ECHA
EUROPEAN CHEMICALS AGENCY

Helsinki, 11 March 2020

Addressee
Registrant of [redacted] listed in the last Appendix of this decision

Date of submission for the dossier subject of a decision
6 March 2019

Registered substance subject to this decision, hereafter 'the Substance'
Substance name: Fatty acids, C12-14, α-sulfo, disodium salts
EC number: 942-523-5
CAS number: NS

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

DECISION ON A TESTING PROPOSAL

Based on Article 40 of Regulation (EC) No 1907/2006 (REACH), ECHA requests that you submit the information listed below by the deadline of ***20 September 2021***.

A. 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. 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 Substance;

3. Long-term toxicity testing on fish (Annex IX, Section 9.1.6.1.; test method OECD TG 210), with the Substance;

   Your originally proposed test using the Substance according to Article 40(3)(d): Long-term toxicity testing on fish (Annex IX, Section 9.1.6.2.; test method: Fish, short-term toxicity test on embryo and sac-fry stages, EU C.15./OECD TG 212) is rejected.

Conditions to comply with the requests

You are bound by the requests for information corresponding to the REACH Annexes applicable to your own registered tonnage of the Substance at the time of evaluation. Therefore you have to comply with the requirements of Annexes VII to IX of REACH, if you have registered a substance at 100-1000 tpa.

The 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.

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.

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 A: Reasons for the requirements applicable to all the Registrants subject to Annex IX of REACH

This decision is based on the examination of the testing proposals you submitted.

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, Section 8.6.2. to REACH.

You have submitted a testing proposal for a sub-chronic toxicity study (90 day) in rats by the oral route according to OECD TG 408.

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.

ECHA agrees with your proposal. According to OECD TG 408, the rat is the preferred species and the most appropriate route of administration is the oral route[2] because, although the information indicate that human exposure to the Substance by the inhalation route is likely, there is no concern for severe local effects following inhalation exposure.

Under Article 40(3)(a) of REACH, you are requested to carry out the proposed test with the Substance.

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

A pre-natal developmental toxicity (PNDT) study (OECD TG 414) in one species is a standard information requirement under Annex IX, Section 8.7.2. to REACH.

You have submitted a testing proposal for a PNDT study according to OECD TG 414 in the rat.

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.

Species

You proposed testing with the rat as a first species. ECHA agrees with your proposal. You may select between the rat or the rabbit because both are preferred species under the OECD TG 414.

Route of administration

You did not specify the route for testing. The oral route is the most appropriate route of administration to investigate reproductive toxicity[3].

Under Article 40(3)(a) of REACH, you are requested to carry out the proposed test with the Substance.

[2] ECHA Guidance R.7a, Section R.7.5.4.3
[3] ECHA Guidance R.7a, Section R.7.6.2.3.2.

3. Long-term toxicity testing on fish (Annex IX, Section 9.1.6.1.)

Long-term toxicity testing on fish is a standard information requirement in Annex IX, Section 9.1.6 to REACH.

You have submitted a testing proposal for a Long-term toxicity testing on fish (Annex IX, Section 9.1.6.2.; test method: Fish, short-term toxicity test on embryo and sac-fry stages, EU C.15./OECD TG 212) with the Substance with the following justification: "*Since fish seems to be the most sensitive species, a long term test with fish is proposed.*"

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.

ECHA agrees that you must conduct a long-term toxicity study on fish to further investigate long-term toxicity to aquatic organisms, as explained in the following.

Regarding the test method, the proposed test using the test guideline Fish, short-term toxicity test on embryo and sac-fry stages, EU C.15./OECD TG 212, is rejected as explained in the following.

Tests on substances must be conducted in accordance with the OECD test guidelines or another recognised international test method (Article 13(3) of REACH). OECD TG 210 is the preferred guideline to fulfil this information requirement, since it is the most sensitive of the standard fish tests available: it covers several life stages of the fish and it examines the potential toxic effects of bioaccumulation (ECHA Guidance R.7b, Sections R.7.8.2 and R.7.8.4.1).

You have provided the following justification on the choice of the test method: "(..) *Since the substance also will be used in cosmetic uses it is the view of the registrant that an animal test is not justified. Therefore, it is the intention of the registrant to perform an OECD 212 test which is not regarded to be an animal test but with sufficient conclusiveness to cover the endpoint "long term toxicity testing on fish". The registrants view is in line with the interpretation and view of Cruelty Free International (2017) that OECD 212 is not an animal test. (..)*"

The proposed OECD TG 212 study is considerably shorter and less sensitive than OECD TG 210 study for the purpose of addressing the information requirement of long-term toxicity to fish (ECHA Guidance R.7b, Section R.7.8.4.1).

In your comments on the draft decision you maintain that you wish to conduct the OECD TG 212 instead of the OECD 210, in principal due to animal welfare considerations. However, besides the important consideration of the length and sensitivity of the tests, ECHA points out that in the FISH TOXICITY TESTING FRAMEWORK (OECD Series on Testing and Assessment, No. 171)[4] the use of the OECD TG 212 is not advised due to animal welfare issues and the guideline is proposed to be deleted (section 11.2 of the framework). Firstly, the larvae used in the study could be subject to pain as the guideline recommends that larvae with severe deformities should be terminated to avoid suffering. Secondly, the test is performed without external food supply and lack of feeding could be considered unacceptably distressful for the test organisms. The test should be terminated just before the yolk sac of any larvae has been

[4] The document is for example available at https://www.oecd-ilibrary.org/docserver/9789264221437-en.pdf?expires=1571648956&id=id&accname=guest&checksum=56A906873CF171D1C405D5C920E79C98.

completely absorbed or before mortality by starvation starts in the controls, however the exact point at which this occurs may be difficult to define in practice. In the context of animal welfare considerations the OECD FISH TOXICITY TESTING FRAMEWORK in Section 5.5.1 therefore highlights that the TG 212 has been described as the "fish starvation test". This further highlights the animal welfare issues.

Furthermore, regarding your claim that no animal testing should be performed since the substance is used also in cosmetics, ECHA points out that the Cosmetics Regulation does not restrict testing under REACH, if this testing is required for environmental endpoints. ECHA notes that recital 5 of the Cosmetics Regulation explains that "*the environmental concerns that substances used in cosmetic products may raise are considered through the application of* [the REACH Regulation], *which enables the assessment of environmental safety in a cross-sectoral manner*". This is also clarified in the ECHA factsheet "*Interface between REACH and Cosmetics Regulations*", which was developed jointly with the European Commission[5]. As indicated above, an OECD TG 210 study is required to fulfil the REACH standard information requirement for the long-term fish toxicity endpoint.

Therefore, under Article 40(3)(d) and (c) of REACH, your originally proposed test is rejected and you are requested to carry out a Long-term toxicity testing on fish (Annex IX, Section 9.1.6.1.; test method OECD TG 210) with the Substance.

Study design

The Substance is difficult to test due to the surface activity (Surface tension = 23.9 mN/m) and adsorptive (LogKoc = 2.43-3.28) properties. OECD TG 210 specifies that for difficult to test substances, the OECD GD 23 is to be followed. To get reliable results, the substance properties need to be considered when performing the test, in particular with regard to the test design; including exposure system, test solution preparation, and sampling. OECD GD 23 (Table 1) describes testing difficulties related to a specific property of the substance. You may use the approaches described in OECD GD 23 or other approaches if more appropriate for your Substance. The approach selected must be justified and documented.

Due to the substance properties it may be difficult to achieve and maintain the exposure concentrations. Therefore, you have to demonstrate that the concentration of the substance is stable throughout the test (i.e. measured concentrations remains within 80-120% of the nominal concentration). If it is not possible to demonstrate the stability, you must express the effect concentration based on measured values as described in the applicable test guideline. In case a dose-response relationship cannot be established (no observed effects), you must demonstrate that the test solution preparation method applied was sufficient to maximise the concentration of the Substance in the test solution. Furthermore, exposure concentrations must be below the critical micelle concentration (CMC). This will ensure that test organisms are exposed to the freely dissolved chemical species and not the micelle which can alter the uptake of the test chemical.

[5] Please see https://echa.europa.eu/documents/10162/13628/reach_cosmetics_factsheet_en.pdf
Further information is available at https://www.echa.europa.eu/-/clarity-on-interface-between-reach-and-the-cosmetics-regulation.

Appendix B: Procedural history

ECHA received your registration containing the testing proposals for examination on 7 March 2019.

ECHA held a third party consultation for the testing proposals from 25 June 2019 until 9 August 2019. ECHA did not receive information from third parties.

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

ECHA notified you of the draft decision and invited you to provide comments within 30 days of the notification.

ECHA took into account your comments and did not amend the request(s).

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

As no amendments were proposed, ECHA adopted the decision under Article 51(3) of REACH.

Appendix C: Observations and technical guidance

1. This testing proposal examination decision does not prevent ECHA from initiating compliance checks at a later stage on the registrations present.

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(s).

3. 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 must 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'[6].

4. Test material

   Selection of the test material(s) for UVCB substances

   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. Any constituents that have harmonised classification and labelling according to the CLP Regulation (Regulation (EC) No 1272/2008) must be identified and quantified using the appropriate analytical methods.

   The OECD Series on Principles of Good Laboratory Practice and Compliance Monitoring, Number 11 [ENV/MC/CHEM(98)16] requires a careful identification of the test material and description of its characteristics. In addition, the Test Methods Regulation (EU) 440/2008, as amended by Regulation (EU) 2016/266, requires that "if the test method is used for the testing of a [...] UVCB [...] sufficient information on its composition should be made available, as far as possible, e.g. by the chemical identity of its constituents, their quantitative occurrence, and relevant properties of the constituents".

   In order to meet this requirement, all the constituents of the test material used for each test must be identified as far as possible. For each constituent the concentration value in the test material must be reported in the Test material section of the endpoint study record.

   Technical reporting of the test material for UVCB substances

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

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

Technical instructions are available in the manual "How to prepare registration and PPORD dossiers"[7].

5. List of references of the ECHA Guidance and other guidance/ reference documents[8]

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)[9]

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.

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.

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
Guidance Document on aqueous-phase aquatic toxicity testing of difficult test chemicals – No 23, referred to as OECD GD 23.

Guidance Document on Standardised Test Guidelines for Evaluating Chemicals for Endocrine Disruption – No 150, referred to as OECD GD 150.

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

Appendix D: 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 fulfilled
[redacted]	[redacted]	[redacted]