EUROPEAN CHEMICALS AGENCY

Helsinki, 27 May 2020

Addressee
Registrant of fatty acids, c12-18 and c18-unsatd., 2-sulfoethyl esters, sodium salts listed in the last Appendix of this decision

Date of submission for the jointly submitted dossier subject of this decision
10/11/2010

Registered substance subject to this decision, hereafter 'the Substance'
Substance name: Fatty acids, C12-18 and C18-unsatd., 2-sulfoethyl esters, sodium salts
EC number: 287-024-7
CAS number: 85408-62-4

Decision number: [Please refer to the REACH-IT message which delivered this communication (in format CCH-D-XXXXXXXXXX-XX-XX/D)]

DECISION ON A COMPLIANCE CHECK

Based on Article 41 of Regulation (EC) No 1907/2006 (REACH), ECHA requests that you submit the information listed below by the deadline of ***4 September 2023***.

A. Requirements applicable to all the Registrants subject to Annex VII of REACH

1. In vitro gene mutation study in bacteria (Annex VII, Section 8.4.1.; test method EU B.13/14. / OECD TG 471) with the Substance

2. Short-term toxicity testing on aquatic invertebrates (Annex VII, Section 9.1.1.; test method: EU C.2./OECD TG 202) with the Substance

3. Growth inhibition study aquatic plants (Annex VII, Section 9.1.2., test method: EU C.1./OECD TG 201) with the Substance

4. Ready biodegradation (Annex VII, Section 9.2.1.1.; test method OECD TG 301B/C/D/F or OECD TG 310) with the Substance

B. Requirements applicable to all the Registrants subject to Annex VIII of REACH

1. In vitro cytogenicity study in mammalian cells (Annex VIII, Section 8.4.2., test method OECD TG 473) or in vitro micronucleus study (Annex VIII, Section 8.4.2., test method OECD TG 487) with the Substance

2. Only if a negative result in Annex VIII, Section 8.4.2. is obtained, In vitro gene mutation study in mammalian cells (Annex VIII, Section 8.4.3.; test method: OECD TG 476 or TG 490) with the Substance

3. Activated sludge respiration inhibition testing (Annex VIII, Section 9.1.4.; test method EU C.11/ OECD TG 209) with the Substance

4. Hydrolysis as a function of pH (Annex VIII, Section 9.2.2.1., test method: OECD TG 111) with the Substance

5. Adsorption/desorption screening (Annex VIII, Section 9.3.1., test method: OECD TG 106) with the Substance

C. Requirements applicable to all the Registrants subject to Annex IX of REACH

1. Sub-chronic toxicity study (90-day), oral route (Annex IX, Section 8.6.2.; test method: OECD TG 408) in rats with the Substance

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

3. Simulation testing on ultimate degradation in surface water (Annex IX, Section 9.2.1.2.; test method: EU C.25./OECD TG 309) at a temperature of 12 °C with the Substance

4. Sediment simulation testing (Annex IX, Section 9.2.1.4.; test method: EU C.24./OECD TG 308) at a temperature of 12 °C with the Substance

5. Bioaccumulation in aquatic species (Annex IX, Section 9.3.2; test method: OECD TG 305) with the Substance

D. Requirements applicable to all the Registrants subject to Annex X of REACH

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

2. Long-term toxicity to sediment organisms (Annex X, Section 9.5.1.; test design: OECD TG 218 or OECD TG 225 or OECD TG 233) with the Substance

Conditions to comply with the requests

You have to comply with the requirements of Annexes VII, VIII, IX and X of REACH, as you have registered the Substance at above 1000 tpa.

The Appendix on general considerations addresses issues relevant for several requests while the other Appendices state the reasons for the requests for information to fulfil the requirements set out in the respective Annexes of REACH.

The Appendix entitled Observations and technical guidance addresses the generic approach for the selection and reporting of the test material used to perform the required studies and provides generic recommendations and references to ECHA guidance and other reference documents.

The studies relating to biodegradation and bioaccumulation (requests A.4 and C.3 to C.5) are necessary for the PBT assessment. However, to determine the testing needed to reach the conclusion on the persistency and bioaccumulation of the Substance you should consider the sequence in which these tests are performed and other conditions described in section Strategy for the PBT/vPvB assessment of Appendix E.

You must submit the information requested in this decision by the deadline indicated above in an updated registration dossier and also update the chemical safety report, where relevant, including any changes to classification and labelling, based on the newly generated information. The timeline has been set to allow for sequential testing where relevant.

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.

Approved[1] under the authority of Christel Schilliger-Musset, Director of 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 on general considerations

(i) Assessment of the Grouping of substances and read-across approach, in light of the requirements of Annex XI, Section 1.5.

You seek to adapt the following standard information requirements listed below by applying read-across approaches in accordance with Annex XI, Section 1.5:

- In vitro gene mutation study in bacteria (Annex VII, Section 8.4.1.)
- In vitro cytogenicity study in mammalian cells or in vitro micronucleus study (Annex VIII, Section 8.4.2.)
- In vitro gene mutation study in mammalian cells (Annex VIII, Section 8.4.3.)
- Sub-chronic toxicity study (90-day), (Annex IX, Section 8.6.2.)
- Short-term toxicity testing on aquatic invertebrates (Annex VII, Section 9.1.1.)
- Activated sludge respiration inhibition testing (Annex VIII, Section 9.1.4.)
- Ready biodegradability (Annex VII, Section 9.2.1.1.)
- Adsorption/desorption screening (Annex VIII, Section 9.3.1.)

ECHA has considered the scientific and regulatory validity of your read-across approaches in general before assessing the specific standard information requirements in the following appendices.

Grouping of substances and read-across approach

Annex XI, Section 1.5. specifies two conditions which must be fulfilled whenever a read-across approach is used. 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.

Additional information on what is necessary when justifying a read-across approach can be found in the ECHA Guidance R.6 and related documents.

You have provided a read-across justification document as an annex (Appendix 1) of your CSR.

For the purpose of this decision, the following abbreviations are used for the target and the structurally similar substances used in your read-across approach:

- DEFI for the Fatty acids, C12-18 and C18-unsatd.,2-sulfoethyl esters, sodium salts (EC no. 287-024-7 / CAS no. 85408-62-4), the Substance (target);
- SCI for Fatty acids, coco, 2-sulfoethyl esters, sodium salts (EC no. 263-052-5 / CAS no. 61789-32-0);
- SLI for Dodecanoic acid, 2-sulfoethyl ester, sodium salt (EC no. 230-949-8 / CAS no. 7381-01-3)
- SI for Sodium Isethionate (EC no. 216-343-6 / CAS no. 1562-00-1).

A. Predictions for toxicological properties

You provide the following reasoning for the prediction of toxicological properties:

The Substance and SCI are chemically very similar:

- "*The key functional groups are the same for both* [the Substance] *and SCI, these are the Isethionate moiety SO3Na which is linked by an Ester linkage between the Isethionate and the Fatty acid R chain*";
- "*The fatty acid carbon chain distribution "R" chemically distinguishes DEFI and SCI (DEFI contains relatively more C12-16-18, whilst SCI contains more C12-14. Analytical chemistry studies are available which quantify the exact amount of each chain length.*"
- "*The fatty acid R chain for* [the Substance] *is derived from a* [redacted] *The R chain for SCI is derived* [redacted] and "[the Substance] *contains relatively more C12-16-18, whilst SCI contains more C12-14*";

"[redacted] *is the key starting material for the manufacture of DEFI and SCI and shares the same Isethionate group with* [the Substance] *and SCI*" and "*the levels of free SI and impurities* [are] *similar*".

The Substance and SCI are expected to be subject to similar (bio)transformation and the effects of (bio)transformation products are expected to be either similar or non-relevant:

- "*From* [redacted] *data it appears that* [the Substance] *and SCI are hydrolysed back to free fatty acids and SI starting material*";
- "[The Substance] *and SCI are either hydrolysed and/or metabolised, in vivo, back to the starting materials of SI and free fatty acids and that therefore data on pure SI is also relevant*";
- You state that "*it is confirmed that the free fatty acids do not exhibit human endpoint toxicity beyond skin and eye irritation and that* [redacted] *are exempted from REACh under Annex V*".

The Substance and SCI have similar toxicological profiles:

- You provide a data matrix that summarizes the information from your technical dossier and that you consider supportive of similar toxicological properties;
- You state that "*differences are seen between* [the Substance]*/SCI and SI are that SI is not a skin or eye irritant but* [the Substance]*/SCI are. Other endpoints are not significantly different, so Acute toxicity, skin sensitization, genetic toxicity, repeated dose toxicity and developmental toxicity are similar*".

ECHA understands that you predict the toxicological properties of the Substance using a read-across hypothesis which is based on similarity in structure and toxicological profiles and on the formation of common (bio)transformation products. The properties of your Substance are predicted to be quantitatively equal to those of the source substance.

You intend to predict the properties of the Substance from information obtained from the following source substances:

SCI with EC no. 263-052-5 for:

- In vitro gene mutation study in bacteria (Annex VII, Section 8.4.1.); [redacted] (1991);
- In vitro cytogenicity study in mammalian cells or in vitro micronucleus study (Annex VIII, Section 8.4.2.); [redacted] 2008); [redacted] (1991);
- In vitro gene mutation study in mammalian cells (Annex VIII, Section 8.4.3.); [redacted] (2007);

SI with EC no. 216-343-6 for Sub-chronic toxicity study (90-day), (Annex IX, Section 8.6.2.); [redacted] (2009);

ECHA notes the following shortcomings with regards to predictions of toxicological properties:

1. *Characterisation of the test materials used in the studies on the source substances*

   Annex XI, Section 1.5 of the REACH Regulation provides that "*substances whose physicochemical, toxicological and ecotoxicological properties are likely to be similar or follow a regular pattern as a result of chemical similarity may be considered as group.*"

   According to the ECHA Guidance, "*the purity and impurity profiles of the substance and the structural analogue need to be assessed*", and "*the extent to which differences in the purity and impurities are likely to influence the overall toxicity needs to be addressed, and where technically possible, excluded*". The purity profile and composition can influence the overall toxicity/properties of the Substance and of the source substance(s) (ECHA Guidance R.6, Section R.6.2.3.1). Therefore, qualitative and quantitative information on the compositions of the Substance and of the source substance(s) should be provided to allow assessment whether the attempted predictions are compromised by the composition and/or impurities.

   Furthermore, whenever the Substance and/or the source substances) are UVCB (Unknown or Variable composition, Complex reaction products or of Biological materials) substances qualitative compositional information of the individual constituents of the category members needs to be provided; as well as quantitative characterisation in the form of information on the concentration of the individual constituents of these substances; to the extent that this is measurable (ECHA Guidance R.6, Section R.6.2.5.5).

   In your read-across justification document, you explain that the Substance and SCI are produced from different fatty acid starting materials and that the Substance "*contains relatively more C12-16-18, whilst SCI contains more C12-14*". You specify that "*analytical chemistry studies are available which quantify the exact amount of each chain length*". You have provided an analytical study report showing the C-chain length distribution of the Substance but not for SCI. You state that the purity of the Substance ranges from [redacted]% while the purity of SCI ranges from [redacted]%. In Section 1.4 of your technical dossier you define the Substance as having a degree of purity from [redacted]%.

   In your technical dossier the test materials corresponding to the source substance SCI are described as [redacted] (purity: [redacted]%) or [redacted] purity: [redacted]%). You have not provided quantitative information on the composition of these test materials including the purity, the presence of unreacted starting material and distribution of C-chain length.

   Without consideration of the purity and adequate compositionnal information, no qualitative or quantitative comparative assessment of the compositions of the Substance and of the source substance can be completed. Therefore, ECHA considers that it is not possible to assess whether the attempted predictions are compromised by the composition of the source substance.

Read-across hypothesis contradicted by existing data

As indicated above, your read-across hypothesis is also based on the (bio)transformation of the Substance and of the source substances to a common compound (i.e. sodium isethionate used in your read-across as a source chemical for the 90-d study). In this context, information characterising the rate and extent of the hydrolysis of the Substance and of the source substances is necessary to confirm the similar and rapid formation of the proposed common hydrolysis product and to to demonstrate that the impact of the exposure to the parent compounds is negligible.

While you have not discussed the toxicokintic data in the read-across justification, you have provided in the technical dossier Section 7.1.1. a hydrolysis study in artificial fluids (i.e. simulated gastric fluid, simulated intestinal fluid & porcine liver esterase) with ^{14}C radiolabelled sodium lauryl isethionate (SLI) and sodium stearyl isethionate (SSI). You report that after 6 hours:

- SLI and SSI showed respectively 30% and 40% degradation in gastric fluid,
- SLI showed 10% degradation while SSI was stable in intestinal fluid, and
- SLI was almost completely degraded in porcine liver esterase while SSI only showed 20% degradation

These data do not support your claim that the Substance and source substances undergo the same, rapid biotransformations *in vivo*. The data rather show that there is significant exposure to the parent substance and that the two source substances used in these studies have different degradation behaviour in similar artificial fluids. This contradicts your read-across hypothesis that the target and source substances undergo the same, rapid biotransformations in vivo. Therefore, you have not demonstrated and justified that the properties of the source substances and of the Substance are likely to be similar despite the observation of these differences. Furthermore, you did not demonstrate the relevance of the data obtained with SLI and SSI for the Substance and source substances.

B. Predictions for ecotoxicological properties

i. Aquatic toxicity

You have provided the following reasoning for the prediction of aquatic toxicity: "[The Substance] *and SCI data for environmental effects and fate are similar. Some differences do exist between SI and* [The Substance]/*SCI with SI less toxic in algae, daphnia and fish than* [The Substance]/*SCI but all three are readily biodegradable"*.

ECHA understands that you predict the properties of the Substance using a read-across hypothesis which assumes that different compounds have the same type of effects. The properties of your Substance are predicted to be quantitatively equal to those of the source substance.

You intend to predict the properties of the Substance from information obtained from the following source substances:

1. Fatty acids, coco, 2-sulfoethyl esters, sodium salts/SCI (EC no. 263-052-5 / CAS no. 61789-32-0), which is used as a source substance for:
   - Short-term toxicity to aquatic invertebrates (Annex VII, Section 9.1.1.); [redacted] (2008) and [redacted] (1984)

2. Sodium Cocoyl Isethionate (EC no. or CAS no. not specified), which is used as a source

substance for:

- Activated sludge respiration inhibition testing (Annex VIII, Section 9.1.4.); [redacted] (1994)

ECHA notes the following shortcomings with regards to prediction(s) of aquatic toxicity:

1) Adequacy and reliability of source study

According to Annex XI, Section 1.5., if the grouping concept is applied then in all cases the results to be read across should have adequate and reliable coverage of the key parameters addressed in the corresponding test method referred to in Article 13(3).

However, none of the following studies were performed according to the testing specifications set out in the corresponding OECD TG:

- [redacted] (2008) used to cover the requirement for a short-term toxicity study to aquatic invertebrates;
- [redacted] (1984) used to cover the requirement for a short-term toxicity to study aquatic invertebrates;

Therefore these studies do not provide an adequate coverage of the key parameters foreseen to be investigated in the corresponding test method. The specific reasons are explained further below under the information requirement for short-term toxicity study to aquatic invertebrates.

2) Missing supporting information to compare properties of the substances

As indicated above, your read-across hypothesis is based on the assumption that the structurally similar substances have ecotoxicological properties. In this context, relevant, reliable and adequate information allowing to compare the properties of the Substance and of the source substance(s) is necessary. Such information can be obtained, for example, from bridging studies of comparable design and duration for the Substance and of the source substance(s).

In your technical dossier you have not provided any bridging study to compare the properties of the Substance and of the selected source substances. Therefore, the data set reported in the technical dossier does not include such relevant, reliable and adequate information for the Substance and of the source substance(s) to support your read-across hypothesis.

ii. Biodegradation

You have not provided any reasoning for the prediction of biodegradation and you only state that the Substance, SCI and SI are "*all three* [...] *readily biodegradable*".

ECHA understands that you predict the properties of the Substance using a read-across hypothesis which assumes that different compounds have similar properties. The properties of your Substance are predicted to be quantitatively equal to those of the source substance.

You intend to predict the properties of the Substance from information obtained from the source substance Fatty acids, coco, 2-sulfoethyl esters, sodium salts (EC no. 263-052-5 / CAS no. 61789-32-0), which is used as a source substance for ready biodegradability (Annex VII, Section 9.2.1.1.); [redacted] (1983) and [redacted] (1983).

ECHA notes the following shortcomings with regards to your prediction on biodegradation:

1) Adequacy and reliability of source study

According to Annex XI, Section 1.5., if the grouping concept is applied then in all cases the results to be read across should have adequate and reliable coverage of the key parameters addressed in the corresponding test method referred to in Article 13(3).

However, none of the studies provided on ready biodegradability was not performed according to the testing specifications set out in the corresponding OECD TG. The specific reasons are explained further below under the information requirement for ready biodegradability.

2) Missing supporting information to compare properties of the substances

As indicated above, your read-across hypothesis is based on the assumption that the structurally similar substances have similar biodegradation properties. In this context, relevant, reliable and adequate information allowing to compare the properties of the Substance and of the source substance(s) is necessary. Such information can be obtained, for example, from bridging studies of comparable design and duration for the Substance and of the source substance(s).

In your technical dossier you have provided ready biodegradability studies on Fatty acids, coco, 2-sulfoethyl esters, sodium salts (EC no. 263-052-5 / CAS no. 61789-32-0). You have not provided any study on the Substance.

However, as already explained under issue 1) above, you have not provided any reliable studies on the selected source substance. In addition, your dossier does not include any relevant information on the Substance. Therefore, the data set reported in the technical dossier does not include such relevant, reliable and adequate information for the Substance and of the source substance(s) to support your read-across hypothesis.

iii. Adsorption/desorption

You have not provided any reasoning for the prediction of biodegradation and you only state that for the Substance and SCI "*data for physchem endpoints agree*".

ECHA understands that you predict the properties of the Substance using a read-across hypothesis which assumes that different compounds have similar properties. The properties of your Substance are predicted to be quantitatively equal to those of the source substance.

You intend to predict the properties of the Substance from information obtained from the source substance Dodecanoic acid, 2-sulfoethyl ester, sodium salt (EC no. 230-949-8 / CAS no. 7381-01-3), which is used as a source substance for Adsorption/desorption screening (Annex VIII, Section 9.3.1.); [redacted] (2009).

ECHA notes the following shortcomings with regards to your prediction on adsorption/desorption screening:

1) Adequacy and reliability of source study

According to Annex XI, Section 1.5., if the grouping concept is applied then in all cases the results to be read across should have adequate and reliable coverage of the key parameters addressed in the corresponding test method referred to in Article 13(3).

The study you have provided ([redacted], 2009) was not performed according to the

testing specifications set out in the corresponding OECD TG. The specific reasons are explained further below under the information requirement for Adsorption/desorption screening.

2) Missing supporting information to compare properties of the substances

As indicated above, your read-across hypothesis is based on the assumption that the structurally similar substances have similar fate properties. In this context, relevant, reliable and adequate information allowing to compare the properties of the Substance and of the source substance(s) is necessary. Such information can be obtained, for example, from bridging studies of comparable design and duration for the Substance and of the source substance(s).

In your technical dossier you have provided an adsorption/desorption screening study on Dodecanoic acid, 2-sulfoethyl ester, sodium salt (EC no. 230-949-8 / CAS no. 7381-01-3). You have not provided any study on the Substance.

However as already explained under issue 1) above, you have not provided any reliable studies on the selected source substance. In addition, your dossier does not include any relevant information on the Substance. Therefore, the data set reported in the technical dossier does not include such relevant, reliable and adequate information for the Substance and of the source substance(s) to support your read-across hypothesis.

C. Conclusions on the read-across approach

As explained above, you have not established that relevant properties of the Substance can be predicted from data on the analogue substances. Therefore, your adaptation does not comply with the general rules of adaptation as set out in Annex XI, Section 1.5. and your read-across approach is rejected.

In your comments on the draft decision you consider that it is possible to significantly improve the read-across justification and documentation. You also state that "*new data may be generated on the substance and/or source substances to either add weight to the read across hypothesis (bridging studies) or addresses outstanding issues with existing study design or reporting*". Finally you note that in some cases, "*additional data from studies not requested (including New Approach Methods (NAMs)) may be provided if they add to the WoE for a particular endpoint*".

ECHA acknowledges your intention to improve the read-across justification and documentation taking into account the issues raised in the decision. You are encouraged to refer to ECHA Read-across assessment framework (RAAF, March 2017)[5].

(ii) Strategy for aquatic testing

Due to lack of reliable acute aquatic toxicity data on invertebrates or on fish it is not possible to determine the sensitivity of species. Therefore, the Integrated testing strategy (ITS) outlined in ECHA Guidance, Chapter R7b (Section R.7.8.5 including Figure R.7.8-4), is not applicable and the long-term studies on invertebrates is requested.

Appendix A: Reasons for the requests to comply with Annex VII of REACH

Under Articles 10(a) and 12(1) of REACH, a technical dossier registered at 1 to 10 tonnes or more per year must contain, as a minimum, the information specified in Annex VII to REACH.

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 in Annex VII to REACH.

You have adapted this information requirement according to Annex XI, Section 1.5. of the REACH Regulation and you have provided:

(i) a key study by [redacted] (1991) corresponding to a bacterial reverse mutation assay performed according to OECD TG 471 with the source substance SCI (EC no. 263-052-5);

For the reasons detailed in the General considerations section the read-across approach to SCI is rejected.

Therefore the information requirement is not fulfiled.

Study design

To fulfil the information requirement for the Substance, the *in vitro* gene mutation study in bacteria (OECD TG 471) is considered suitable.

2. 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 in Annex VII to REACH.

You have adapted this information requirement according to Annex XI, Section 1.5. of the REACH Regulation and you have provided:

(i) a key study by [redacted] (2007) corresponding to a short-term toxicity study to aquatic invertebrates performed according to OECD TG 202 with the source substance SCI (EC no. 263-052-5);
(ii) a supporting study by [redacted] (1984) corresponding to a short-term toxicity to study aquatic invertebrates performed similar to OECD TG 202 with the source substance SCI (EC no. 263-052-5).

We have assessed this information and identified the following issue:

A. According to Annex XI, Section 1.5., if the grouping concept is applied then in all cases the results to be read across should have adequate and reliable coverage of the key parameters addressed in the corresponding test method referred to in Article 13(3). OECD TG 202 requires that all the following conditions are met (among others):
   - an adequate description of the test material including purity, the presence (or not) of any co-formulant, the relative abundance of unreacted material(s), the

distribution of the c-chain length for the active substance) is provided,
- an analytical monitoring of exposure concentrations is provided (including method description and results).

For study (i) above, you have not reported information on the purity of the test material, the distribution of the C-chain length of constituents or the presence of co-solvent (if any). Your report that an analytical monitoring of exposure concentrations was conducted using LC/MS but you have not reported a detailed description of the results (including quantitative information on constituents).
For study (ii) above, you have not reported information C-chain length distribution of the test material. You report that an analytical monitoring of exposure was conducted "*using the small scale MBAS method (Methylene Blue Spectraphotometric method)*". You have not reported any performance parameters for the analytical monitoring method including the limit of quantification and a justification that the method allows a specific quantification of the non-hydrolysed form of the test substance.

Based on the above none of the studies reported in your technical dossier meets the conditions listed above and therefore these studies do not provide an adequate coverage of the key parameters foreseen to be investigated in an OECD TG 202 study.

B. For the reasons detailed in the General considerations section the read-across approach to SCI is rejected.

Therefore the information requirement is not fulfiled.

3. Growth inhibition study aquatic plants (Annex VII, Section 9.1.2.)

Growth inhibition study aquatic plants is a standard information requirement in Annex VII to REACH.

You have provided in your dossier:

(i) a key study by [redacted] (2008) corresponding to a growth inhibition study to algae and cyanobacteria performed according to OECD TG 201 with the Substance.

We have assessed this information and identified the following issue:

Tests on substances must be conducted in accordance with the OECD test guidelines or other internationally recognised test method (Article 13(3) of REACH). OECD TG 201 require(s) that the following conditions are met (among others):
- an adequate description of the test material including purity, the presence (or not) of any co-formulant, the relative abundance of unreacted material(s), the distribution of the c-chain length for the active substance) is provided,
- the algal biomass in each flask is determined at least daily during the test period and the biomass for each flask at each measuring point must be reported (along with the method for measuring biomass).

You have not reported information on the purity of the test material, the distribution of the C-chain length of constituents or the presence of co-solvent (if any). You have provided biomass data at 0h, 48h and 72h. However, you have not provided biomass data at 24h.

Therefore the documentation of this study is insufficient and does not allow an independent assessment of the adequacy of this study, its results and its use for hazard assessment.

Therefore the information requirement is not fulfiled.

4. Ready biodegradability (Annex VII, Section 9.2.1.1.)

Ready biodegradability is a standard information requirement in Annex VII to REACH.

You have adapted this information requirement according to Annex XI, Section 1.5. of the REACH Regulation and you have provided:

(i) a key study by [redacted] (1983) corresponding to a ready biodegradability study performed according to OECD TG 301B with the source substance SCI (EC no. 263-052-5);
(ii) a supporting study by [redacted] (1983) corresponding to a ready biodegradability without specifications on the method used with the source substance SCI (EC no. 263-052-5).

We have assessed this information and identified the following issues:

A. Tests on substances must be conducted in accordance with the OECD test guidelines or other internationally recognised test method (Article 13(3) of REACH). OECD TG 301B requires that all the following conditions are met (among others):
   - adequate information need to be provided on the identity of the tests material including purity, the presence (or not) of any co-formulant, the relative abundance of unreacted material(s), the distribution of the C-chain length for the active substance,
   - the calculation of the ThCO2 needs to be provided,
   - data on inorganic carbon (IC) content of the test substance suspension in the mineral medium need to be provided,
   - data on the inoculum concentration used to conduct the test need to be provided (in mg/L SS and in approx. cells/L),
   - the source of the inoculum and any adaptation to the test substance must be described,
   - CO_2 production data in tabular form must be provided.

   For study (i) above, you have not provided a description of the C-chain length distribution of the test material. You have not reported how the ThCO2 was calculated. You have not reported data on inorganic carbon (IC) content of the test substance suspension in the mineral medium. You describe the inoculum as "*sewage microorganisms*" but you have not spcified the source of the inoculum and whether or not it was adapted to the test substance. You have not specified the incolcum density at the start of the test period. You have not provided a detailled reporting of the CO_2 production data in tabular form.

   Therefore study (i) is not appropriate to conclude on the ready biodegradability of the selected source substance.

B. Tests on substances must be conducted in accordance with the OECD test guidelines or other internationally recognised test method (Article 13(3) of REACH). OECD TG

301 specifies that degradation must be followed by the determination of parameters such as DOC, CO2 production and oxygen uptake.

In study (ii) above, the parameter monitored is the disappearance of the test substance as measured using the Methylene Blue Anionic Surface active spectrophotometry (MBAS). Therefore it does not provide a measure of the mineralization of the test substance.

Therefore study (ii) is not appropriate to conclude on the ready biodegradability of the selected source substance.

C. For the reasons detailed in the General considerations section the read-across approach to SCI is rejected.

Therefore the information requirement is not fulfiled.

Appendix B: Reasons for the requests to comply with Annex VIII of REACH

Under Articles 10(a) and 12(1) of REACH, a technical dossier registered at 10 to 100 tonnes or more per year must contain, as a minimum, the information specified in Annexes VII and VIII to REACH.

1. In vitro cytogenicity study in mammalian cells or in vitro micronucleus study (Annex VIII, Section 8.4.2.)

An *in vitro* cytogenicity study in mammalian cells or an *in vitro* micronucleus study is a standard information requirement in Annex VIII to REACH.

You have adapted this information requirement according to Annex XI, Section 1.5. of the REACH Regulation and you have provided:

(i) a key study by [redacted] (1991) corresponding to an *in vitro* mammalian chromosome aberration test performed similar to OECD TG 473 with the source substance Sodium Cocoyl Isethionate (EC no. 263-052-5)
(ii) a key study by [redacted] (2008) corresponding to an *in vitro* mammalian cell micronucleus test performed according to OECD TG 487 with the source substance Sodium Cocoyl Isethionate (EC no. 263-052-5)

For the reasons detailed in the General considerations section on aquatic toxicity the read-across approach to Sodium Cocoyl Isethionate is rejected.

Therefore the information requirement is not fulfiled.

Study design

To fulfil the information requirement for the Substance, both *in vitro* cytogenicity study in mammalian cells (Annex VIII, Section 8.4.2., test method OECD TG 473) and *in vitro* micronucleus study (Annex VIII, Section 8.4.2., test method OECD TG 487) are considered suitable.

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 a standard information requirement in Annex VIII to REACH in case of a negative result in the *in vitro* gene mutation test in bacteria and the *in vitro* cytogenicity test.

You have adapted this information requirement according to Annex XI, Section 1.5. of the REACH Regulation and you have provided:

(i) a key study by [redacted] (2007) corresponding to an *in vitro* mammalian cell gene mutation assay performed similar to OECD TG 476 with the source substance Sodium Cocoyl Isethionate (EC no. 263-052-5)

For the reasons detailed in the General considerations section on aquatic toxicity the read-across approach to Sodium Cocoyl Isethionate is rejected.

Therefore the information requirement is not fulfiled.

Your dossier contains no data for *in vitro* gene mutation study in bacteria and for *in vitro* cytogenicity study in mammalian cells.

The result of the requests for information A.1 and B.1 will determine whether the present requirement for an *in vitro* mammalian cell gene mutation study in accordance with Annex VIII, Section 8.4.3 is triggered.

Consequently, you are required to provide information for this endpoint, if the *in vitro* gene mutation study in bacteria and the *in vitro* cytogenicity study in mammalian cells or an *in vitro* micronucleus study provide a negative result.

Study design

To fulfil the information requirement for the Substance, both the *in vitro* mammalian cell gene mutation tests using the hprt and xprt genes (OECD TG 476) and the thymidine kinase gene (OECD TG 490) are considered suitable.

3. Activated sludge respiration inhibition testing (Annex VIII, Section 9.1.4.)

Activated sludge respiration inhibition testing is a standard information requirement in Annex VIII to REACH.

You have adapted this information requirement according to Annex XI, Section 1.5. of the REACH Regulation and you have provided:

(i) a key study by [redacted] (1984) corresponding to an activated sludge respiration inhibition study performed according to OECD TG 209 with the source substance Sodium Cocoyl Isethionate (EC no. or CAS no. not specified).

For the reasons detailed in the General considerations section on aquatic toxicity the read-across approach to Sodium Cocoyl Isethionate is rejected.

Therefore the information requirement is not fulfiled.

4. Hydrolysis as a function of pH (Annex VIII, Section 9.2.2.1.)

Hydrolysis as a function of pH is a standard information requirement in Annex VIII to REACH.

You have adapted the information with reference to Annex VIII, Section 9.2.2.1., Column 2.

This information requirement can be adapted according to column 2 of Annex VIII, if the substance is readily biodegradable.

You justified the adaptation by stating that the substance is readily biodegradable. However, the information you provided for Ready biodegradability (Annex VII, Section 9.2.1.1.) cannot be considered to be reliable as explained under request A.3 above. Therefore, it cannot be used to waive the endpoint Hydrolysis as a function of pH.

Therefore, your adaptation is rejected and the information requirement is not fulfilled.

5. Adsorption/desorption screening (Annex VIII, Section 9.3.1.)

Adsorption/desorption screening is a standard information requirement in Annex VIII to REACH.

You have adapted this information requirement according to Annex XI, Section 1.5. of the REACH Regulation and you have provided:

(i) a key study by [redacted] (2009) corresponding to an adsorption / desorption: screening study performed according to OECD TG 106 with the source substance Dodecanoic acid, 2-sulfoethyl ester, sodium salt (EC no. 230-949-8 / CAS no. 7381-01-3).

We have assessed this information and identified the following issues:

A. Tests on substances must be conducted in accordance with the OECD test guidelines or other internationally recognised test method (Article 13(3) of REACH). OECD TG 106 aims at estimating the adsorption/desorption behaviour of a substance in soils.

You have provided a single study by [redacted] (2009) performed according to OECD TG 106 with radiolabelled Dodecanoic acid, 2-sulfoethyl ester, sodium salt (SLI) performed on sewage sludge. Your report that the log Koc of the test material was 3.2.

The study reported in your technical dossier was conducted on sewage sludge and not on soils and therefore it does not provide an adequate coverage of the key parameter foreseen to be investigated in an OECD TG 106 study.

B. For the reasons detailed in the General considerations section the read-across approach to Dodecanoic acid, 2-sulfoethyl ester, sodium salt/ SLI is rejected.

Therefore the information requirement is not fulfiled.

Appendix C: Reasons for the requests to comply with Annex IX of REACH

Under Articles 10(a) and 12(1) of REACH, a technical dossier registered at 100 to 1000 tonnes or more per year must contain, as a minimum, the information specified in Annexes VII to IX to REACH.

1. Sub-chronic toxicity study (90-day), oral route (Annex IX, Section 8.6.2.)

A Sub-chronic toxicity study (90 day) is a standard information requirement in Annex IX to REACH.

You have adapted this information requirement according to Annex XI, Section 1.5. of the REACH Regulation and you have provided:

(i) a key study by [redacted] (2009) corresponding to a sub-chronic toxicity study (90 day) performed according to OECD TG 408 with the source substance Sodium Isethionate (EC no. 216-343-6)

However, for the reasons detailed in the Appendix on General considerations the read-across approach to Sodium Isethionate is rejected.

Therefore the information requirement is not fulfiled.

Study design

Referring to the criteria provided in Annex IX, Section 8.6.2, Column 2, the oral route is the most appropriate route of administration to investigate repeated dose toxicity, because the Substance is a granular powder, but is not marketed or supplied as a powder. It is only marketed in finished solid personal care [redacted]

Therefore the sub-chronic toxicity study must be performed according to the OECD TG 408, in rats and with oral administration of the Substance

2. 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 in Annex IX to the REACH Regulation.

You have provided in your technical dossier:

(i) a key study by [redacted] (2010) corresponding to a long-term toxicity study to aquatic invertebrates performed according to OECD TG 211 with the Substance.

We have assessed this information and identified the following issue:

Toxicological and eco-toxicological tests and analyses on substances must be carried out in compliance with the principles of good laboratory practice (GLP) provided for in Directive 2004/10/EC or other international standards recognised as being equivalent by the Commission or ECHA and with the provisions of Directive 86/609/EEC, if applicable (Article 13(4) of REACH). According to Article 141(2), Article 13 applies from

1 June 2008.

However, the provided study was not performed according to GLP.

Therefore, the provided study is rejected and the information requirement is not fulfilled.

3. Simulation testing on ultimate degradation in surface water (Annex IX, Section 9.2.1.2.)

and

4. Sediment simulation testing (Annex IX, Section 9.2.1.4.)

Simulation testing on ultimate degradation in surface water is a standard information requirement in Annex IX to REACH.

Sediment simulation testing is a standard information requirement in Annex IX to REACH for substances with a high potential for adsorption to sediment. The Substance has low surface tension (42.5 mN/m at 1 g/L and 22°C) and is ionisable, indicating high adsorptive properties. Therefore the sediment compartment is relevant to evaluate the fate of the Substance.

You have adapted these information requirements according to Annex XI, Section 1.5. of the REACH Regulation and you have provided:

(ii) a key study by [redacted] (2010) corresponding to a simulation test – Activated sludge unit performed according to OECD TG 303A with ^{14}C radiolabelled Sodium Lauryl Isethionate and performed on the Substance,
(iii) a key study by [redacted] (2010) corresponding to a simulation test to assess the biodegradability of chemicals discharged in wastewater performed according to OECD TG 314D with ^{14}C radiolabelled Sodium Lauryl Isethionate.

We have assessed this information and identified the following issues:

A. For the reasons detailed in the General considerations section the read-across approach to SLI is rejected.

B. The information used for the purpose of assessment of the PBT/vPvB properties must be based on data obtained under relevant conditions (Annex XIII). The test conducted must simulate degradation in a relevant environment i.e. regarded as equivalent to a simulation test in surface water or in sediment (ECHA Guidance R.11.4).

The study by [redacted] (2010) according to OECD TG 303A is a test to simulate degradation in an aerobic sewage treatment plant. The study by [redacted] (2010) according to OECD TG 314D is a test to simulate biodegradation in treated effluent-surface water mixing zone. None of these studies are regarded as equivalent to a simulation test in relevant environment such as fresh or estuarine water, marine water or fresh or estuarine sediment or marine sediment.

Therefore the information requirement is not fulfiled.

As shown in your dossier and CSA, environmental exposure to water and sediment cannot be excluded. Your report a number of consumer uses in cosmetic and personal care products. In

addition, the exposure estimations that you provided in the Chemical Safety Report (CSR) indicate that there is exposure to water and sediment in number of your exposure scenarios. Therefore, ECHA concludes that simulation testing in water and in sediment are relevant to investigate the P or vP properties of the substance.

Study design

Under Annex XIII, the information must be based on data obtained under conditions relevant for the PBT/vPvB assessment. Therefore:

- You must perform the OECD TG 309 test, by following the pelagic test option with natural surface water containing approximately 15 mg dw/L of suspended solids (acceptable concentration between 10 and 20 mg dw/L) (ECHA Guidance R.11).

- You must perform the test at the temperature of 12 °C, the average environmental temperature for the EU (ECHA Guidance R.16, Table R.16-8). Performing the tests at this temperature is in line with the applicable test conditions of the OECD TG 308 and TG 309.

Non-extractable residues (NER) must be quantified in all simulation studies. The reporting of results must include a scientific justification of the used extraction procedures and solvents. By default, total NER is regarded as non-degraded Substance. However, if reasonably justified and analytically demonstrated a certain part of NER may be differentiated and quantified as irreversibly bound or as degraded to biogenic NER. Such fractions could be regarded as removed when calculating the degradation half-life(s) (ECHA Guidance Chapter R.11).

5. Bioaccumulation in aquatic species (Annex IX, Section 9.3.2.), aqueous exposure

Bioaccumulation in aquatic species, preferably fish is a standard information requirement in Annex IX to REACH.

You have adapted this information requirement Annex IX, Section 9.3.2., Column 2 with the following justification: "*Waiving according to "column 2" in Annex IX of REGULATION (EC) No 1907/2006 (low potential for bioaccumulation - log KOW < 3)*".

We have assessed this information and identified the following issue:

> Annex IX, Section 9.3.2., column 2 specifies that a study does not need to be conducted if the substance has a low potential for bioaccumulation (for instance a log Kow ≤ 3). To adapt this information requirement based on low potential to partition to lipids (i.e. log Kow ≤ 3), lipophilicity must be the sole characteristic driving the bioaccumulation potential of a substance. However, for some groups of substances (e.g. organometals, ionisable substances, surfactants) other mechanisms than partitioning to lipids may drive bioaccumulation (e.g. binding to protein/cell membranes). For those substances log Kow is not considered a valid descriptor of the bioaccumulation potential and therefore for measured BCF values are preferred (ECHA Guidance R.7c, Appendix R.7.10-3).
>
> You have justified the low potential low potential for bioaccumulation because the partition coefficient value (log Kow) of sodium Octanoyl Isethionate is ≤ 3 (-1,56).

> The Substance is surface active (with a surface tension in water of 42.5 mN/m at 1 g/L and 22°C) and is ionisable. Hence binding to protein/cell membranes cannot be excluded. Therefore log Kow is not a valid descriptor for assessing the bioaccumulation potential of the Substance and your adaptation is rejected.

Therefore, the information requirement is not fulfilled.

Study design

Bioaccumulation in fish: aqueous and dietary exposure (test method EU C.13. / OECD TG 305) is the preferred test to investigate bioaccumulation (ECHA Guidance R.7c, Section R.7.10.3.1). Whenever technically feasible, the aqueous route of exposure (OECD TG 305-I) must be used as the results obtained can be used directly for comparison with the B and vB criteria of Annex XIII of REACH. Therefore, the requested study must be conducted with aqueous exposure. If testing through aquatic exposure is technically not possible, you must provide scientifically valid justification for the infeasibility.

Appendix D: Reasons for the requests to comply with Annex X of REACH

Under Articles 10(a) and 12(1) of REACH, a technical dossier at a tonnage abve 1000 tonnes per year must contain, as a minimum, the information specified in Annexes VII to X to REACH.

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

Pre-natal developmental toxicity (PNDT) studies (OECD TG 414) in two species is a standard information requirement under Annex X to REACH.

You have have provided in the dossier:

(i) a key study by [redacted] (2008) corresponding to a Pre-natal developmental toxicity (PNDT) study performed according to OECD TG 414 with the Substance.

We have assessed this information and identified the following issue(s):

In order to be compliant and enable concluding if the Substance is a developmental toxicant, information provided has to meet the requirements of OECD TG 414 in two species.

Based on the above, the information you provided do not fulfil the information requirement.

Study design

The test in the first species was carried out by using a rodent species (rat). A PNDT study according to the test method OECD TG 414 must be performed in rabbit as preferred non-rodent species.

The study shall be performed with oral (ECHA Guidance R.7a, Section R.7.6.2.3.2.) administration of the Substance.

2. Long-term toxicity to sediment organisms (Annex X, Section 9.5.1.)

Long-term toxicity to sediment organisms is a standard information requirement in Annex X to REACH.

You have adapted this information requirement Annex IX, Section 9.1., Column 2 with the following justification: *"Waiving according to "column 2" in Annex IX and X of REGULATION (EC) No 1907/2006: Direct and indirect exposure of the sediment compartment is unlikely due to the physico-chemical properties and the readily biodegradability of the substance. Due to low kow no sediment testing is necessary according to Guidance R.7B, chapter 7.8.12".*

We have assessed this information and identified the following issues:

A. The substance is used in cosmetics and personal care products and therefore it has a wide dispersive use. In your CSR you provided an exposure assessment for the Substance which support that exposure to the sediment compartment is likely. Therefore the exposure of the sediment compartment cannot be ruled out.

B. ECHA Guidance R.10, Section R.10.5.2.1. specifies that for compounds with a log Kow greater than 5 or with a corresponding adsorption or binding behaviour not triggered

by the lipophilicity (e.g. log Kow) of the substance but by other mechanisms (e.g. ionisable substances, surface active substances, substances forming covalent bound to sediment, components like e.g. aromatic amines) the equilibrium method is used in a modified way. In such case, the PECsed/PNECsed ratio is increased by a factor of 10.

Based on a study conducted according to EU method A.5, you report that the surface tension of the Substance is 42.5 mN/m at 1 g/L and 22°C and the Substance is ionisable. Hence the extra assessment factor of 10 must be applied. In your Chemical Safety Report (CSR) you have not applied an extra assessment of 10 in the calculation of the PECsed/PNECsed ratio for the reported exposure scenarios.

The information in your dossier indicates that the Substance is ionisable and surface active. You have not applied the extra assessment of 10 in the calculation of the PECsed/PNECsed ratios. Therefore your CSR currently underestimates the risks to the sediment compartment by a factor of 10.

C. As specified in Annex X, Section 9.5.1., Column 2, a long-term toxicity to study on sediment organisms must be performed unless the Chemical Safety Assessment demonstrates that risks towards the aquatic compartment arising from the use of the Substance are controlled (as per Annex I, section 0.1). The justification must be documented in the Chemical Safety Assessment.

In particular, the Chemical Safety Assessment must take into account the following elements to support that long-term toxicity testing is not required:
- all relevant hazard information from your registration dossier,
- the outcome of the exposure assessment in relation to the uses of the Substance,
- the outcome of the PBT/vPvB assessment including information on relevant degradation products and constituents present in concentration at or above 0.1% (w/w).

In your CSR you rely on the results of long-term aquatic toxicity data included in your dossier to extrapolate the PNECs sediment using the equilibrium partitioning method and the outcome of the exposure assessment showing risk characterisation ratios (RCRs) below 1 for the freshwater and marine sediment compartments. The highest RCR reported for freshwater sediment in your CSR is [redacted].

As specified in request C.2, the data on long-term toxicity to aquatic invertebrates are not compliant. Hence your dossier currently does not include adequate information to characterize the hazard property of the Substance. Furthermore as explained under issue B. above, You have not applied the extra assessment of 10 in the calculation of the PECsed/PNECsed ratios and hence your CSR currently underestimates the risks to the sediment compartment by a factor of 10. Hence your Chemical Safety Assessment does not demonstrate that the risks of the Substance are adequately controlled.

Therefore, your adaptation is according to Annex X, Section 9.5.1., Column 2 is rejected and the information requirement is not fulfilled.

Study design

The Sediment-water Chironomid toxicity using spiked sediment (OECD TG 218), Sediment-water Lumbriculus toxicity test using spiked sediment (OECD TG 225) and Sediment-Water

Chironomid Life-Cycle Toxicity Test Using Spiked Sediment (OECD TG 233) are in principle each considered capable of generating information appropriate for the fulfilment of the information requirements for sediment long-term toxicity testing. ECHA is not in a position to determine the most appropriate test protocol, since this decision is dependent upon species sensitivity, substance properties and uses. ECHA considers that it is your responsibility to choose the most appropriate test protocol and to give a justification for the choice. You may carry out more than one of the sediment tests listed above if you consider that further testing is required.

Appendix E: Procedural history

For the purpose of the decision-making, this decision does not take into account any updates of registration dossiers after the date on which you were notified the draft decision according to Article 50(1) of REACH.

The compliance check was initiated on 12 April 2019.

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 did not amend 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 F: Observations and technical guidance

1. The information requirement under Section 8.7.3. of Annex IX/X to REACH (Extended one-generation reproductive toxicity study, EOGRTS) is not addressed in this decision, because the information from the Sub-chronic toxicity study (90-day), requested in the present this decision, is relevant for the design of the EOGRTS.

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

3. Failure to comply with the requests in this decision, or to otherwise fulfil the information requirements with a valid and documented adaptation, will result in a notification to the enforcement authorities of the Member States.

4. Test guidelines, GLP requirements and reporting

   Under Article 13(3) of REACH, all new data generated as a result of this decision needs to be conducted according to the test methods laid down in a European Commission Regulation or according to international test methods recognised by the Commission or ECHA as being appropriate.

   Under Article 13(4) of REACH, ecotoxicological and toxicological tests and analyses shall be carried out according to the GLP principles (Directive 2004/10/EC) or other international standards recognised by the Commission or ECHA.

   Under Article 10 (a) (vi) and (vii) of REACH, all new data generated as a result of this decision must be reported as study summaries, or as robust study summaries, if required under Annex I of REACH. See ECHA Practical Guide: 'How to report robust study summaries'[2].

5. Test material

   Selection of the test material(s)

   The registrants of the Substance are responsible for agreeing on the composition of the test material to be selected for carrying out the tests required by the present decision. The test material selected must be relevant for all the registrants of the Substance, i.e. it takes into account the variation in compositions reported by all members of the joint submission. The composition of the test material(s) must fall within the boundary composition(s) of the Substance.

   While selecting the test material you must take into account the impact of each constituent/ impurity on the test results for the endpoint to be assessed. For example, if a constituent/ impurity of the Substance is known to have an impact on (eco)toxicity, the selected test material must contain that constituent/ impurity.

   Technical reporting of the test material

   The composition of the selected test material must be reported in the respective endpoint study record, under the Test material section. The composition must include all constituents of the test material and their concentration values. Without such detailed

[2] https://echa.europa.eu/practical-guides

reporting, ECHA may not be able to confirm that the test material is relevant for the Substance and to all the registrants of the Substance.

Technical instructions are available in the manual "How to prepare registration and PPORD dossiers"[3].

6. Strategy for the PBT/vPvB assessment

You are advised to consult ECHA Guidance R.7b, Section R.7.9., R.7c, Section R.7.10 and R.11 on PBT assessment to determine the sequence of the tests and the necessity to conduct all of them. The guidance provides advice on 1) integrated testing strategies (ITS) for the P, B and T assessments and 2) the interpretation of results in concluding whether the Substance fulfils the PBT/vPvB criteria of Annex XIII.

You are advised to first conclude whether the Substance may fulfil the Annex XIII criteria of being P or vP, and then continue with the assessment for bioaccumulation. The sequence of the simulation tests also needs to consider the intrinsic properties of the Substance, its identified use and release patterns as these could significantly influence the environmental fate of the Substance. You shall revise the PBT assessment when the new information is available.

7. List of references of the ECHA Guidance and other guidance/ reference documents[4]

Evaluation of available information
Guidance on information requirements and chemical safety assessment, Chapter R.4 (version 1.1., December 2011), referred to as ECHA Guidance R.4 in this decision.

QSARs, read-across and grouping
Guidance on information requirements and chemical safety assessment, Chapter R.6 (version 1.0, May 2008), referred to as ECHA Guidance R.6 in this decision.

ECHA Read-across assessment framework (RAAF, March 2017)[5]

Physical-chemical properties
Guidance on information requirements and chemical safety assessment, Chapter R.7a (version 6.0, July 2017), referred to as ECHA Guidance R.7a in this decision.

Toxicology
Guidance on information requirements and chemical safety assessment, Chapter R.7a (version 6.0, July 2017), referred to as ECHA Guidance R.7a in this decision.

Guidance on information requirements and chemical safety assessment, Chapter R.7c (version 3.0, June 2017), referred to as ECHA Guidance R.7c in this decision.

Environmental toxicology and fate
Guidance on information requirements and chemical safety assessment, Chapter R.7a (version 6.0, July 2017), referred to as ECHA Guidance R.7a in this decision.

[3] https://echa.europa.eu/manuals
[4] https://echa.europa.eu/guidance-documents/guidance-on-information-requirements-and-chemical-safety-assessment
[5] https://echa.europa.eu/support/registration/how-to-avoid-unnecessary-testing-on-animals/grouping-of-substances-and-read-across

Guidance on information requirements and chemical safety assessment, Chapter R.7b (version 4.0, June 2017), referred to as ECHA Guidance R.7b in this decision.

Guidance on information requirements and chemical safety assessment, Chapter R.7c (version 3.0, June 2017), referred to as ECHA Guidance R.7c in this decision.

Guidance on information requirements and chemical safety assessment, Chapter R.10 (version 1.0, May 2008), referred to as ECHA Guidance R.10 in this decision.

PBT assessment
Guidance on information requirements and chemical safety assessment, Chapter R.11 (version 3.0, June 2017), referred to as ECHA Guidance R.11 in this decision.

Guidance on information requirements and chemical safety assessment, Chapter R.16 (version 3.0, February 2016), referred to as ECHA Guidance R.16 in this decision.

OECD Guidance documents[6]
Guidance Document on aqueous-phase aquatic toxicity testing of difficult test chemicals – No 23, referred to as OECD GD23.
Guidance Document on Mammalian Reproductive Toxicity Testing and Assessment – No 43, referred to as OECD GD43.

[6] http://www.oecd.org/chemicalsafety/testing/series-testing-assessment-publications-number.htm

Appendix G: List of the registrants to which the decision is addressed and the corresponding information requirements applicable to them

Registrant Name	Registration number	(Highest) Data requirements to be fufilled
[redacted]	[redacted]	[redacted]

Note: where applicable, the name of a third party representative (TPR) may be displayed in the list of recipients whereas the decision is sent to the actual registrant.