EUROPEAN CHEMICALS AGENCY

Helsinki, 8 May 2020

Addressees
Registrants of Gelb Sulfato listed in the last Appendix of this decision

Date of submission for the jointly submitted dossier subject of a decision
12/06/2019

Registered substance subject to this decision, hereafter 'the Substance'
Substance name: 1,3,6-Naphthalenetrisulfonic acid, 7-[2-[2-[(aminocarbonyl)amino]-4-[[4-chloro-6-[[4-[[2-(sulfooxy)ethyl]sulfonyl]phenyl]amino]-1,3,5-triazin-2-yl]amino]phenyl]diazenyl]-, sodium salt
EC number: 474-870-9
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 ***15 November 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;

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;

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

4. Identification of degradation products (Annex IX, Section 9.2.3.) using an appropriate test method;

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, since you have registered a substance at 100-1000 tpa.

Registrants are only required to share the costs of information they are required to submit to fulfil the information requirements for their registration.

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.

Authorised[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 with the Substance.

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.

You proposed testing by the oral route, in rats. 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] since the Substance is a liquid of very low vapour pressure and no uses with spray application that could potentially lead to aerosols of inhalable size, are reported.

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 with the Substance, in the rat, by the oral route.

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 considers that the proposed study requires modification to fulfil the information requirement of Annex IX, Section 8.7.2. of the REACH Regulation.

In your testing proposal, you propose to perform the following investigation: *"Internal foetal sex determination for dead foetuses and foetuses allocated to the skeletal examination."*
However, OECD TG 414 (paragraph 31) states that *"External fetal sex (as determined by gross examination) should be compared with internal (gonadal) sex in all fetuses (examined for both skeletal and soft tissue malformations)."*
Therefore, the internal sex determination must be performed for all foetuses, as required in OECD TG 414.

In addition, you mention the following. *"Treatment period and frequency: Daily from Day 3 to Day 19 post coitum".* You don't specify the day of the planned caesarean section.

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

ECHA notes that the proposed exposure duration is adequate as long as the administration of the test material is at least from implantation until the day prior to scheduled caesarean section, as required in OECD TG 414 (paragraphs 5, 13).
Therefore, you must perform the study with adequate exposure of the foetuses, from at least implantation, until the day prior to scheduled caesarean section.

In your comments you clarified that external examination and sex determination of all foetuses (live and dead) will be performed. Internal sex determination will be confirmed by gonadal inspection during necropsy for all dead foetuses and foetuses allocated to the skeletal examination group (half the foetuses of litters from all groups with single staining). During the soft tissues examination, sex will be confirmed by internal examination of gonads inspection.

In addition, you clarified that the planned caesarean section will be at day 20 of gestation.

ECHA agrees with the provided clarifications and the study outline regarding the confirmation of sex determination and the exposure of the foetuses.

Regarding the single staining method mentioned for the skeletal examinations, ECHA notes that double staining would be preferable.

Species
You proposed testing with the rat as a first species. You may select between the rat or the rabbit because both are preferred species under the OECD TG 414[3].

Route
You proposed testing by the oral route. ECHA agrees with your proposal. The oral route is the most appropriate route of administration to investigate reproductive toxicity[4].

Under Article 40(3)(b) of REACH, you are requested to carry out the proposed test under modified conditions, as explained above, with the Substance.

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

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

You have submitted a testing proposal for simulation testing on ultimate degradation in surface water (OECD TG 309).

You have noted that, there are no adequate GLP studies on water/sediment simulation testing on the test substance. You further state that the substance is not readily biodegradable and is highly soluble in water. You propose testing at a temperature of 12 °C.

ECHA agrees with your assessment.

Study design

OECD TG 309 is an appropriate method for studying the degradation in surface water. However, when performing the OECD TG 309 test, the pelagic test option with natural surface

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

water containing approximately 15 mg dw/L of suspended solids (acceptable concentration between 10 and 20 mg dw/L) must be followed (ECHA Guidance R.11).

The requested simulation tests must be performed under relevant conditions (12°C, as proposed).

Consequently, under Article 40(3)(a) of the REACH Regulation, you are required to carry out the proposed test.

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

The biodegradation of each relevant constituent present in concentration at or above 0.1% (w/w) or, if not technically feasible, in concentrations as low as technically detectable, must be assessed. This can be done simultaneously during the same study. Alternatively, if you consider that this assessment is not relevant for the PBT/vPvB assessment of the Substance, you must provide a documented justification.

If you should encounter technical difficulties to perform the requested OECD TG 309 test, such difficulties and attempted solutions must be clearly demonstrated and documented in the registration dossier.

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

Identification of the degradation products is a standard information requirement at Annex IX of REACH.

You have submitted a testing proposal for simulation testing on ultimate degradation in surface water (OECD TG 309) and proposed to include identification of the degradation products in the study design. You further specify that the biodegradation of each relevant constituent present in concentration at or above 0.1% (w/w) or, if not technically feasible, in concentrations as low as technically detectable shall be assessed.

You also state that the substance is not readily biodegradable.
ECHA agrees with your assessment, and consequently under Article 40(3)(a) of the REACH Regulation, you are required to carry out the proposed test.

Study selection and design

If any other method is used for identification of the transformation/degradation products, you must provide a scientifically valid justification for the chosen method.

Identity, stability, behaviour, and molar quantity of the degradation/transformation products relative to the Substance must be evaluated and reported, when analytically possible. In addition, degradation half-life, potential for bioaccumulation and toxicity of the degradation product must be investigated.

Appendix B: Procedural history

ECHA received your registration containing the testing proposals for examination on 27 June 2019.

ECHA held a third party consultation for the testing proposals from 17 September 2019 until 1 November 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.

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

In your comments you agreed to the draft decision. ECHA took your comments into account and did not amend the requests.

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

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

Appendix 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'[5].

4. Test material

   Selection of the test material(s)

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

   Technical reporting of the test material

   The composition of the selected test material must be reported in the respective endpoint study record, under the Test material section. The composition must include all constituents of the test material and their concentration values. Without such detailed reporting, ECHA may not be able to confirm that the test material is relevant for the Substance and to all the registrants of the Substance.
   Technical instructions are available in the manual "How to prepare registration and PPORD dossiers"[6].

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

   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.

   PBT assessment

[5] https://echa.europa.eu/practical-guides
[6] https://echa.europa.eu/manuals
[7] https://echa.europa.eu/guidance-documents/guidance-on-information-requirements-and-chemical-safety-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.

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]