in paragraph 24 of OECD TG 202, the concentration used in this limit study (i.e. 65 mg a.i./L) is below the threshold of 100 mg/L of active substance. In addition, the test material is not clearly identified in the technical dossier. ECHA notes that the test material is described as "*Phenol sulfonic acid and Eltesol PA 65; confirmed by study owner a being benzene sulphonic acid (CAS No. 98-11-3) based on records from study sponsor*". Eltesol PA 65 appears to correspond to phenol sulphonic acid (i.e. EC no 202-691-6). Therefore it is not clear whether the tested material was indeed benzene sulphonic acid (CAS No. 98-11-3) as indicated in the technical dossier. Thus, this study does not provide the information required by Annex VII Section 9.1.1.

Therefore, 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 sp.* acute immobilisation test (test method EU C.2. / OECD TG 202) is the preferred test to cover the standard information requirement of Annex VII, Section 9.1.1.

In your comments and your attachment on the draft decision you agree with the request. You indicate that you will use an existing study on the corresponding salt (sodium xylene sulphononate) to fulfil the current information requirement. ECHA agrees with your approach for this endpoint. In addition, ECHA notes in your attachment, you have summarised your testing strategy for each substance in this group. ECHA notes that, you have stated you will undertake a test in the group member using an OECD TG 201 for this endpoint. However, ECHA notes that the specific OECD TG for this endpoint is OECD TG 202. Futhermore, in Table 6 in your attachment, you have indicate to use a new test on sodium xylene sulphonate for this endpoint. Whilst in your comment and elsewhere in your attachment, you state that you will use an existing study on sodium xylene sulphonate.

ECHA will evaluate your information after the deadline of this decision according to the specific rules of column 2 adaptations, and in support of an adaptation according to Annex XI, section 1.5.

Therefore, pursuant to Article 41(1) and (3) of the REACH Regulation, you are requested to submit the following information derived with the corresponding salt (sodium xylene sulphononate): *Daphnia sp.* Acute immobilisation test, EU C.2./OECD TG 202).

6. Short-term toxicity testing on fish (Annex VIII, Section 9.1.3.)

"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.

You have sought to adapt this information requirement according to Annex XI, Section 1.5. of the REACH Regulation by providing the following study record:

1. Key study on the analogue substance toluene sulphonic acid according to EPA OTS 797.1400 (Fish Acute Toxicity Test): [redacted] reliability 2, GLP compliance: No.

However, as explained above, your adaptation of the information requirement according to Annex XI, Section 1.5. is rejected.

Therefore, 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 acute toxicity test (test method EU C.1. / OECD TG 203) is the preferred test to cover the standard information requirement of Annex VIII, Section 9.1.3.

In your comments and your attachment on the draft decision you agree with the request. You indicate that you will use an existing study on the corresponding salt (sodium xylene sulphononate) to fulfil the current information requirement. ECHA agrees with your approach for this endpoint. In addition, ECHA notes in your attachment, you have summarised your testing strategy for each substance in this group. ECHA notes you have stated you will

undertake a test in the group member using an OECD TG 201 for this endpoint. However, ECHA notes that the specific OECD TG guidline for this endpoint is OECD TG 203.

Therefore, pursuant to Article 41(1) and (3) of the REACH Regulation, you are requested to submit the following information derived with the corresponding salt (sodium xylene sulphononate): Fish, acute toxicity test (test method: EU C.1./OECD TG 203).

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

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

You have sought to adapt this information requirement according to Annex IX, Section 9.1.5., column 2. You provided the following justification for the adaptation: *"An environmental risk assessment has indicated that the members of the Aromatic Sulphonic Acids category do not pose a risk to the aquatic environment for all relevant uses. In Annex IX of Regulation (EC) No 1907/2006 it is laid down that chronic toxicity tests shall be proposed by the registrant if the chemical safety assessment indicates the need to investigate further. Since the chronic testing would not change the outcome of the environmental risk assessment no additional chronic testing on aquatic invertebrates appears to be justified."*

However, ECHA notes that your adaptation does not meet the specific rules for adaptation of Annex IX, Section 9.1.5., column 2. Firstly, as discussed in request 6. above, the short-term fish information you have used as basis for PNEC derivation and the current Chemical Safety Assessment (CSA) for environment cannot be considered acceptable. Secondly, the ready biodegradability data available in the technical dossier cannot be considered reliable, as discussed in request 9. below. As a result, the exposure assessment based on the conclusion that the substance is ready biodegradable is currently not reliable. For these two reasons, the Chemical Safety Assessment (CSA) including the exposure assessment and the risk characterisation sections cannot, with the available information, be used to adapt this information requirement .

However, your adaptation of the information requirement is rejected.

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

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

In your comments and in your attachment on the draft decision you propose a stepwise testing strategy for this endpoint.

You agree to first complete the requirements on short-term aquatic studies (requests 5 and 6). In addition, you inidcate that if the updated CSA shows that further investigation of effects

on aquatic organism(s) is required, you indicate that you will perfom the appropriate long-term test(s).

ECHA agrees that an Integrated Testing Strategy (ITS) can be used to determine the order of the studies to be performed and the necessity to conduct the long-term toxicity testing on aquatic invertebrates and on fish, as explained in the *Note for your consideration* below. In addition, ECHA notes as stated above, you need to also consider the current exposure assessment based on the conclusion that the substance is ready biodegradable is currently not reliable.

ECHA notes you have not specified the test substance to test the long-term studies in your comments or your attachment. However, as stated above, ECHA highlights that this request for this endpoint is for the registered substance or the corresponding salt.

ECHA will evaluate your information after the deadline of this decision.

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 *or* the corresponding salt: *Daphnia magna* reproduction test (test method: EU C.20./OECD TG 211).

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

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

You have not provided any study record of a long-term toxicity on fish in the dossier that would meet the information requirement of Annex IX, Section 9.1.6.1 / 9.1.6.2 / 9.1.6.3.

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: *"An environmental risk assessment has indicated that the members of the Aromatic Sulphonic Acids category do not pose a risk to the aquatic environment for all relevant uses. In Annex IX of Regulation (EC) No 1907/2006 it is laid down that chronic toxicity tests shall be proposed by the registrant if the chemical safety assessment indicates the need to investigate further the effects on fish."*

However, ECHA notes that your adaptation does not meet the specific rules for adaptation of Annex IX, Section 9.1.6., column 2. As already discussed in point 7. above, the risk characterisation is currently not reliable. Therefore, the CSA cannot be currently used to adapt the current information requirement.

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

Therefore, 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 3.0, February 2016) fish early-life stage (FELS) toxicity test (test method OECD TG 210), fish short-term toxicity test on embryo and sac-fry stages (test method EU C.15. / OECD TG 212) and fish juvenile growth test (test method EU C.14. / OECD TG 215) are the preferred tests to cover the standard information requirement of Annex IX, Section 9.1.6.

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 you propose a stepwise testing strategy for this endpoint.ECHA's response under request 7 also applies to this endpoint.
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 or the corresponding salt: Fish, early-life stage (FELS) toxicity test (test method: OECD TG 210).

Note for your consideration for requests 5- 8

Before conducting the tests requested above under points 7. and 8., you shall consult the ECHA Guidance on information requirements and chemical safety assessment (version 4.0, June 2017), Chapter R7b, Section R.7.8.5 to determine the necessity to conduct the long-term toxicity testing on aquatic invertebrates and on fish.

Concerning the order of studies to be conducted, you may first complete the requirements on short-term aquatic studies requested under requests 5. and 6. in this decision, as well as on ready biodegradability requested under request 9. in this decision, and subsequently update the CSA according to Annex I of the REACH Regulation.

If you come to the conclusion that no further investigation of chronic effects on aquatic organisms is required, you shall update your technical dossier by clearly stating the reasons for adapting the standard information requirement of Annex IX, 9.1.5 and 9.1.6. taking into account the new data generated by the short-term aquatic studies requested by the present decision and exposure assessment and risk characterisation.

On the other hand, if after the update of the CSA you come to the conclusion that the long-term toxicity tests are still required to refine the risk assessment, you should further consider

the Integrated Testing Strategy (ITS) for aquatic toxicity as described 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). According to the ITS, if based on acute aquatic toxicity data neither fish nor invertebrates are shown to be substantially less sensitive than other trophic levels (i.e. fish, invertebrates, algae), long-term studies may be required on both fish and invertebrates. In such case, according to the ITS, the long-term 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.

10. Robust study summary (RSS) for [redacted] ready biodegradability (Annex VII, Section 9.2.1.1.);

OR

Ready biodegradability (Annex VII, Section 9.2.1.1.)

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

You have provided the following sixteen study summaries to fulfill the Annex VII section 9.2.1.1. information requirement of Ready biodegradability (IUCLID section 5.2.1):

1. Weight of evidence on the analogue substance sodium toluene sulphonate according to OECD Guideline 301B (Ready Biodegradability: CO2 Evolution Test): [redacted] reliability 2, GLP compliance: yes, result: 99.8% degradation after 28d.
2. Weight of evidence on the analogue substance sodium cumene sulphonate according to OECD Guideline 301D (Ready Biodegradability: Closed Bottle Test): [redacted] reliability 2, GLP compliance: not specified, result: 50% degradation after 28d.
3. Weight of evidence on the analogue substance sodium cumene sulphonate according to OECD Guideline 301B (Ready Biodegradability: CO2 Evolution Test): [redacted] rcliability 2, GLP compliance: yes, result: >100% degradation after 28d.
4. Weight of evidence on the analogue substance calcium (xylenes and 4-ethylbenzene) sulphonate according to OECD Guideline 301B (Ready Biodegradability: CO2 Evolution Test): [redacted] reliability 2, GLP compliance: yes, result: 69-87% degradation after 29d.
5. Weight of evidence on the analogue substance sodium (xylenes and 4-ethylbenzene) sulphonate according to OECD Guideline 301 D (Ready Biodegradability: Closed Bottle Test): [redacted] reliability 2, GLP compliance: not specified, result: 40% degradation after 28d.
6. Weight of evidence on the analogue substance sodium (xylenes and 4-ethylbenzene) sulphonate according to OECD Guideline 301B (Ready Biodegradability: CO2 Evolution Test): [redacted] reliability 2, GLP compliance: not specified, result: 86-88% degradation after 28d.
7. Weight of evidence on the analogue substance sodium (xylenes and 4-ethylbenzene)

sulphonate according to OECD Guideline 301B (Ready Biodegradability: CO2 Evolution Test): [redacted] reliability 2, GLP compliance: yes, result: 83-85% degradation after 28d.

8. Weight of evidence on the analogue substance benzenesulphonic acid according to OECD Guideline 301D (Ready Biodegradability: Closed Bottle Test): [redacted], reliability 2, GLP compliance: not specified, results: 54% degradation after 28d (inherently biodegradable).
9. Weight of evidence on the analogue substance benzenesulphonic acid according to EU method C.6 (Degradation: Chemical Oxygen Demand): [redacted] reliability 4, GLP compliance: not specified, results: 98.5 % degradation after 120 hours and inherently biodegradable.
10. Other information on the registered substance benzenesulphonic acid, No guideline available: [redacted] reliability 4, GLP compliance: not specified, results: No degradation observed.
11. Other information on the registered substance benzenesulphonic acid, No guideline available: [redacted] reliability 4, GLP compliance: no, results: Test substance is reported to be biodegradable.
12. Other information on the registered substance benzenesulphonic acid, no guideline followed [redacted] reliability 4, GLP compliance: not specified, results: No degradation was observed.
13. Other information on the analogue substance hydroxybenzene sulphonic acid, no guideline specified: [redacted] reliability 4, GLP compliance: no, conclusion: The test cannot be used to evaluate the biodegradability of the test substance.
14. Weight of evidence on the analogue substance toluene-4-sulphonic acid according to EU method C.6 (Degradation: Chemical Oxygen Demand): [redacted] reliability 4, GLP compliance: not specified, results: 98.7% degradation after 120h.
15. Weight of evidence on the analogue substance toluene-4-sulphonic acid, Publication, no guideline indicated: [redacted] reliability 4, GLP compliance: not specified, results: 90 % degradation (no duration mentioned).
16. Supporting study on the analogue substance toluene-4-sulphonic acid, Sccondary source literature review: [redacted] reliability 4, GLP compliance: not specified, conclusuion: p-toluene solphonic acid is readily biodegradable.

ECHA agrees that studies no 9-16 are not reliable (Klimisch score 4) since they do not give sufficient experimental details. Thus, they do not provide the information required by Annex VII, Section 9.2.1.1. and therefore ECHA has not evaluated them further.

ECHA acknowledges that you have intended to submit the results from study no 1-8, in a weight of evidence (WoE) approach as made possible by the provisions of Annex XI section 1.2. ECHA understands that you seek to adapt this information requirement for ready biodegradability according to Annex XI, Section 1.2., weight of evidence. Hence, ECHA has evaluated your adaptation with respect to this provision.

ECHA notes that an adaptation pursuant to Annex XI, Section 1.2. requires sufficient weight of evidence from several independent sources of information leading to the 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.

However, ECHA notes that while you have indicated that a weight of evidence approach has been submitted, you have not provided any explanation or justification on how the sources of information/studies that you have provided enable to conclude on the endpoint. In addition, studies no 1-8 do not provide the information required by Annex VII, Section 9.2.1.1., as explained in details below.

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.

In addition, ECHA notes that you have sought to adapt the information requirement for ready biodegradability according to Annex XI, Section 1.5. of the REACH Regulation by providing seven studies on the salts of "sulphonic acid" category members (studies no 1-7). However, as explained above, your adaptation of the information requirement according to Annex XI, Section 1.5. is rejected.. Moreover, as described below, studies no 2-7 do not provide the information required by Annex VII, Section 9.2.1.1., because the information reported is insufficient to make an independent assessment of the study (study no 2 and no 5), or they are not adequate (studies no 3-4, 6-7).

Finally, regarding study no 8 on the registered substance as described below, it does not provide the information required by Annex VII, Section 9.2.1.1., because the information reported is insufficient to make an independent assessment of the study.

Specifically, ECHA has identified the following issues regarding the provided studies:

a) Studies not adequate due to significant deviations from standard test guidelines and due to missing information

For studies no 3-4 and no 6-7 ECHA has identified the following deficiencies:

- Adaptation of the inoculum

  According to par. 18 of OECD TG 301, the inoculum used should not be pre-adapted to the test substance. For studies no 3 and 7, you report "adaptation not specified" for the inoculum, but you indicate that the inoculum used in these studies was acclimated in SCAS units for 9 days. ECHA considered this treatment as a not acceptable deviation from the requirements of OECD TG 301, as also explained in ECHA *Guidance on information requirements and chemical safety assessment*, Chapter R.7b (version 4.0, June 2017) Section R.7.9.4.1. Therefore, studies no 3 and no 7 cannot be considered adequate to conclude on this endpoint.

- No duplicates

  According to par. 12 of OECD TG 301, determinations should be carried out at least in duplicate. However, in studies no 3 and no 6 only one flask was used per test substance concentration. ECHA considers that this a significant deviation from OECD TG 301, also because results in replicates are needed to verify the validity of the ready biodegradability tests as described in par. 24 of OECD TG 301. Therefore, studies no 3 and 6 cannot be considered adequate to conclude on this endpoint.

- Concentration of inoculum

The inoculum concentrations of studies no 4 and no 6 are not compliant with the test conditions specified in Table 2 of OECD TG 301, since you report that the cell concentration was "*5.2 x 10-7*" cfu/mL in study 4 and "*10x8 germs viable*"/mL in study 6, while it should be between 10^7 and 10^8 cells/L. ECHA considers these inoculum concentrations as a significant deviation from the requirements of OECD TG 301, and you have not explained how this deviation might have affected the results. Therefore, studies no 4 and 6 cannot be considered adequate to conclude on this endpoint.

- Missing information to assess the validity and reliability of the study

ECHA notes that for studies no 3-4 and no 6-7 you have not provided all information required in paragraph 27 of the OECD TG 301, Art. 3(28) of REACH and in ECHA's Practical Guide 3 "*How to report robust study summaries*". In particular, the following information is missing:

- Detailed description of the test substance
  For all mentioned studies, composition of the test material is not provided, hence it is not possible to verify whether the test material is representative of the registered substance.

- Detailed description of the inoculum
  You have not specified whether the inoculum was pre-adapted in studies no 4 and 6, and you have not provided information on inoculum concentration in studies no 3 and 7. In the absence of this information, it is not possible to verify whether the test conditions would comply with the requirement of par. 18 of OECD TG 301 regarding inoculum adaptation and of Table 2 of OECD TG 301 regarding inoculum concentration.

- Number of replicates per test substance concentration
  For studies no 7 you have not reported the number of flasks per concentration, hence ECHA cannot verify whether it would comply with the requirements of par. 12 of OECD TG 301.

- Any deviations in the standard test protocols

- A clear reporting of the test results including all raw data in a tabular form
  In the absence of this information, ECHA cannot verify that the validity critieria, as defined in paragraphs 24 and 25 of OECD TG 301, have been fulfilled.

Due to the deficiencies listed above, ECHA concludes that studies no 3-4 and no 6-7 are not adequate and hence cannot be used to conclude on this endpoint nor to adapt the standard information requirment according to Annex XI, Section 1.5..

b) Insufficient information provided to assess the studies

Under Article 3(28) of the REACH Regulation, a Robust study summary "*means 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*".

Specifically, for studies no 2 (on salt of the cumene sulphonic acid), no 5 (on sodium salt of the registered substance) and no 8 (on benzene sulphonic acid), ECHA notes that, contrary to Article 3(28) of the REACH Regulation, the information provided in the robust study summary is insufficient to allow an independent assessment of these studies.

In this regard, ECHA notes that the Robust study summaries do not include critical information required in the OECD TG 301 and in ECHA's Practical Guide 3 *"How to report robust study summaries"*, which is needed to assess the validity and reliability of the studies. This critical information concerns in particular:

- Details on the test substance (e.g. composition);
- Details on inoculum (concentration and any pre-conditioning treatment);
- Information on the test design as specified in the OECD TG 301 and any deviations in the standard test protocols;
- clear reporting of the test results (e.g. all raw data in a tabular form).

Due to the absence of this critical information, the robust study summaries of studies no 2, 5 and 8 cannot be relied on for an independent assessment of the properties of the registered substance. As a consequence, while as explained above studies no 2 and 8 on the analogue substances cannot be used to adapt the information requirement according to Annex XI, Section 1.5., for study no 5, it cannot be established whether the information requirement is met.

Conclusions

ECHA has evaluated according to the criteria in Annex XI, 1.2. and 1.5 and concluded that the studies considered alone or in combination do not provide the information required by Annex VII, Section 9.2.1.1.

In your comments and in your attachment to the draft decision, you agree with this request. You indicate that there you will evaluate the study report in order to find missing information. In addition, ECHA notes in your attachment, you have summarised your testing strategy for each substance in this group.

In conclusion, 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.

Furthermore, ECHA notes that you have considered the registered substance readily biodegradable in your chemical safety assessment (CSA). ECHA considers that reliable information is missing for such conclusion for the risk assessment of the registered substance, and therefore this conclusion must be rejected.

In order to allow an independent assessment of the study no 5 submitted, pursuant to Article 41(1) and (3) of the REACH Regulation, you are requested to provide complete robust study summary for the study: [redacted] with the above missing information for the study.

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 *or* the corresponding salt:

Ready biodegradability (Annex VII, Section 9.2.1.1.; test method: DOC die-away test, OECD TG 301A) or

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

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

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

Ready biodegradability (Annex VII, Section 9.2.1.1.; test method: Modified OECD screening test, OECD TG 301E) or

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

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

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 24 July 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 within 30 days of the notification.

ECHA took into account your comments and amended the test material for some of the requests.

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

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

Appendix 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.