ECHA
EUROPEAN CHEMICALS AGENCY

Helsinki, 10 December 2019

Addressee: [redacted]

Decision number: CCH-D-2114493646-34-01/F
Substance name: Ammonium (xylenes and 4-ethylbenzene)sulfonates
EC number: 943-024-5
CAS number: NS
Registration number: [redacted]
Submission number: [redacted]
Submission date: 21/12/2015
Registered tonnage band: 10-100

DECISION ON A COMPLIANCE CHECK

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

1. **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 analogue substance Sodium (xylenes and 4-ethylbenzene)sulfonates (EC No. 701-037-1).

You have to submit the requested information in an updated registration dossier by ***17 June 2022***. You shall also update the chemical safety report, where relevant.

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

Appeal

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

Authorised[1] by Ofelia Bercaru, 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

In accordance with Articles 10(a) and 12(1) of the REACH Regulation, a technical dossier registered at 10 to 100 tonnes per year must contain, as a minimum, the information specified in Annexes VII to VIII to the REACH Regulation. The information to be generated for the dossier must fulfil the criteria in Article 13(4) of the same regulation.

I. Grouping and read-across approach

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 'hydrotropes' 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:

- 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 IUCLID Section 13.

You have defined the structural basis for the category/grouping as simple salts (ammonium, calcium, potassium and sodium salts) of toluene, xylene and cumene sulphonic acids.

You have identified the following substances as 'Hydrotrope' category members:

[1] Sodium toluene-4-sulphonate (EC No. 211-522-5);
[2] Sodium (xylenes and 4-ethylbenzene) sulphonate (EC No. 215-090-9[4]);
[3] Calcium (xylenes and 4-ethylbenzene) sulphonate (EC No. 248-829-9);
[4] Ammonium (xylenes and 4-ethylbenzene) sulphonate (EC No. 943-024-5);
[5] Sodium cumene sulphonate (EC No. 239-854-6);
[6] Potassium cumene sulphonate (EC No. 629-764-9); and
[7] Ammonium cumene sulphonate (EC No. 253-519-1).

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.

[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
[4] The current EC number for this substance is 701-037-1.

In Section 2.2. of the read-across justification document, you address the composition of the category members. The toluene and cumene sulphonates are mono-constituent substances whereas the (xylenes and 4-ethylbenzene) sulphonates are UVCB substances. Toluene-, cumene- and 4-ethyl- benzene sulphonate are mainly in the from of the para-isomer (approximately [redacted] For xylene-benzene sulphonate the alkyl groups are mainly in the [redacted]

ECHA considers the information with regard to the composition of the category members as sufficient in order to establish structural similarity (and structural differences) between the category members.

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 described the applicability domain of the category as ammonium, calcium, potassium and sodium salts of cumene, toluene, and xylene sulphonic acids.

Considering the UVCB nature of the (xylene and 4-ethylbenzene) sulphonate, ECHA considers that the the applicability domain of the category to be: ammonium, calcium, potassium and sodium salts of cumene, toluene, and xylene (containing up to [redacted] ECHA notes that the category consists of ammonium, calcium, potassium and sodium salts of cumene-, toluene- and xylene (containing up to [redacted] The structural variation within the category is defined by the type of cation and which sulphonic acid that forms the anion. Because ECHA accepts unrestricted read-across between the ammonium, calcium, potassium and sodium salts of each individual sulphonic acid provided that the source study is adequate and reliable for the endpoint concerned, the structural variation within this group is defined by the sulphonic acid used; i.e. cumene-, toluene-, and xylene (containing up to [redacted] ECHA assessed your proposed predictions on this basis.

B. Prediction of ready biodegradability properties

You have provided the following reasoning for your read-across predictions: "*The*

Hydrotrope category comprises seven substances which have similar chemical structures and demonstrate the same type of effects. [...] The same absence of or type of effect are observed for the different source substances. There are no relevant variations in the strength of the effects observed among the source substances and the same strength is predicted for the target substances".

Specifically for ready biodegradability, you claim that *"The experimental data [..] is consistent and confirms the ready biodegradability of these substances. The data support the similar behaviour in the environment of this substances.".*

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

i. Insufficient information to support a claim of the same 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.

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 which demonstrate the ready biodegradability of the substances and refer to the OECD HPV programme.

ECHA notes that you predict (or propose to predict) the ready biodegradability properties of the cumene sulphonates and of (xylenes and 4-ethylbenzene) sulphonates from the available data on toluene sulphonate (and *vice versa*).

ECHA notes that the source study on toluene sulphonate is valid. However, for the reasons explained under 'Deficiencies of the provided ready biodegradability studies' below, the studies available on cumene- and on (xylenes and 4-ethylbenzene) sulphonates are either not adequate (four studies according to OECD TG 301B) or the information provided is insufficient to make an independent assessment of the study (two studies according to OECD TG 301D). As a consequence, there is currently no reliable information for cumene- and (xylenes and 4-ethylbenzene) sulphonates and thus the available information does not cover the range of structural variations. Therefore, ECHA considers that the read-across is not supported.

Further, ECHA points out that the OECD HPV programme report was not provided and could not be assessed. Moreover, this previous evaluation under the OECD HPV programme has not applied the requirements of Annex XI, Section 1.5 for predicting the properties of the

category members. For these reasons, the reference to the previous evaluation under the OECD HPV programme does not provide a basis for adaptation under Annex XI, Section 1.5.

In conclusion, in the absence of reliable ready biodegradability data on cumene and (xylenes and 4-ethylbenzene) sulphonates, ECHA considers that there is no support for your claim of a regular pattern with the same ready biodegradability properties.

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

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 which demonstrate the ready biodegradability of the substances.

ECHA notes that the source study on toluene sulphonate is valid and shows that this substance is ready biodegradable. You use this study as a key study in order to conclude on this endpoint for all category members. Regarding the source studies available on cumene- and on (xylenes and 4-ethylbenzene) sulphonates, you report the following in Section 2.4.2 of the read-across justification: "*Consistent and similar biodegradation was seen in C2 evolutionary studies (OECD TG 301B) (..). Lower biodegradation rates were observed when using the oxygen consuption test (OECD 301D), although it was still concluded that the test substances (..)cumene sulphonate and (..)(xylenes and 4-ethylbenzene) sulphonate, were biodegradable.*" As explained under 'Deficiencies of the provided ready biodegradability studies' below, the OECD TG 301B studies, showing that these substances are readily biodegradable, are not adequate. Nevertheless, although ECHA cannot currently establish the reliability of the two OECD 301D studies, you consider them reliable since you have assigned Klimisch score 2. The results of these two OECD 301D studies, used as supporting studies, indicate that cumene and (xylenes and 4-ethylbenzene) sulphonate are not ready biodegradable and hence contradict your hypothesis that the category members are ready biodegradable. Therefore, ECHA considers that you have not demonstrated that the read-across is supported.

In conclusion, ECHA considers that the data available in your dossier do not support your claim of a regular pattern with the same ready biodegradability properties.

C. Conclusions

ECHA accepts unrestricted read-across between the ammonium, calcium, potassium and sodium salts of each individual sulphonic acid, i.e. cumene-, toluene- and (xylene and 4-

ethyl benzene)- sulphonic acid; provided that the source study is adequate and reliable for the endpoint concerned.

Reading across from toluene sulphonate to (xylene and 4-ethyl benzene) sulphonates and to cumene sulphonates, ECHA considers 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

1. **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.

Furthermore, pursuant to Article 10 (a)(vii) and Annex I, Section 3.1.5. if there are several studies addressing the same effect, then, the study or studies giving rise to the highest concern shall be used to draw the conclusion and a robust study summary shall be prepared for that study or studies and included as part of the technical dossier. Robust study summaries will be required of all key data used in the hazard assessment.

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

1. Key study on sodium toluene sulphonate, according to OECD Guideline 301B (Ready Biodegradability: CO2 Evolution Test): [redacted] reliability 1, GLP, result: 99.8% degradation after 28d.
2. Supporting study on sodium cumene sulphonate according to OECD Guideline 301D (Ready Biodegradability: Closed Bottle Test): [redacted] reliability 2, GLP not specified, result: 50% degradation after 28d.
3. Supporting study on sodium cumene sulphonate according to OECD Guideline 301B (Ready Biodegradability: CO2 Evolution Test): [redacted] reliability 1, GLP, result: >100% degradation after 28d.
4. Supporting study on calcium (xylenes and 4-ethylbenzene) sulphonate according to OECD Guideline 301B (Ready Biodegradability: CO2 Evolution Test): [redacted] reliability 1, GLP, result: 69-87% degradation after 29d.
5. Supporting study on sodium (xylenes and 4-ethylbenzene) sulphonate according to OECD Guideline 301 D (Ready Biodegradability: Closed Bottle Test): [redacted] reliability 2, GLP not

specified, result: 40% degradation after 28d.

6. Supporting study on sodium (xylenes and 4-ethylbenzene) sulphonate according to OECD Guideline 301B (Ready Biodegradability: CO2 Evolution Test): [redacted] reliability 2, GLP not specified, result: 86-88% degradation after 28d.
7. Supporting study on sodium (xylenes and 4-ethylbenzene) sulphonate according to OECD Guideline 301B (Ready Biodegradability: CO2 Evolution Test): [redacted] reliability 1, GLP, result: 83-85% degradation after 28d.

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 study no 1 above as the key study. However, as explained below under 'Grouping and read-across approach', your adaptation of the information requirement is rejected.

For the same reasons, also the supporting studies no 2 and 3 on cumene sulphonates cannot be used to adapt the information requirement for ready biodegradability according to Annex XI, Section 1.5. of the REACH Regulation. Furthermore, as described further below under 'Deficiencies of the provided ready biodegradability studies', studies no 2 and 3 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), or they are not adequate (study no 3).

Regarding the supporting studies no 4 to 7 on sodium and calcium (xylenes and 4-ethylbenzene) sulphonates, ECHA accepts read-across between the salts of (xylenes and 4-ethylbenzene) and the registered substance (ammonium salt) provided that the source study is adequate and reliable for the endpoint concerned. However, as described below under 'Deficiencies of the provided ready biodegradability studies', studies no 4 to 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 5), or they are not adequate (studies no 4,6-7).

Deficiencies of the provided ready biodegradability studies

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 further 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 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 study 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 requirement 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 sodium cumene sulphonate) and no 5 (on sodium (xylenes and 4-ethylbenzene) sulphonate), 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 and 5 cannot be relied on for an independent assessment of the properties of the registered substance. As a consequence, while as explained above study no 2 on the analogue substance cumene sulphonate 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.

Comments on the draft decision

In your comments on the draft decision, you agree to complete the RSS for this endpoint to allow an independent assessment. You indicate that you aim to complete the RSS for the study [redacted] with the missing critical information and to verify that the available study is reliable and adequate. If this is not the case, you agree to perform a new study. In your comments on the draft decision, you also indicate that the analogue substance Sodium (xylenes and 4-ethylbenzene)sulfonates (EC No. 701-037-1) is the most appropriate substance to test since the sodium ion is ubiquitous in the environment. ECHA agrees with your proposal and has amended the request to state the analogue substance Sodium (xylenes and 4-ethylbenzene)sulfonates (EC No. 701-037-1), only.

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 analogue substance Sodium (xylenes and 4-ethylbenzene)sulfonates (EC No. 701-037-1):

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.

Conclusions

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 needed for the risk assessment of the registered substance.

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 14/09/2018.

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 request(s).

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

As no amendments were proposed, ECHA 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.