~~Confidential~~

Helsinki, 5 October 2021

Addressees
Registrants of JS_SFS_2010 listed in the last Appendix of this decision

Date of submission of the dossier subject of a decision
28 October 2019

Registered substance subject to this decision, hereafter 'the Substance'
Substance name: Sodium hydroxymethanesulphinate
EC number: 205-739-4
CAS number: 149-44-0

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

DECISION ON TESTING PROPOSAL(S)

Based on Article 40 of Regulation (EC) No 1907/2006 (REACH), you must submit the information listed below by ***11 July 2024***. The deadline for this testing proposal decision takes into account the decision on a compliance check on the same Substance to allow for sequential testing.

The requested information must be generated using the Substance unless otherwise specified.

A. Information required from the Registrants subject to Annex IX of REACH

1. Pre-natal developmental toxicity study in a second species also requested below (triggered by Annex IX, Section 8.7.2., column 2)

B. Information required from the Registrants subject to Annex X of REACH

1. Pre-natal developmental toxicity study (Annex X, Section 8.7.2.; test method: EU B.31./OECD TG 414) by oral route, in a second species (rabbit)

Reasons for the request(s) are explained in the following appendix:

- Appendices entitled "Reasons to request information required under Annexes VII to X of REACH", respectively.

Information required depends on your tonnage band

You must provide the information listed above for all REACH Annexes applicable to you, and in accordance with Articles 10(a) and 12(1) of REACH:

- the information specified in Annexes VII, VIII and IX to REACH, for registration at 100-1000 tpa;
- the information specified in Annexes VII to X to REACH, for registration at more than 1000 tpa.

You are only required to share the costs of information that you must submit to fulfil your information requirements.

For certain endpoints, ECHA requests the same study from registrants at different tonnages. In such cases, only the reasoning why the information is required at lower tonnages is provided in the corresponding Appendices. For the tonnage where the study is a standard information requirement, the full reasoning for the request including study design is given. Only one study is to be conducted; the registrants concerned must make every effort to reach an agreement as to who is to carry out the study on behalf of the other registrants under Article 53 of REACH.

How to comply with your information requirements

To comply with your information requirements you must submit the information requested by this decision in an updated registration dossier by the deadline indicated above. You must also update the chemical safety report, where relevant, including any changes to classification and labelling, based on the newly generated information.

You must follow the general testing and reporting requirements provided under the Appendix entitled "Requirements to fulfil when conducting and reporting new tests for REACH purposes". In addition, you should follow the general recommendations provided under the Appendix entitled "General recommendations when conducting and reporting new tests for REACH purposes". For references used in this decision, please consult the Appendix entitled "List of references".

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 to request information required under Annex IX of REACH

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

1. Pre-natal developmental toxicity study

A pre-natal developmental toxicity (PNDT) study for a first species is a standard information requirement in Annex IX, Section 8.7.2. to REACH. Annex IX, Section 8.7.2., column 2 provides that the decision on the need to perform a PNDT study on a second species at Annex IX should be based on the outcome of the first test and all other relevant and available data.

The dossier contains a PNDT study in rats. You have identified a need to perform a PNDT study in a second species and submitted a testing proposal for a PNDT study in rabbit according to OECD TG 414. You provided the following justification: "*In a GLP-compliant pre-natal developmental toxicity study according to OECD Guideline 414 clear developmental toxic effects with the test item sodium hydroxymethanesulphinate (hydrate) were observed. These findings trigger a classification of the substance into the hazard class "Reproductive toxicity", Category 2 (H361d) according to the Regulation (EC) No 1272/2008. Therefore, to comply with Annex IX 8.7.2, Colum 2 of the REACH Regulation and the respective explanation in the ECHA Guidance on Information Requirements and Chemical Safety Assessment Chapter: R. 7a, a pre-natal developmental toxicity study in a second species is triggered.*"

You have self-classified your Substance as Repr. 2 in view of the following observed effects in foetuses: Pubis unossified, ischium unossified, increased presence of additional rudimentary 14th rib (variant), incomplete ossification of sternebrae (variant), metatarsals of the hind paw incompletely or unossified (anomaly), anophtalmia, hydrourether, and umbilical hernia.

ECHA agrees with your consideration that based on the outcome of the first test that there is a need for a PNDT study on a second species already at Annex IX.

The provided considerations on alternative methods and the study design are addressed under Section B.1 below.

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

Appendix B: Reasons to request information required under Annex X of REACH

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

1. Pre-natal developmental toxicity study

Pre-natal developmental toxicity (PNDT) studies on two species is the standard information requirement under Annex X, section 8.7.2, to REACH.

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

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.

You proposed a study with the rabbit as a second species. The study in the first species was carried out with rats. The rat or rabbit is the preferred species under the OECD TG 414[2]. On the basis of this default consideration, the study should be performed with the rabbit as a second species.

You proposed administration by the oral route. ECHA agrees with your proposal. The oral route is the most appropriate route of administration to investigate reproductive toxicity[2].

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

[2] ECHA Guidance R.7a Section R.7.6.2.3.2.

Appendix C: Requirements to fulfil when conducting and reporting new tests for REACH purposes

A. Test methods, GLP requirements and reporting

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

2. 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.

3. 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 on How to report robust study summaries[3].

B. Test material

Before generating new data, you must agree within the joint submission on the chemical composition of the material to be tested (Test material) which must be relevant for all the registrants of the Substance.

1. Selection of the Test material(s)

   The Test material used to generate the new data must be selected taking into account the following:
   - the variation in compositions reported by all members of the joint submission,
   - the boundary composition(s) of the Substance,
   - 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.

2. Information on the Test material needed in the updated dossier
   - You must report the composition of the Test material selected for each study, under the "Test material information" section, for each respective endpoint study record in IUCLID.
   - The reported composition must include all constituents of each Test material and their concentration values and other parameters relevant for the property to be tested.

This information is needed to assess whether the Test material is relevant for the Substance and whether it is suitable for use by all members of the joint submission.

Technical instructions on how to report the above is available in the manual on How to prepare registration and PPORD dossiers[4].

[3] https://echa.europa.eu/practical-guides
[4] https://echa.europa.eu/manuals

Appendix D: Procedure

The Substance is listed in the Community rolling action plan (CoRAP) for the start of substance evaluation in 2022.

ECHA started the testing proposal evaluation in accordance with Article 40(1) on 29 April 2019.

ECHA held a third party consultation for the testing proposal(s) from 27 May 2019 until 11 July 2019. ECHA did not receive information from third parties.

ECHA followed the procedure detailed in Articles 50 and 51 of REACH.

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

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

Deadline

In your comments on the draft decision, you requested with reference to this testing proposal decision and the compliance check decision on the same Substance an extension of the deadline to provide the requested information from 30 to 41 months from the date of adoption of the decision.

You explain the timelines as follows:
- PNDT study: 12 months,
- EOGRT study: 18 months,
- Preparing the reports for each study: up to 4 months, and
- Preparing the dossier update: 3 months.

In your comments, you have not provided evidence for your claims that extension of the timeline is needed, *e.g.* in form of a written, case-specific statement by a test laboratory explaining why an extension of deadline is needed.

Therefore, ECHA invited you by letter of 31 May 2021 to substantiate your request by submission of documentary evidence from the selected test laboratory indicating the scheduling timelines for the studies in question of the laboratory facility in order to justify why an extension to the stated deadlines from 30 months to 41 months is required.

You provided a letter from a test laboratory relating to a proposal for the PNDT study in rabbits. From this letter, the timelines for conducting the preliminary and main studies is 10 months form start of experimental phase to draft report, although the experimental phase is calculated to be around 11 months. The timeline for conducting the EOGRT study is 14/15 months from start of experimental phase to draft report, although the experimental phase is calculated to be around 19 months. You add "*another 3 months for study commissioning and procurement of the animals per study, in total another 6 months, as the studies are to be conducted consecutively. The dossier update will take another 3 months.*" Furthermore, you have provided a letter issued by a consultant relating to a quote to update the IUCLID dossier and Chemical Safety Report within 3 months.

You state that the studies "*are to be conducted consecutively*" but you state no reason for this. ECHA emphasises that in this case it is not necessary to finalise one study before initiating the other study. In particular, the PNDT study in rabbits and EOGRT study in rats could be run in parallel because these studies are conducted with different species and therefore have only very limited use to inform on each other. Furthermore, the registration dossier of the Substance already contains OECD TG 408, 422 and 414 studies in rats, which should be sufficient to inform on designing and conducting the EOGRT study in rats.

The set deadline, relevant for both this testing proposal decision and the compliance check decision on the same Substance, already includes time for administrative tasks and is considered sufficient for all the necessary tasks including preparatory work, reporting and dossier submission.

On this basis, ECHA has not modified the deadline to provide the information.

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 E: List of references - ECHA Guidance[5] and other supporting documents

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 where relevant.

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 where relevant.

Read-across assessment framework (RAAF, March 2017)[6]

RAAF - considerations on multi-constituent substances and UVCBs (RAAF UVCB, March 2017)**Error! Bookmark not defined.**

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.

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.

Data sharing
Guidance on data-sharing (version 3.1, January 2017), referred to as ECHA Guidance on data sharing in this decision.

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

OECD Guidance documents[7]
Guidance Document on aqueous–phase aquatic toxicity testing of difficult test chemicals – No 23, referred to as OECD GD 23.

Guidance document on transformation/dissolution of metals and metal compounds in aqueous media – No 29, referred to as OECD GD 29.

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

Guidance Document supporting OECD test guideline 443 on the extended one-generation reproductive toxicity test – No 151, referred to as OECD GD 151.

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

Appendix F: Addressees of this decision and the corresponding information requirements applicable to them

You must provide the information requested in this decision for all REACH Annexes applicable to you.

Registrant Name	Registration number	Highest REACH Annex applicable to you
[redacted]	[redacted]	[redacted]
[redacted]	[redacted]	[redacted]
[redacted]	[redacted]	[redacted]
[redacted]	[redacted]	[redacted]

Where applicable, the name of a third party representative (TPR) may be displayed in the list of recipients whereas ECHA will send the decision to the actual registrant.