EUROPEAN CHEMICALS AGENCY

Helsinki, 15 December 2016

Addressee: [redacted]

Decision number: CCH-D-2114350923-48-01/F
Substance name: PARAFFIN OILS, SULFOCHLORINATED, SAPONIFIED
EC number: 269-144-1
CAS number: 68188-18-1
Registration number: [redacted]
Submission number: [redacted]
Submission date: 04.12.2013
Registered tonnage band: 1000+T

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. **Name or other identifiers (Annex VI, Section 2.1.) of the registered substance;**
   - **Manufacturing process**

2. **Composition (Annex VI, Section 2.3.) of the registered substance;**
   - **Identity of the constituents**

3. **High-pressure liquid chromatogram, gas chromatogram (Annex VI, Section 2.3.6) of the registered substance;**
   - **Identification and quantification of the constituents**

4. **Description of the analytical methods (Annex VI, Section 2.3.7) of the registered substance;**
   - **Identification and quantification of the counter-ionz**

5. **Robust study summaries for toxicological and ecotoxicological endpoints with respect to identity of the substance tested (Annex VII-X, Sections 8 and 9 in conjunction with Annex I, Section 1.1.4.).**

You are required to submit the requested information in an updated registration dossier by **22 March 2017**. 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. 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, shall 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 Claudio Carlon, Head of Unit, Evaluation E2

[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

Pursuant to Article 10(a)(ii) of the REACH Regulation, the technical dossier shall contain information on the identity of the substance as specified in Annex VI, Section 2 of the REACH Regulation. In accordance with Annex VI, Section 2 the information provided shall be sufficient to enable the identification of the registered substance.

1. Name or other identifier of the substance (Annex VI, Section 2.1.)

Information required to be provided according to Annex VI section 2.1 of the REACH Regulation on the naming of UVCB substances shall consist of two parts: (1) the chemical name and (2) a more detailed description of the manufacturing process, as indicated in chapter 4.3 of the Guidance for identification and naming of substances under REACH and CLP (Version: 1.4, June 2016) - referred to as "the SID Guidance" thereinafter.

You have assigned EC number 269-144-1 and CAS number 68188-18-1 corresponding to "Paraffin oils, sulfochlorinated, saponified" in section 1.1 of the IUCLID dossier and used caustic soda (sodium hydroxide) for the saponification reaction based on the provided manufacturing process.

Furthermore, you have provided the IUPAC name "other name: main component of the UVCB substance [redacted]" in section 1.1 of the IUCLID dossier.

ECHA observes that the identifiers and information provided in section 1.1 refer to a substance of Unknown, or Variable Composition, or of Biological origin (UVCB substance) that consists of sodium salts of sulfonated "[redacted]".

You have not provided elements of the manufacturing process, in particular the identity of the starting materials, which are relevant for the identification of the substance as manufactured or imported.

Firstly, the identity of the starting materials, including the composition of the "[redacted]", has not been provided. Other elements of the manufacturing process description which are essential for the identification of the registered substance are also missing from the dossier. More specifically, the ratio of starting materials used, specifications of any other relevant manufacturing process parameters, and any relevant isolation and purification steps have not been indicated. Furthermore, you have stated "[redacted]" in section 1.1 which indicates that the substance is manufactured using a [redacted], but no information has been provided on whether the process parameters lead e.g. to a full or partial sulfonation.

ECHA therefore concludes that the manufacturing process has not been provided to a sufficient level of detail.

Secondly, the only information that can be derived based on the IUPAC name "other name: main component of the UVCB substance [redacted]" provided in section 1.1 is that the main component of the substance is "[redacted]". However, the IUPAC name needs to be representative for the substance as manufactured or imported, which is not the case since the information on the composition of your substance indicates that the substance is a UVCB with other constituents in addition to "[redacted]".

In line with the above observation, you are asked to provide the missing information on the manufacturing process description. This information shall include:

- the exact ratio of starting materials used in the process
- accurate identity (such as EC/List/CAS number, if available) and compositional information on the "[redacted]" starting material, including
  - upper and lower concentration levels of the groups of constituents presenting the same carbon number (*e.g.* C10, C11, C12, ...), and
  - alkyl chain type (*e.g.* linear, branched)
- other relevant process parameters, including degree of sulfonation
- isolation and purification steps

The information provided must be sufficient to verify the identity and composition of the starting materials that need to be reflected in the name of the registered substance, including the accurate identity and composition of the "[redacted]".

You are also required to provide a representative chemical name in the IUPAC field in section 1.1 of IUCLID dossier. ECHA notes the following in relation to the naming of your specific substance:

- If you name your substance based on the source and process, the chemical name should reflect the exact identity of the "[redacted]" starting material used. Constructing the chemical name on the basis of
  - the main alkanes: those linear alkanes, *e.g.* [redacted] and those alkanes with a specific branched structure, *e.g.* [redacted], if present, which individually have an upper concentration level ≥ 10% (w/w) in the starting material; and
  - the groups of alkanes of the same carbon number with an undefined branched structure (*e.g.* C12 (branched) alkane), if present, which have an upper concentration level ≥ 10% (w/w) in the starting material,

is considered appropriate provided that they altogether compose at least 80 % (w/w) of the substance.

If this condition is not met, all alkane constituents in the starting material, as identified by the carbon number and alkyl chain type (e.g. linear, branched), shall be taken into account for the naming of that starting material.

Where the starting material is composed of one specific alkane at a concentration level of ≥ 80% (w/w), this starting material shall be designated, in the chemical name of the registered substance, by the chemical name of that alkane.

- You should ensure that the reference to the main group(s) of constituents presenting the same degree of sulfonation (e.g. [redacted] groups of constituents) is correctly reflected in the chemical name. Such main group is the group present at a concentration level of ≥ 80% (w/w) in the registered substance. If such group does not exist, all the groups present at a concentration of ≥ 10% (w/w) designate the main group(s) to be reflected to in the chemical name.

You should also ensure that the identifiers reported in section 1.1 are representative for the substance which is the subject of the current registration.

As for the reporting of the information in IUCLID, the manufacturing process description shall be specified in the "Description of composition" field in IUCLID v.6 section 1.2."

If the CAS number is not appropriate to describe the substance which is the subject of the current registration, you shall delete from the dossier the CAS information currently assigned to the substance and provide instead any available CAS information specifically corresponding to the substance. If you deem it appropriate, you can however specify the current CAS information as "related CAS information" for the registered substance.

In case the current identifiers are not appropriate to describe the registered substance, you should not remove or modify at this stage this EC entry for technical reasons, the registration being linked to that EC entry in REACH-IT. To ensure unambiguous identification of the registered substance, you should however indicate, in the "Remarks" field of the reference substance in IUCLID section 1.1, the following: "The EC number 269-144-1 currently assigned does not specifically correspond to the registered substance. This identifier cannot be modified or deleted at this stage in the present registration update for technical reasons". You should also specify, in the same "Remarks" field, any available and appropriate EC number for the substance. Any available CAS entry for the registered substance should be reported under the "CAS information" header of the reference substance in IUCLID section 1.1.

You should note that ECHA has established a process, subject to certain conditions, enabling registrants to adapt the EC identifier of an existing registration, while maintaining the regulatory rights already conferred to the substance concerned.

Pending the resolution of the non-compliances addressed in the present decision, any possible adaptation of the identifier can only become effective once ECHA is in a position to establish unambiguously the identity of the substance intended to be covered by you with this registration. Should the information submitted by you as a result of the present decision enable ECHA to identify the substance unambiguously and result in a need to modify the identifier of the substance, the process of adapting the identifier will be considered relevant. In that case, ECHA will inform you in due time as to when and how the identifier adaptation process shall be initiated.

In any case, you should note that the application of the process of adapting the identifier does not affect your obligation to fulfil the requirements specified in this decision.
In your comments to the draft decision, you outlined how you intend to address the information requirement, name or other identifiers of the substance (Annex VI, 2.1.). Irrespective of whether the newly provided information may be sufficient to meet the information requirement addressed in the decision, ECHA can already point out the following:

- The information in the comments would seem to be in line with the expectations in the decision. However, the information to be provided by you will be assessed on the basis of the updated dossier.
- You indicated your intention to provide the missing information on the manufacturing process while stating that the exact ratio of starting materials used in the process cannot be given due to the continuous manufacturing process used. ECHA notes that a detailed description of the manufacturing process is information required to be provided on the naming of UVCB substances. Therefore, if a continuous manufacturing process is used that is designed to manufacture mainly mono-sulphonated products, this information should be provided as part of the description of the manufacturing process. If the exact ratio of starting materials cannot be given due to the manufacturing process used, information on the ratio of starting materials should be provided to the extent possible e.g. in the form of ranges.
- You indicated that you would "revise the name of the main component and create a more general identifier" in order to provide a representative chemical name in the IUPAC field in section 1.1. ECHA notes that the decision requires you to provide a representative chemical name in the IUPAC field in section 1.1 of IUCLID dossier and provides instructions in relation to the naming of the specific substance. ECHA highlights that the IUPAC name provided in section 1.1 should be representative for the substance which is the subject of the current registration instead of being representative for only a single main component of the substance.

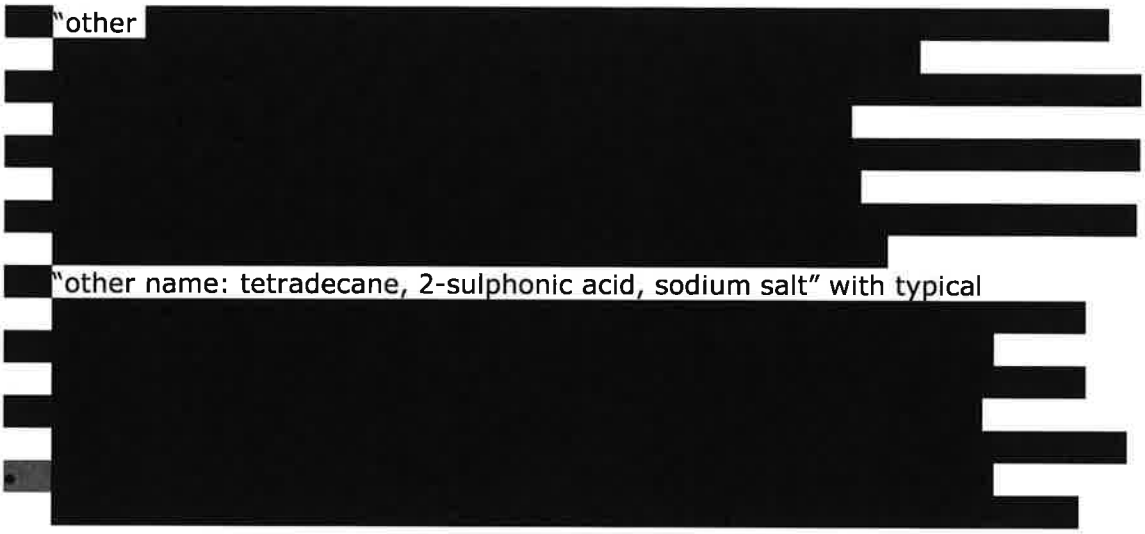
2. Composition of the substance (Annex VI, Section 2.3.)

Annex VI, section 2.3 of the REACH Regulation requires that each registration dossier contains sufficient information for establishing the composition of the registered substance and therefore its identity.

In that respect, according to chapter 4.3 of the SID Guidance, for UVCB substances presenting a large number of constituents, such as the registered substance, the following applies:

- All constituents present in the substance with a concentration of ≥ 10 % shall be identified and reported individually,
- All constituents relevant for the classification and/or PBT assessment of the registered substance shall be identified and reported individually; and
- Other constituents shall be identified by a generic description of their chemical nature.

In the present dossier, you have reported the constituents:



The presence of other constituents was not indicated in the reported composition.

The information you provided in section 1.2 is not fully consistent with the information you provided in section 1.1 and section 1.4. The information given in the "IUPAC name" fields and structural formulae of the constituents reported in section 1.2 correspond to specific , where the groups are attached to the 2-position of the linear alkyl chains. However, the manufacturing process provided in section 1.1 refers to subsequent which would be expected to yield products that are not specific regarding the substitution of the group on the linear alkyl chains.

Furthermore, ECHA notes that the registration dossier does not contain sufficient information for establishing the composition of the registered substance and therefore its identity, as required under Annex VI, section 2.3 of the "REACH Regulation". You have stated " " provided in section 1.4. However, constituents have not been reported in section 1.2. For UVCB substances, all known constituents, constituents present at concentrations ≥ 10%, and constituents that are relevant for the classification and/or PBT assessment of the substance should be specified. Unknown constituents should be identified as far as possible by a generic description of their chemical nature.

ECHA therefore concludes that the compositional information is inconsistent with the information provided in sections 1.1 and 1.4 and has not been provided to the required level of detail.

Therefore, ECHA requests you to clarify the composition reported in section 1.2 and ensure that the reported composition is representative of the substance and consistent with the information provided in other sections of the dossier. For this purpose, you should report:

- All constituents present in the substance with a concentration of ≥ 10 %,
- all constituents relevant for the classification and/or PBT assessment of the substance, and
- other constituents should be identified by a generic description of their chemical nature. The identification of these other constituents must be provided for ECHA to establish the composition of the substance as manufactured and to use the compositional information as an identifier for the registered substance. For the substance which is the subject of the current registration, the reporting of the constituents according to groups presenting the same carbon number (*i.e.* C10, C11, C12, ...) and the same level of sulfonation (*e.g.* [redacted] ...) is necessary for this aforementioned purpose. Additionally, it needs to be clearly stated if the position of the [redacted] group is not specific in the alkyl chain or if this group is attached only to position 2 of the alkyl chain.

You shall ensure that the reported composition is consistent with the description of the process used for the manufacturing of the registered substance, including the identity of the starting materials used. You shall also ensure that the composition is verifiable and therefore supported by a description of the analytical methods for the quantification of the constituents required to be reported, as required under Annex VI, section 2.3.7.

Regarding how to report the composition in IUCLID, the following applies:
You shall indicate the composition of the registered substance in IUCLID Section 1.2.

For each constituent required to be reported individually, the IUPAC name, CAS name and CAS number (if available), molecular and structural formula, as well as the minimum, maximum and typical concentration, should be reported in the appropriate fields in IUCLID.

For the other constituents to be reported under a generic description, a generic chemical name describing the group of constituents, generic molecular and structural information (if applicable), as well as the minimum, maximum and typical concentration, shall be reported in the appropriate fields in IUCLID.

Further technical details on how to report the composition of UVCB substances in IUCLID are available in the Manual "How to prepare registration and PPORD dossiers" on the ECHA website.

3. High-pressure liquid chromatogram, gas chromatogram (Annex VI, Section 2.3.6)

"High-pressure liquid chromatogram, gas chromatogram" is an information requirement as laid down in Annex VI, Section 2.3.6 of the "REACH Regulation". Adequate information needs to be present in the registration dossier to meet this information requirement.

You have provided analytical information in section 1.4 of the IUCLID dossier in support of the identity and composition of the registered substance.

ECHA notes the following:

- You have provided a LC/MS analysis ([redacted]). However, the chromatogram is missing in the analytical report.
- You have also provided the following justifications for not providing a chromatographic analysis:
  - Justification for not providing GC analysis: "Conducting is technically not possible, as the substance is chromatographically not determinable (does not evaporate)".
  - Justification for not providing HPLC analysis: "Conducting is scientifically not necessary, as the substance is chromatographically not determinable (lack of groups which absorb in the UV)".

ECHA concludes that the provided analytical information is not sufficient for the quantification of the (groups of) constituents required to be reported in the IUCLID dossier.

Furthermore, the provided justifications are not sufficient for not providing a complete chromatographic analysis that includes the chromatogram and a peak table, or other quantitative analysis. Alternative strategies are also possible, such as those summarised below.

ECHA notes that the composition information provided in section 1.2 shows that the substance includes significant amount of constituents that bear C14, C15, and C16 linear saturated alkyl chains.

- The provided methods together with the interpretation of the results do not provide sufficient information on how the results from the analysis could be translated into the identities and concentration values of the different constituents that you have reported in the composition.
- Furthermore, the provided methods together with the interpretation of the results do not provide quantitative information on groups of constituents presenting the same level of sulfonation (*i.e.* [redacted] ...). ECHA notes that you have stated "[redacted]" in the analytical report "[redacted]" provided in section 1.4. If [redacted] constituents are present in the substance at significant concentrations, these must be quantified and reported.

Therefore, the information provided is not sufficient to support the quantification of the (groups of) constituents required to be reported in the IUCLID dossier.

You are accordingly requested to submit an appropriate chromatographic analysis including the chromatogram and a peak table containing the retention times and peak area % of the constituents. If other analytical methods are more suitable for quantification of the constituents required to be reported in section 1.2, such methods may also be used.

If the LC/MS analysis is used for the quantification and identification of the substance, a chromatogram and a peak table for the LC/MS analysis should be provided, including the identification of the peaks in the peak table.

Furthermore, you are requested to provide sufficient information to establish the relative content of the groups of constituents presenting the same level of sulfonation (i.e. [redacted] ...).

The description of the analytical methods shall be sufficient for the methods to be reproduced and shall therefore include details of the experimental protocol followed, any calculation made, and the results obtained.

Taking into account the complexity of the composition of the registered substance, and possible technical limitations, information on the identification and quantification of its groups of constituents may be derived by combining information on the manufacturing process, results of the qualitative and quantitative analysis of the starting materials, and results of the qualitative and quantitative analysis of the substance as manufactured or imported.

The analytical information provided in section 1.4 must be sufficient to quantify the constituents that are required to be reported in section 1.2 individually.

As for the reporting of the information in the registration dossier, the information should be attached in IUCLID section 1.4.

4. Description of the analytical methods (Annex VI, Section 2.3.7.)

Description of the analytical methods is a formal information requirement of Annex VI Section 2.3.7 of the REACH Regulation.

According to Annex VI Section 2 of the REACH Regulation, for each substance, the information given in this section shall be sufficient to enable each substance to be identified.

You have identified your substance with EC name "Paraffin oils, sulfochlorinated, saponified", used caustic soda ([redacted]) for the saponification reaction based on the provided manufacturing process, and provided IUPAC name "other name: main component of the UVCB substance [redacted]" in section 1.1, which indicates that [redacted] is present as a counter-ion in your substance and must be identified and quantified. However you have not provided a description of the analytical methods to identify and quantify the [redacted] counter-ion.

In the absence of the description of the analytical methods to identify and quantify the [redacted] counter-ion (including the results of the analyses), your dossier does not meet the requirements of Annex VI Section 2.3.7 of the REACH Regulation and does not have sufficient information to establish the composition of the registered substance and therefore its identity.

Accordingly, you are required to provide the description of the analytical method(s) for the identification and quantification of the [redacted] counter-ion (including the results of the analyses). Examples of suitable methods include spectral methods such as Atomic Adsorption Spectroscopy or Inductively Coupled Plasma Optical Emission Spectroscopy, and titration.

The description shall be sufficient for the methods to be reproduced and shall therefore include details of the experimental protocol followed, any calculation made and the results obtained.

As for the reporting of the information in the registration dossier, the information should be attached in IUCLID section 1.4.

5. Robust study summaries for toxicological and ecotoxicological endpoints (Annex VII-X, Sections 8 and 9 in conjunction with Annex I, Section 1.1.4.).

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

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

ECHA notes that your reporting for the test material used in (eco)toxicity testing does not provide sufficient information to enable the relevance of the tests to be assessed.

For example, you have referred to the substance "Hostapur (SAS 60)" (also described as "secondary alkane sulfonates") for the chronic toxicity study ([redacted] 1977), the mammalian *in vivo* micronucleus study ([redacted] 1978), and the two-generation reproductive toxicity ([redacted] 1978); and also "Hostapur SAS 93" (also described as "secondary alkane sulfonates") for the *in vitro* mammalian cell gene mutation assay" study ([redacted] 2010). However, you have not defined these test substances adequately by providing IUPAC name, EC number and CAS number as part of the robust study summaries.

The same occurs to the "sek. Alkansulfonat C14-17 (Alkanosulfonat-Na)" for the long-term toxicity study to *Daphnia magna* ([redacted], 1994).

Furthermore, you have referred to "*Emulgator E 30*, fest" (also described as "*secondary alkane sulfonates")* for the *in vitro* bacterial reverse mutation assay ([redacted], 1992). ECHA notes that you have listed "[redacted]" as a trade name for the registered substance. However, ECHA cannot conclude if "[redacted]" could represent the registered substance since you have not provided valid test substance identifiers.

Similarly, you have referred to "[redacted]" (CAS number [redacted] EC number [redacted]) for the short-term toxicity to aquatic invertebrates and fish, and toxicity to aquatic algae ([redacted], 1992). In this case, the substance used for testing has the same commercial name as the registered substance ([redacted]), although it has another CAS number. ECHA notes that the registered substance does not include the described [redacted] among its constituents, and observes the need to clarify whether the test material is considered as the registered substance or whether it is indeed an analogue substance as the information provided suggests.

In case it would be an analogue substance, pursuant to Annex XI, Section 1.5. of the REACH Regulation, you would need to consider whether it would be possible to predict effects from data of the analogue substance, and – if so - provide sufficient justification.

Hence, ECHA considers that you have not properly defined the test substance used for the provided eco(toxicological) studies for the reasons described above.

Hence, the information provided on these endpoints for the registered substance in the technical dossier with respect to identity of the substance tested does not meet the information requirement. Consequently there are information gaps and it is necessary to provide information for these endpoints.

Therefore, pursuant to Article 41(1) and (3) of the REACH Regulation, you are requested to submit the following information:

Robust study summary with respect to identity of the substance tested for, at least, the following studies:

- short-term toxicity to aquatic invertebrates ([redacted] 1992 a);
- short-term toxicity to fish ([redacted] 1992 b);
- toxicity to aquatic algae ([redacted] 1992 c);
- *in vitro* bacterial reverse mutation assay ([redacted], 1992);
- *in vitro* mammalian cell gene mutation assay ([redacted] 2010);
- mammalian *in vivo* micronucleus study ([redacted] 1978);
- chronic toxicity study ([redacted] 1977);
- two-generation reproductive toxicity study ([redacted] 1978).

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 27 May 2016.

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

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

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

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

As no amendments were proposed, ECHA took the decision according to Article 51(3) of the REACH Regulation.

Appendix 3: Further information, observations and technical guidance

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

2. Failure to comply with the request(s) in this decision, or to fulfil otherwise the information requirement(s) with a valid and documented adaptation, will result in a notification to the enforcement authorities of your Member State.