EUROPEAN CHEMICALS AGENCY

Helsinki, 16 March 2020

Addressees
Registrants of [redacted] listed in the last Appendix of this decision

Date of submission for the jointly submitted dossier subject of a decision
29 April 2019

Registered substance subject to this decision, hereafter 'the Substance'
Substance name: pentasodium 5-{[4-chloro-6-({4-[2-(sulfooxy)ethanesulfonyl]phenyl}amino)-1,3,5-triazin-2-yl]amino}-3-[2-(1,5-disulfonaphthalen-2-yl)diazen-1-yl]-4-hydroxynaphthalene-2,7-disulfonate
EC number: 402-420-3
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 ***23 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. 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, with the Substance;

3. Identification of degradation products (Annex IX, Section 9.2.3.) using the test method required under point 2. above, with the Substance;

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.

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 and on scientific information submitted by third parties.

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.

Based on the information provided in the technical dossier and/or in the chemical safety report, ECHA agrees that the oral route - which is the preferred one as indicated in ECHA Guidance R.7a, Section R.7.5.4.3 - is the most appropriate route of administration. More specifically, the Substance is reported to occur as a powder but no significant proportion (>1% on weight basis) of particles of inhalable size (MMAD < 50 µm) is reported. Additionally, apart from being water soluble (299 g/L), the Substance has a very low vapour pressure with no spray applications reported that could potentially lead to aerosols of inhalable size. Also, from the available sub-acute oral study, although there are no clear toxic effects, there is evidence of deposition of the Substance in the kidneys, which requires further investigation on repeated dose toxicity by the oral route.

According to OECD TG 408, the rat is the preferred species. ECHA agrees with your proposal to perform testing in rats.

Therefore, the test must be performed by the oral route using the test method EU B.26./OECD TG 408.

Consideration of the information received during third party consultation

ECHA received information concerning the testing proposal during the third party consultation. For the reasons explained below, the information provided by third parties is not sufficient to fulfil this information requirement.

The third party provided their considerations on the necessity of the study and stated that "*REACH requires to use alternative study methods before testing on animals. It seems there are no other methods used for this product, so this application for a 90-days oral test on animals seems to*[o] *early. Please use other methods first*". However, the third party did not provide any scientific data, which would fulfil this information requirement.

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

2. 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) with the Substance.

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 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.

3. 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) with the Substance 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 29 April 2019.

ECHA held a third party consultation for the testing proposals from 25 June 2019 until 9 August 2019. ECHA received information from third parties (see Appendix A).

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.

ECHA did not receive any comments within the 30-day notification period.

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'[2].

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"[3].

5. List of references of the ECHA Guidance and other guidance/ reference documents[4]

[2] https://echa.europa.eu/practical-guides
[3] https://echa.europa.eu/manuals
[4] https://echa.europa.eu/guidance-documents/guidance-on-information-requirements-and-chemical-safety-assessment

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)[5]

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.

[5] 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]