EUROPEAN CHEMICALS AGENCY

Helsinki, 3 April 2019

Addressee: [redacted]

Decision number: CCH-D-2114462284-49-01/F
Substance name: 6-[(p-tosyl)amino]hexanoic acid, compound with 2,2',2''-nitrilotriethanol (1:1)
EC number: 301-097-5
CAS number: 93981-14-7
Registration number: [redacted]
Submission number: [redacted]
Submission date: 26/09/2013
Registered tonnage band: 100-1000

DECISION ON A COMPLIANCE CHECK

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

1. **In vitro gene mutation study in bacteria (Annex VII, Section 8.4.1.; test method: Bacterial reverse mutation test, EU B.13/14. / OECD TG 471) with the analogue substance 6-[[(4-methylphenyl)sulphonyl]amino]hexanoic acid or, if duly justified under Article 13(1) and (3) of the REACH Regulation, with the registered substance;**

2. **Sub-chronic toxicity study (90-day), oral route (Annex IX, Section 8.6.2.; test method: OECD TG 408) in rats with the analogue substance 6-[[(4-methylphenyl)sulphonyl]amino]hexanoic acid or, if duly justified under Article 13(1) and (3) of the REACH Regulation, with the registered substance;**

3. **Pre-natal developmental toxicity study (Annex IX, Section 8.7.2.; test method: OECD TG 414) in a first species (rat or rabbit), oral route with the analogue substance 6-[[(4-methylphenyl)sulphonyl]amino]hexanoic acid or, if duly justified under Article 13(1) and (3) of the REACH Regulation, with the registered substance;**

4. **Identification of degradation products (Annex IX, 9.2.3.) using an appropriate test method with the registered substance.**

You may adapt the testing requested above according to the specific rules outlined in Annexes VI to X and/or according to the general rules contained in Annex XI to the REACH Regulation. To ensure compliance with the respective information requirement, any such adaptation will need to have a scientific justification, referring and conforming to the appropriate rules in the respective annex, and adequate and reliable documentation.

You have to submit the requested information in an updated registration dossier by **12 April 2021**. You also have to update the chemical safety report, where relevant.

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

Appeal

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

Authorised[1] by **Claudio Carlon**, Head of Unit, Hazard assessment

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

Appendix 1: Reasons

TOXICOLOGICAL INFORMATION
In accordance with Articles 10(a) and 12(1) of the REACH Regulation, a technical dossier registered at 100 to 1000 tonnes per year must contain, as a minimum, the information specified in Annexes VII to IX to the REACH Regulation. The information to be generated for the dossier must fulfil the criteria in Article 13(4) of the same regulation.

Your registration dossier contains for multiple endpoints adaptation arguments in the form of a grouping and read-across approach according to Annex XI, 1.5. of the REACH Regulation. ECHA has assessed first the scientific and regulatory validity of your Grouping and read-across approach in general before the individual endpoints (sections 1, 2 and 3).

Grouping and read-across approach for toxicological information
You have sought to adapt information requirements by applying a read-across approach in accordance with Annex XI, Section 1.5, for the endpoints:

- *in vitro* gene mutation study in bacteria (Annex VII, Section 8.4.1.)
- sub-chronic toxicity (90-day) study (Annex IX, Section 8.6.2.)
- pre-natal developmental toxicity study (Annex IX, Section 8.7.2.).

According to Annex XI, Section 1.5., two conditions shall be necessarily fulfilled. Firstly, there needs to be structural similarity between substances which results in a likelihood that the substances have similar physicochemical, toxicological and ecotoxicological properties so that the substances may be considered as a group or category. Secondly, it is required that the relevant properties of a substance within the group may be predicted from data for reference substance(s) within the group (read-across approach). ECHA considers that the generation of information by such alternative means should offer equivalence to prescribed tests or test methods.

Based on the above, a read-across hypothesis needs to be provided. This hypothesis establishes why a prediction for a toxicological or ecotoxicological property is reliable and should be based on recognition of the structural similarities and differences between the source and registered substances[2]. This hypothesis explains why the differences in the chemical structures should not influence the toxicological/ ecotoxicological properties or should do so in a regular pattern. The read-across approach must be justified scientifically and documented thoroughly, also taking into account the differences in the chemical structures. There may be several lines of supporting evidence used to justify the read-across hypothesis, with the aim of strengthening the case.

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

[2] Please see for further information ECHA *Guidance on information requirements and chemical safety assessment* (version 1, May 2008), Chapter R.6: QSARs and grouping of chemicals.

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

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

i. Description of the grouping and read-across approach proposed by you

You consider to achieve compliance with the REACH information requirements for the registered substance 6-[(p-tosyl)amino]hexanoic acid, compound with 2,2',2"-nitrilotriethanol (1:1) using data of structurally similar substances 6-[[(4-methylphenyl)sulphonyl]amino]hexanoic acid (EC number 278-934-5), and triethanolamine (or nitrilotriethanol, EC number 203-049-8) (hereafter the 'source' substances).

You have provided a read-across documentation in each of the endpoint summaries, using the following arguments to support the prediction of properties of the registered substance from data for source substances within the group: *"Read-across between the tosyl salt carboxylic acid (6-[(p-Tosyl)amino]hexanoic acid)* [=source substance] *and the registered substance is considered justified as the registered substance is manufactured directly from 6-[(p-Tosyl)amino]hexanoic acid by simple neutralisation with triethanolamine (TEA). Other than ionization of the carboxylic acid group, the 6-[(p-Tosyl)amino]hexanoic acid remains chemically unchanged upon salt formation.*
In water, the acid and amine components of 6-[(p-Tosyl)amino]hexanoic acid, compound with 2,2',2''-nitrilotriethanol (1:1) dissociate completely and behave essentially as independent substances.
Since TEA can be considered non-hazardous, it is the acid component of the salt that will have a more significant impact on the outcome of any (eco)toxicological or environmental tests. The pKa of the carboxylic acid group in 6-[(p-Tosyl)amino]hexanoic acid (pKa = 4.90) is the same in the free acid as it is in the TEA salt.
As a result, 6-[(p-Tosyl)amino]hexanoic acid will respond to changes of pH in the same way whether it is in the salt form or as the parent carboxylic acid and hence it's bioavailability will be the same."

As an integral part of this prediction, you propose that the source and the registered substances have similar properties for the above-mentioned information requirements. ECHA considers that this information is your read-across hypothesis.

ii. ECHA analysis of the grouping and read-across approach in light of the requirements of Annex XI, 1.5.

With regard to the proposed predictions ECHA has the following observations:

The substance characterisation of the source substance(s) need to be sufficiently detailed in order to assess whether the attempted prediction is not compromised by the composition and/or impurities. In the ECHA's Practical Guide on "How to use alternatives to animal testing to fulfil your information requirements" (chapter 4.4), it is recommended to follow the ECHA *Guidance for identification and naming of substances under REACH and CLP*

[3] Please see ECHA's Read-Across Assessment Framework (https://echa.europa.eu/support/registration/how-to-avoid-unnecessary-testing-on-animals/grouping-of-substances-and-read-across).

(version 2.1, May 2017) also for the source substances. This ensures that the identity of the source substance and its impurity profile allows an assessment of the suitability of the substances for read-across purposes.

Currently the identity of the source substance and its impurity profile is not detailed in the registration dossier. However for read-across purposes, ECHA can reach the conclusion that the source substances can be used to predict properties for the registered substance.

In order to meet the provisions in Annex XI, Section 1.5. to predict human health effects from data for a reference substance within the group by interpolation to other substances in the group, ECHA considers that structural similarity alone is not sufficient. It has to be justified why such prediction is possible in view of the identified structural differences and the provided evidence has to support such explanation. In particular, the structural similarities must be linked to a scientific explanation of how and why a prediction is possible.
In this particular situation ECHA notes that the read-across from the source acid analogue to the salt may be considered plausible as it is based on the biological conditions where the registered salt will dissociate into the acid and the base components. It is thus plausible even if the supporting information may be considered sparse; for example you have not provided a data matrix to compare the properties of source and target substances and to establish whether indeed they are similar or follow a regular pattern. Furthermore you have not discussed in detail why the properties of TEA would not influence the predicted properties of the registered substance. As per the information available on ECHA Dissemination Portal relative to triethanolamine, there is no data suggesting that it may be hazardous. ECHA notes that, for your read-across to be accepted, while respecting data sharing rights of the data owner, your dossier shall contain all necessary information from the TEA studies.

Finally, Annex XI, Section 1.5 provides with regard to the reliability and adequacy of the source studies that in all cases the results of the read-across should:

- *be adequate for the purpose of classification and labelling and/or risk assessment,*
- *have adequate and reliable coverage of the key parameters addressed in the corresponding test method referred to in Article 13(3),*
- *cover an exposure duration comparable to or longer than the corresponding test method referred to in Article 13(3) if exposure duration is a relevant parameter, and*
- *adequate and reliable documentation of the applied method shall be provided.*

The specific observations on the source studies you submitted will be discussed in the sections below (1, 2, and 3), under the property specific endpoints.

iii. Conclusion on the read-across approach

The adaptation of the standard information requirements, *in vitro* gene mutation study in bacteria (Annex VII, Section 8.4.1.), sub-chronic toxicity (90-day) study (Annex IX, Section 8.6.2.) and pre-natal developmental toxicity study (Annex IX, Section 8.7.2.), in the technical dossier is based on the proposed read-across approach examined above.

For the reasons as set out above, ECHA considers that the read-across approach is a plausible basis to predict the properties of the registered substance from the source substances, given that there are adequate and reliable source studies for the appropriate endpoints. However, as set out below (sections 1-3), the studies which are to be read-across are not adequate and reliable.

Consequently, the adaptation does not comply with the general rules of adaptation as set out in Annex XI, 1.5. Therefore, ECHA rejects the adaptations in the technical dossier that are based on Annex XI, 1.5 for *in vitro* gene mutation study in bacteria (Annex VII, Section 8.4.1.), sub-chronic toxicity (90-day) study (Annex IX, Section 8.6.2.) and pre-natal developmental toxicity study (Annex IX, Section 8.7.2.).

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

An "*In vitro* gene mutation study in bacteria" is a standard information requirement as laid down in Annex VII, Section 8.4.1. of the REACH Regulation. Adequate information on this endpoint needs to be present in the technical dossier for the registered substance to meet this information requirement.

You have sought to adapt this information requirement according to Annex XI, Section 1.5. of the REACH Regulation by providing study records for an *In vitro* gene mutation study in bacteria (OECD TG 471) with the analogue substance(s) (6-[[(4-methylphenyl)sulphonyl]amino]hexanoic acid, EC number 278-934-5 and with the analogue 2,2',2''-nitrilotriethanol (or triethanolamine, EC number 203-049-8).

Furthermore, while you have not explicitly claimed an adaptation, you have provided information labelled as "weight-of-evidence" in your IUCLID 6 dossier, and which could be interpreted as an attempt to adapt the information requirement according to, Annex XI, Section 1.2. However, ECHA notes that your adaptation does not meet the general rule for adaptation of Annex XI; Section 1.2. because although you have provided *"several independent sources of information leading to the conclusion that the registered substance has not [genotoxic] property"* you have not provided "*adequate and reliable documentation*" to support your adapation. Therefore, your adaptation of the information requirement according to the general rule for adaptation of Annex XI; Section 1.2. is rejected.

As explained above in Appendix 1 of this decision under "Grouping and read-across approach for toxicological information", ECHA agrees that the read-across approach is plausible and that you can rely on the results of studies performed with 6-[[(4-methylphenyl)sulphonyl]amino]hexanoic acid, if these studies are adequate and reliable.

However, the *in vitro* gene mutation study in bacteria (OECD TG 471, 2012) you have submitted does not provide the information required by Annex VII, Section 8.4.1., because you report in the dossier that the *"Range-finding and confirmatory assay performed with all 5 strains. Definitive assay performed with 2 strains (TA98 and TA1535)"*.
According to paragraph 13 of the current OECD TG 471 (updated 1997) at least five strains of bacteria should be used: S. typhimurium TA1535; TA1537 or TA97a or TA97; TA98; TA100; *S. typhimurium* TA102 or E. coli WP2 uvrA or E. coli WP2 uvrA (pKM101). This includes four strains of *S. typhimurium* (TA1535; TA1537 or TA97a or TA97; TA98; and TA100) that have been shown to be reliable and reproducibly responsive between laboratories. These four *S. typhimurium* strains have GC base pairs at the primary reversion site and it is known that they may not detect certain oxidising mutagens, cross-linking agents and hydrazines. Such substances may be detected by *E.coli* WP2 strains or *S. typhimurium* TA102 which have an AT base pair at the primary reversion site. The definitive assay that you have submitted used two strains. Therefore, the provided definitive assay does not meet the current guideline, nor can it be considered as providing equivalent data according to the criteria in Annex XI, 1.1.2. of the REACH Regulation. ECHA concludes that a test using *E. coli* WP2 uvrA, or *E. coli* WP2 uvrA (pKM101), or *S. typhimurium* TA102 has not been submitted and that the test using one of these is required to conclude on *in vitro* gene mutation in bacteria.

Moreover, ECHA notes that a robust study summary is required under Article 10(a)(vii), and ECHA considers that the information provided in the endpoint study record does not meet the requirements of a robust study summary, as defined in Article 3(28). Specifically, the endpoint study record does not provide information on positive controls with and without metabolic activation, individual plate counts, tabular data, number of revertant colonies per plate and per negative and positive controls. ECHA has provided a practical guide for "How to report robust study summaries", available at: http://echa.europa.eu/documents/10162/13643/pg_report_robust_study_summaries_en.pdf. ECHA considers there is not sufficient information to make an independent assessment of the study minimising the need to consult the full study report, and accordingly considers that for this study, you have failed to meet the requirement of Annex XI, Section 1.5. that adequate and reliable documentation of the applied method shall be provided.

As detailed above, ECHA concludes that the source study, does not provide the information required by Annex VII, Section 8.4.1., because it does not meet the requirements of Annex XI, 1.5, for adequate and reliable coverage of the key parameters and adequate and reliable documentation. Consequently there is an information gap and it is necessary to provide information for this endpoint.

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

Therefore, pursuant to Article 41(1) and (3) of the REACH Regulation, you are requested to submit the following information derived with the analogue substance (6-[[(4-methylphenyl)sulphonyl]amino]hexanoic acid, EC number 278-934-5): Bacterial reverse mutation test (test method: EU B.13/14. / OECD TG 471).

Note for your consideration

If duly justified, according to Article 13(1) and (3) of the REACH Regulation, and if no reliable and adequate documentation is provided in the technical dossier, including on TEA, you may perform the test with the registered substance.

2. 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 as laid down in Annex IX, Section 8.6.2. of the REACH Regulation. Adequate information on this endpoint needs to be present in the technical dossier for the registered substance to meet this information requirement.

You have not provided any study record of a sub-chronic toxicity study (90 day) in the dossier that would meet the information requirement of Annex IX, Section 8.6.2.

You have sought to adapt this information requirement according to Annex XI, Section 1.5. of the REACH Regulation by providing a study record for a "combined repeated dose toxicity study with the reproduction/developmental toxicity screening test" (test method: OECD TG 422) with the analogue substance 6-[[(4-methylphenyl)sulphonyl]amino]hexanoic acid (EC number 278-934-5), and a study record for a 2-year chronic toxicity via oral route (non test guideline, 1986, reliability 2 [redacted] with triethanolamine (EC number 203-049-8).

As explained above at the beginning of Appendix 1 of this decision, ECHA agrees that the read-across approach is plausible and that you can rely on the results of studies performed

with 6-[[(4-methylphenyl)sulphonyl]amino]hexanoic acid, if these studies are adequate and reliable.

However, the study you have submitted "combined repeated dose toxicity study with the reproduction/developmental toxicity screening test" (test method: OECD TG 422) does not provide the information required by Annex IX, Section 8.6.2., because exposure duration is less than 90 days and the number of animals examined per dose group for histopathology and clinical chemistry is significantly lower than in the 90 day sub-chronic toxicity study (OECD TG 408). Therefore, there is not adequate and reliable coverage of the key parameters addressed in the corresponding test method referred to in Article 13(3), and so the requirements of Annex XI, 1.5 are not met.

As detailed above, ECHA concludes that the source study does not provide the information required by Annex IX, Section 8.6.2., because the read-across adaptation fails due to the inadequacy of the source study. Consequently there is an information gap and it is necessary to provide information for this endpoint.

ECHA has evaluated the most appropriate route of administration for the study. Based on the information provided in the technical dossier and/or in the chemical safety report, ECHA considers that the oral route - which is the preferred one as indicated in ECHA *Guidance on information requirements and chemical safety assessment* (version 5.0, December 2016) Chapter R.7a, Section R.7.5.4.3 - is the most appropriate route of administration. More specifically, the substance is a waxy solid used in liquid formulations of very low vapour pressure and no uses with spray application are reported that could potentially lead to aerosols of inhalable size.
According to the test method OECD TG 408 the rat is the preferred species. ECHA considers this species as being appropriate and testing should be performed with the rat.

Therefore, pursuant to Article 41(1) and (3) of the REACH Regulation, you are requested to submit the following information derived with the analogue substance 6-[[(4-methylphenyl)sulphonyl]amino]hexanoic acid (EC number 278-934-5): Repeated dose 90-day oral toxicity study (test method: OECD TG 408) in rats.

Note for your consideration

If duly justified, according to Article 13(1) and (3) of the REACH Regulation, and if no reliable and adequate documentation is provided in the technical dossier, including on TEA, you may perform the test with the registered substance.

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

A "pre-natal developmental toxicity study" (test method OECD TG 414) for a first species is a standard information requirement as laid down in Annex IX, Section 8.7.2. of the REACH Regulation. Adequate information on this endpoint needs to be present in the technical dossier for the registered substance to meet this information requirement.

You have not provided any study record of a pre-natal developmental toxicity study in the dossier that would meet the information requirement of Annex IX, Section 8.7.2.

In the technical dossier you have sought to adapt this information requirement according to Annex XI, Section 1.5. of the REACH Regulation by providing a study record for a "combined Repeated Dose Toxicity Study with the Reproduction/Developmental Toxicity Screening Test" (OECD TG 422), with the analogue substance 6-[[(4-

methylphenyl)sulphonyl]amino]hexanoic acid (EC number 278-934-5), and two study records for non-test guideline studies with reliability 2: (i) [redacted], and (ii) [redacted]; with triethanolamine (EC number 203-049-8).

As explained above at the beginning of Appendix 1 of this decision, ECHA agrees that the read-across approach is plausible and that you can rely on the results of studies performed with 6-[[(4-methylphenyl)sulphonyl]amino]hexanoic acid, if these studies are adequate and reliable.

However, the study you have submitted "combined repeated dose toxicity study with the reproduction/developmental toxicity screening test" (test method: OECD TG 422) does not provide the information required by Annex IX, Section 8.7.2., because it does not cover key parameters of a pre-natal developmental toxicity study, such as examinations of foetuses for skeletal and visceral alterations. Therefore, there is not adequate and reliable coverage of the key parameters addressed in the corresponding test method referred to in Article 13(3), and so the requirements of Annex XI, 1.5 are not met.

As detailed above, ECHA concludes that the source study does not provide the information required by Annex IX, Section 8.7.2., because the read-across adaptation fails due to the inadequacy of the source study. Consequently there is an information gap and it is necessary to provide information for this endpoint.
According to the test method OECD TG 414, the rat is the preferred rodent species and the rabbit the preferred non-rodent species. On the basis of this default assumption ECHA considers testing should be performed with rats or rabbits as a first species.

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

Therefore, pursuant to Article 41(1) and (3) of the REACH Regulation, you are requested to submit the following information derived with the analogue substance 6-[[(4-methylphenyl)sulphonyl]amino]hexanoic acid (EC number 278-934-5): Pre-natal developmental toxicity study (test method: OECD TG 414) in a first species (rat or rabbit) by the oral route.

Note for your consideration

If duly justified, according to Article 13(1) and (3) of the REACH Regulation, and if no reliable and adequate documentation is provided in the technical dossier, including on TEA, you may perform the test with the registered substance.

ECOTOXICOLOGICAL INFORMATION
In accordance with Articles 10(a) and 12(1) of the REACH Regulation, a technical dossier registered at 100 to 1000 tonnes per year must contain, as a minimum, the information specified in Annexes VII to IX to the REACH Regulation. The information to be generated for the dossier must fulfil the criteria in Article 13(4) of the same regulation.

4. Identification of degradation products (Annex IX, 9.2.3.)

The identification of degradation products is a standard information requirement according to column 1, Section 9.2.3. of Annex IX of the REACH Regulation. Adequate information on this endpoint needs to be present in the technical dossier for the registered substance to meet this information requirement.

The technical dossier does not contain an adaptation in accordance with column 2 of Annex IX, Sections 9.2 or 9.2.3. or with the general rules of Annex XI for this standard information requirement.

In the technical dossier you have provided a study record for a screening test for ready biodegradation in water (OECD TG 301B) with the registered substance (test material referred as [redacted]; active ingredient content: 86.6%; water content: 13.4%). Biodegradation of the test substance reached 76.84% after 28 days (based on theoretical CO_2 consumption) but the test failed the 10-day windows criterion. You provided the following conclusion: "*The test item is regarded as readily biodegradable without meeting the 10 day window under the conditions of the test*".

ECHA notes that the registered substance is a mono-constituent substance. Accordingly, according to *ECHA Guidance on information requirements and chemical safety assessment, Chapter R7b, Section R.7.9.4.1.* (version 4.0, June 2017), the 10-day criterion needs to be fulfilled for the substance to be considered as readily biodegradable. Based on the results of the screening test for ready biodegradation in water on [redacted], ECHA considers that the registered substance is not readily biodegradable.
You also provided the results of an inherent biodegradation study (OECD TG 302B) with a formulation containing the registered substance and an excess of triethanolamine and deionised water. Test vessels were prepared by adding 0.1825 ml/l (equivalent to 142.9 mg/l COD) of test substance to 357.1 mg/l of activated sludge. The biodegradability of the test material attained 78.6% based on COD after 56 days. You concluded that "*From the results of this study it can be concluded that p-TSA Triethanolamine salt does not meet the criteria for classification as 'inherently biodegradable' according to the OECD 302B method, with >70% biodegradation being achieved within the 56 day test period. The test material shows good potential for ultimate biodegradation under the conditions of this study*".

ECHA considers that, while the results of the test may be regarded as evidence of inherent, ultimate biodegradability, this data cannot be used directly for the assessment of environmental persistence of the substance or its degradation products (see section R.7.9.5.2 and Chapter R.11 of the Guidance on IR&CSA) as the pass level of 70% degradation in the Zahn-Wellens/EMPA Test was not reached within seven days, including the lag-phase and the degradation-phase, i.e. the exponential growth phase of the microorganisms. However, as biodegradation was above 20% of theoretical, ECHA considers that the results may be regarded as evidence of inherent, primary, biodegradability and that stable degradation products are likely to be formed. Accordingly, further testing should be considered to conclude on the persistence of degradation products.

In addition, ECHA notes that you provided, under the simulation studies endpoint, two biodegradation in seawater studies (based on OECD TG 306). The first test (2007) was conducted with a formulation containing the registered substance with an excess of triethanolamine and deionised water. In this study, the biodegradability attained 29.6% and 22.1% (based on COD) after 28 days with an initial test concentration of 2.5 and 3.5 mg/L, respectively. In the second study (1996), a formulation containing 6-[methyl(phenylsulphonyl)amino]hexanoic acid, compound with 2,2', 2"-nitrilotriethanol (1:1) (EC number 248-107-3) with an excess of triethanolamine and deionised water at

2.04 mg/L. Under the conditions of this test, the biodegradability in seawater after 28 days reached 21.5%.

While ECHA agrees that the marine environment is a relevant environmental compartment owing to the reported use of the registered substance (i.e., offshore oilfield drilling), the test substance used in these studies contained an excess of triethanolamine and you did not provide any quantitative information on the composition of the test material. As the information available on ECHA Dissemination Portal relative to triethanolamine suggests that it might be easily biodegraded, ECHA considers that the degradation estimates provided in these test reports might overestimate the true biodegradability of the registered substance.

ECHA also emphasizes that, owing to the relatively high test concentrations used as compared with most natural systems (and consequently an unfavourable ratio between the concentrations of test substances and other carbon sources), the OECD TG 306 is to be regarded as a preliminary test. Such test can be used to indicate whether or not a substance is easily biodegradable and not is not equivalent as a simulation testing on ultimate degradation in surface water. ECHA considers that the provided information support the fact that the registered substance is not easily degraded in seawater.

According to Annex IX, Section 9.2.3., column 2 of the REACH Regulation, identification of degradation products is not needed if the substance is readily biodegradable. ECHA notes that based on the information in the technical dossier, the registered substance is not readily biodegradable in water. In addition, the results of the OECD 302B and OECD 306 test on a formulated product containing the registered substance and an excess of triethanolamine suggest that stable degradation products might be formed.

Furthermore, ECHA notes that you have not provided any appropriate justification in your CSA or in the technical dossier as to why there is no need to provide information on degradation products. ECHA considers that this information is needed with regards to the PBT/vPvB assessment and risk assessment.

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

Regarding the design of an appropriate and suitable test method, it will have to be substance-specific. When analytically possible, identification, stability, behaviour, molar quantity of metabolites relative to the parent compound should be evaluated. In addition, degradation half-life, log K_{ow} and potential toxicity of the metabolite may be investigated. You will need to provide a scientifically valid justification for the chosen method.

Therefore, pursuant to Article 41(1) and (3) of the REACH Regulation, you are requested to submit the following information derived with the registered substance subject to the present decision: Identification of the degradation products (Annex IX, Section 9.2.3.) by using an appropriate and suitable test method, as explained above in this section.

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 11 August 2017.

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. ECHA did not receive any comments by the end of the commenting period.

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

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

Appendix 3: Further information, observations and technical guidance

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

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

3. In carrying out the tests required by the present decision, it is important to ensure that the particular sample of substance tested is appropriate to assess the properties of the registered substance, taking into account any variation in the composition of the technical grade of the substance as actually manufactured or imported. If the registration of the substance covers different grades, the sample used for the new tests must be suitable to assess these.

   Furthermore, 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.