ECHA
EUROPEAN CHEMICALS AGENCY

Helsinki, 24 April 2019

Addressee: [redacted]

Decision number: TPE-D-2114465848-30-01/F
Substance name: Amines, tallow alkyl, dodecylbenzenesulfonates
EC number: [redacted]
CAS number: NS
Registration number: [redacted]
Submission number: [redacted]
Submission date: 22/03/2019
Registered tonnage band: 100-1000

DECISION ON A TESTING PROPOSAL

Based on Article 40 of Regulation ((EC) No 1907/2006) (the REACH Regulation), ECHA examined your testing proposal(s) and decided as follows.

While your originally proposed test for **Sub-chronic toxicity study (90-day), oral route (Annex IX, Section 8.6.2.;** test method: Combined Repeated Dose Toxicity Study with the Reproduction/Developmental Toxicity Screening Test OECD TG 422) using the registered substance is rejected, you are requested to perform:

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

While your originally proposed test for Pre-natal developmental toxicity study (Annex IX, Section 8.7.2.; test method: Combined Repeated Dose Toxicity Study with the Reproduction/Developmental Toxicity Screening Test TG OECD 422) using the registered substance is rejected, you are requested to perform:

2. **Pre-natal developmental toxicity study (Annex IX, Section 8.7.2.; test method: OECD TG 414) in a first species (rats or rabbits), oral route using the registered substance.**

Your testing proposal is accepted and you are requested to carry out:

3. **Long-term toxicity on terrestrial invertebrates (Annex IX, Section 9.4.1.; column 2; test method: Earthworm reproduction test, OECD TG 222 Earthworm reproduction test (Eisenia fetida/Eisenia andrei) OECD 222, or Enchytraeid reproduction test OECD 220, or Collembolan reproduction test in soil OECD 232)) using the registered substance.**
4. **Effects on soil micro-organisms (Annex IX, Section 9.4.2., test method: Soil microorganisms: nitrogen transformation test, EU C.21./OECD TG 216) using the registered substance.**

5. **Effects on soil micro-organisms (Annex IX, Section 9.4.2.; test method: Soil microorganisms: carbon transformation test, EU C.22/OECD TG 217) using the registered substance.**
6. **Long-term toxicity testing on plants (Annex IX, Section 9.4.3., column 2; test method: Terrestrial plants, growth test, OECD TG 208) using the registered substance.**

You have to submit the requested information in an updated registration dossier by **3 May 2021**. You also have to update the chemical safety report, where relevant. The timeline has been set to allow for sequential testing.

The reasons for 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 **Wim De Coen**, Head of Unit, Hazard Assessment.

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

Appendix 1: Reasons

The decision of ECHA is based on the examination of the testing proposals submitted by you.

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

Pursuant to Article 40(3)(d) and (c) of the REACH Regulation, ECHA may reject a proposed test and require the Registrant to carry out other tests in cases of non-compliance of the testing proposal with Annexes IX, X or XI.

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. The information on this endpoint is not available for the registered substance but needs to be present in the technical dossier to meet the information requirements. Consequently there is an information gap and it is necessary to provide information for this endpoint.

You have submitted a testing proposal for a Combined Repeated Dose Toxicity Study with the Reproduction/Developmental Toxicity Screening Test (TG OECD 422). However, you have not justified how the relevant information requirement for sub-chronic toxicity could be met with a screening study that involves significantly shorter duration of the exposure to the test substance. Hence, your proposed test cannot fulfil the requirements for a sub-chronic toxicity study.

ECHA requested your considerations for alternative methods to fulfil the information requirement for Sub-chronic toxicity (90-day): oral. ECHA notes that you provided your considerations concluding that there were no alternative methods which could be used to adapt the information requirement(s) for which testing is proposed. ECHA has taken these considerations into account.

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 6.0, July 2017) Chapter R.7a, Section R.7.5.4.3 - is the most appropriate route of administration. More specifically, the substance is a liquid of very low vapour pressure. Uses with professional spray application are reported in the chemical safety report. However, the substance is classified as a skin sensitizer, and for that reason risk management measures to minimise exposure are reported in the CSR. Hence, the test shall be performed by the oral route using the test method OECD TG 408.

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.

In your comments to the draft decision according to Article 50(1) of the REACH Regulation you agree to perform the test as requested.

Therefore, pursuant to Article 40(3)(c) of the REACH Regulation, you are requested to carry out the additional study with the registered substance subject to the present decision: Sub-chronic toxicity study (90-day) in rats, oral route (test method: OECD TG 408),
while your originally proposed test for a "combined repeated dose toxicity study with the reproduction/developmental toxicity screening test" according to OECD TG 422 is rejected according to Article 40(3)(d) of the REACH Regulation.

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

Pursuant to Article 40(3)(d) and (c) of the REACH Regulation, ECHA may reject a proposed test and require the Registrant to carry out other tests in cases of non-compliance of the testing proposal with Annexes IX, X or XI.

A pre-natal developmental toxicity study for a first species is a standard information requirement as laid down in Annex IX, Section 8.7.2. of the REACH Regulation. The information on this endpoint is not available for the registered substance but needs to be present in the technical dossier to meet the information requirements. Consequently there is an information gap and it is necessary to provide information for this endpoint.

You have submitted a testing proposal for a Combined Repeated Dose Toxicity Study with the Reproduction/Developmental Toxicity Screening Test (TG OECD 422). However, you have not justified how the relevant information requirement for pre-natal developmental toxicity could be met with a screening study that does not cover key parameters of a pre-natal developmental toxicity study like examinations of foetuses for skeletal and visceral alterations. Hence, your proposed test cannot fulfil the information requirements for a pre-natal developmental toxicity study.

ECHA requested your considerations for alternative methods to fulfil the information requirement for Reproductive toxicity (pre-natal developmental toxicity). ECHA notes that you provided your considerations concluding that there were no alternative methods, which could be used to adapt the information requirement(s) for which testing is proposed. ECHA has taken these considerations into account.

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 consideration, ECHA considers testing should be performed with the rat or rabbit as a first species.

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

In your comments to the draft decision according to Article 50(1) of the REACH Regulation you agree to perform the test as requested.

Therefore, pursuant to Article 40(3)(c) of the REACH Regulation, you are requested to carry out the additional study with the registered substance subject to the present decision: Pre-natal developmental toxicity study in a first species (rats or rabbits), oral route (test method: OECD TG 414), while your originally proposed test for a "combined repeated dose toxicity study with the reproduction/developmental toxicity screening test" according to OECD TG 422 is rejected according to Article 40(3)(d) of the REACH Regulation.

Notes for your consideration

For the selection of the appropriate species you are advised to consult ECHA *Guidance on information requirements and chemical safety assessment* (version 6.0, July 2017), Chapter R.7a, Section R.7.6.2.3.2.

3. Long-term toxicity to terrestrial invertebrates (Annex IX, Section 9.4.1., column 2)

Pursuant to Article 40(3)(a) of the REACH Regulation, ECHA may require the Registrant to carry out the proposed test.

"Effects on terrestrial organisms" is a standard information requirement as laid down in Annex IX, Section 9.4. of the REACH Regulation. The Registrant must address the standard information requirements set out in Annex IX, Section 9.4., for different taxonomic groups: short-term toxicity testing on invertebrates (Annex IX, Section 9.4.1.), effects on soil micro-organisms (Annex IX, Section 9.4.2.), and short-term toxicity testing on plants (Annex IX, Section 9.4.3.). Furthermore, Annex IX, Section 9.4., column 2 specifies that long-term toxicity testing shall be considered by the Registrant instead of short-term, in particular for substances that have a high potential to adsorb to soil or that are very persistent.

The information on "short-term and long-term toxicity to invertebrates" is not available for the registered substance but needs to be present in the technical dossier to meet the information requirements. Consequently there is an information gap and it is necessary to provide information for this endpoint.

You have submitted a testing proposal for a long-term toxicity test on terrestrial invertebrates (OECD TG 208) without further justification.

According to section R.7.11.5.3., Chapter R.7c of the ECHA *Guidance on information requirements and chemical safety assessment* ((version 3.0, June 2017)), substances that are ionisable or have a log K_{ow}/K_{oc} >5 are considered highly adsorptive, whereas substances with a half-life >180 days are considered very persistent in soil. ECHA notes that, according to the evidence presented within the Registration dossier, the substance has potentially a high potential to adsorb to soil as the substance is ionisable and is considered very persistent which is default setting for not readily biodegradable substances, when value of the half-life in soil is not available and therefore meets the column 2 adaptation criteria of Annex IX, section 9.4. concerning the use of long-term testing instead of short-term. Therefore, considering the properties of the substance, ECHA concludes that only a long-term toxicity test on invertebrates (and not the short-term) will provide the adequate information.

The earthworm reproduction test (OECD TG 222), Enchytraeid reproduction test (OECD TG 220), and Collembolan reproduction test (OECD TG 232) are each considered capable of generating information appropriate for the fulfilment of the information requirements for long-term toxicity testing to terrestrial invertebrates. ECHA is not in a position to determine the most appropriate test protocol, since this decision is dependent upon species sensitivity and substance properties.

In your comments to the draft decision according to Article 50(1) of the REACH Regulation you agree to perform the test as requested.

Therefore, pursuant to Article 40(3)(a) of the REACH Regulation, you are required to carry out one of the following studies using the registered substance subject to the present decision: Earthworm reproduction test (*Eisenia fetida/Eisenia andrei*) OECD 222, or Enchytraeid reproduction test OECD 220, or Collembolan reproduction test in soil OECD 232).

4. and 5. Effects on soil micro-organisms (Annex IX, Section 9.4.2.)

Pursuant to Article 40(3)(a) of the REACH Regulation, ECHA may require the Registrant to carry out the proposed test.

"Effects on terrestrial organisms" is a standard information requirement as laid down in Annex IX, Section 9.4. of the REACH Regulation. The Registrant must address the standard information requirements set out in Annex IX, Section 9.4., for different taxonomic groups: short-term toxicity testing on invertebrates (Annex IX, Section 9.4.1.), effects on soil micro-organisms (Annex IX, Section 9.4.2.), and short-term toxicity testing on plants (Annex IX, Section 9.4.3.).

The information on "effects on soil micro-organisms" is not available for the registered substance but needs to be present in the technical dossier to meet the information requirements. Consequently there is an information gap and it is necessary to provide information for this endpoint.

You have submitted a testing proposal for effects on soil micro-organisms (EU C.21/OECD TG 216 and EU C.22/OECD TG 217) without further description of the tests.

To address this endpoint, either a nitrogen transformation test (test method: EU C.21/OECD TG 216) or a carbon transformation test (test method: EU C.22/OECD TG 217) could be performed. According to Section R.7.11.3.1, Chapter R.7c of the ECHA *Guidance on information requirements and chemical safety assessment* (version 3.0, June 2017), ECHA considers the nitrogen transformation test (EU C.21/OECD TG 216) suitable for non-agrochemicals. For agrochemicals the carbon transformation test (EU: C.22/OECD TG 217) is also required.

In your comments to the draft decision according to Article 50(1) of the REACH Regulation you agree to perform the tests as requested.

Therefore, pursuant to Article 40(3)(a) of the REACH Regulation, you are requested to carry out the following proposed test using the registered substance subject to the present decision: Soil microorganisms: nitrogen transformation test, EU C.21/OECD TG 216;

and

Soil microorganisms: carbon transformation test, EU C.22/OECD TG 217.

6. Long-term toxicity to terrestrial plants (Annex IX, Section 9.4.3., column 2)

Pursuant to Article 40(3)(a) of the REACH Regulation, ECHA may require the Registrant to carry out the proposed test.

"Effects on terrestrial organisms" is a standard information requirement as laid down in Annex IX, Section 9.4. of the REACH Regulation. The Registrant must address the standard information requirements set out in Annex IX, Section 9.4., for different taxonomic groups: short-term toxicity testing on invertebrates (Annex IX, Section 9.4.1.), effects on soil micro-organisms (Annex IX, Section 9.4.2.), and short-term toxicity testing on plants (Annex IX, Section 9.4.3.). Furthermore, Annex IX, Section 9.4., column 2 specifies that long-term

toxicity testing shall be considered by the Registrant instead of short-term, in particular for substances that have a high potential to adsorb to soil or that are very persistent.

The information on "short-term or long-term toxicity to plants" is not available for the registered substance but needs to be present in the technical dossier to meet the information requirements. Consequently there is an information gap and it is necessary to provide information for this endpoint.

You have submitted a testing proposal for effects on terrestrial plants (OECD TG 208) without further description of the tests.

ECHA notes that there is no information available in the dossier demonstrating no concern to terrestrial plants.

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

As the long-term aquatic toxicity studies are not available in the dossier (short-term toxicity studies on aquatic organisms are not considered relevant, as the substance is poorly water soluble (WS<1 mg/l), also PNEC values for aquatic organisms are not available. Consequently, it is not possible to waive the standard information requirements for the terrestrial compartment through an initial screening assessment based upon the Equilibrium Partitioning Method (EPM), mentioned in Column 2 of Annex IX, section 9.4. Consequently there is an information gap and it is necessary to provide information for the standard information requirement of Annex IX, Section 9.4.3.

Based on the substance properties, ECHA considers that the substance has potentially a high potential to adsorb to soil as the substance is ionisable and is considered very persistent which is default setting for not readily biodegradable substances, when value of the half-life in soil is not available. High absorbance potential and persistence of the substance indicates the need for long-term testing to be performed (Column 2 of Section 9.4. of Annex IX). No argument has been provided in the dossier as to why, despite the potential to adsorb and persistence of the substance, long-term testing is not appropriate. Therefore ECHA concludes that only a long-term toxicity test on plants (and not the short-term) will provide the necessary useful information.

Furthermore, ECHA *Guidance on information requirements and chemical safety assessment* Chapter R10, section R.10.6.2., (version May 2008) allows the potential application of a lower assessment factor (AF) if information on additional long-term terrestrial toxicity test of two trophic levels were available. In contrast, the Guidance does not allow for a lower AF to be applied if information on a short-term study were to become available in addition to the long-term invertebrate study.

In your comments to the draft decision according to Article 50(1) of the REACH Regulation you agree to perform the test as requested.

Therefore, pursuant to Article 40(3)(a) of the REACH Regulation, you are required to carry out one of the following studies using the registered substance subject to the present decision: Terrestrial plants, growth test (OECD 208), with at least six species tested (with as a minimum two monocotyledonous species and four dicotyledonous species), or Soil Quality – Biological Methods – Chronic toxicity in higher plants (ISO 22030).

Deadline to submit the requested information

In a draft decision submitted to you, the deadline indicated to provide the requested information is set to 36 months from the date of adoption of the decision. You submitted a dossier update and removed the following TPEs; Dissociation constant (Annex IX, Section 7.16.; test method: OECD TG 112); Viscosity (Annex IX, Section 7.17.; test method: OECD TG 114); Simulation testing on ultimate degradation in surface water (Annex IX, Section 9.2.1.2.; test method: Aerobic mineralisation in surface water – simulation biodegradation test, EU C.25./OECD TG 309) at a temperature of 12°C using the registered substance; Soil simulation testing (Annex IX, Section 9.2.1.3.; test method: Aerobic and anaerobic transformation in soil, EU C.23./OECD TG 307) at a temperature of 12°C using the registered substance; Sediment simulation testing (Annex IX, Section 9.2.1.4.; test method: Aerobic and anaerobic transformation in aquatic sediment systems, EU C.24. / OECD TG 308) at a temperature of 12°C using the registered substance; Identification of degradation products (Annex IX, Section 9.2.3.) using the registered substance. Due to the remaining draft decision requests, ECHA has set the deadline of the decision to 24 months.

Appendix 2: Procedural history

ECHA received your registration containing the testing proposals for examination in accordance with Article 40(1) on 20 December 2017.

ECHA held a third party consultation for the testing proposals from 26 March 2018 until 11 May 2018. ECHA did not receive information from third parties.

This decision does not take into account any updates after **19 October 2018**, 30 calendar days after the end of the commenting period.

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 took into account your comments and dossier update and amended the requests and the deadline.

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 decision does not imply that the information provided in your registration dossier is in compliance with the REACH requirements. The decision does not prevent ECHA from initiating a compliance check on the registration at a later stage.

2. Failure to comply with the requests in this decision will result in a notification to the enforcement authorities of the Member States.

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.