EUROPEAN CHEMICALS AGENCY

Helsinki, 5 June 2020

Addressees
Registrants of JS SL part_hydrolysed listed in the last Appendix of this decision

Date of submission for the jointly submitted dossier subject of a decision
29/05/2019

Registered substance subject to this decision, hereafter 'the Substance'
Substance name: Sophorolipids: fermentation products of glucose and fatty acids, C18 (unsaturated), glycerol esters with yeast Candida Bombicola, partially hydrolysed
EC number: 941-809-7
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 ***14 June 2021***.

A. Requirements applicable to all the Registrants subject to Annex VIII of REACH

1. Pre-natal developmental toxicity study (Annex VIII, Section 8.7.1., Column 2; test method OECD TG 414) in Sprague-Dawley rat, oral gavage route of administration 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 and VIII of REACH, if you have registered a substance at 10-100 tpa.

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 VIII of REACH

This decision is based on the examination of the testing proposal you submitted and on scientific information submitted by third parties.

1. Pre-natal developmental toxicity study (Annex VIII, Section 8.7.1., Column 2)

According to Annex VIII, 8.7.1., Colum 2, at the tonnage level of 10 to 100 tonnes per annum, the Registrant may propose a pre-natal developmental toxicity study (Annex IX, section 8.7.2) instead of a screening study in cases where there are serious concerns about the potential for adverse effects on fertility or development.

The dossier contains a screening study (OECD TG 421) with the registered substance subject to the present decision. You have identified a need to perform a PNDT study and submitted a testing proposal for a PNDT study 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 justify your testing proposal with findings in a dose range finding study for a reproduction/developmental toxicity screening study where malrotated hindlimbs were observed in one foetus each in one low (100 mg/kg/day) and one mid-dose (300 mg/kg/day) female, and in three foetuses in two high dose (500 mg/kg/day) litters. In the subsequently performed OECD TG 421 (GLP complaint study) the malformations could not be clarified, which you suggest could be due to the different testing set up.

ECHA has evaluated your proposal to perform a pre-natal developmental toxicity study according to OECD TG 414 at Annex VIII.

ECHA considers that the malformations reported in the dose range finding study raise serious concerns about the potential for adverse effects on pre-natal development. As the OECD TG 421 study design is considerably less sensitive than the OECD TG 414 study in detecting malformations ECHA agrees that the concern for prenatal developmental toxicity remains despite the lack of findings in the performed OECD TG 421 study. ECHA concludes that the effects have not been followed up in the most suitable study available for malformations and they should therefore be investigated further. The mere fact that a screening study is already available cannot be considered a valid reason why the adverse effects should not be followed up further.

Pursuant to Article 12(1) and Annex VI of the REACH Regulation the standard information requirements listed in Annex VII to X of the REACH Regulation are considered minimum requirements. Annex VI, step 4 of the 'Guidance note on fulfilling the requirements of Annexes VI to XI' provides that the rules set out in Annexes VII to XI may require certain tests to be undertaken earlier than or in addition to the standard requirements. Furthermore, in accordance with Annex I of the REACH Regulation, certain additional information may have to be generated if it is necessary for producing the chemical safety report (CSR). According to the last subparagraph of Section 0.5. of Annex I of REACH, if the manufacturer or importer considers that further information is necessary for producing his CSR and that this information can only be obtained by performing tests in accordance with Annex IX and X, he shall submit a proposal for a testing strategy, explaining why he considers that additional information is necessary and record this in the CSR under the appropriate heading.

This means that where justified, higher tier/further studies may be conducted already at a stage where the tonnage level of the substance registered would not require, as a standard, generating this data. In order to understand the toxicological properties of the registered substance in light of the adverse effects observed, it is necessary to investigate these effects further already at this stage so that appropriate risk management measures can be put in place and a safe use of the substance can be ensured.

You proposed testing with the rat. ECHA agrees with your proposal and specifies that the strain must be Sprague-Dawley because the concern for prenatal developmental toxicity stems from a study with Sprague-Dawley rat strain.

You proposed testing by the oral route. ECHA agrees with your proposal and specifies the oral administration to gavage to mimic the route of administration that raises the concern.

Furthermore, 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 test with the Substance.

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

Appendix B: Procedural history

ECHA started the testing proposal evaluation in accordance with Article 40(1) on 3 June 2019.

ECHA held a third party consultation for the testing proposal from 24 July 2019 until 9 September 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.

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.

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'[3].

4. Test material

   Selection of the test material(s) for UVCB substances

   The test material selected must be relevant for all the registrants of the Substance, i.e. it takes into account the variation in compositions reported by all members of the joint submission. 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 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. 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

[3] 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 and to all the registrants of the Substance.

Technical instructions are available in the manual "How to prepare registration and PPORD dossiers" on the ECHA website[4].

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

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)[6]

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.

[4] https://echa.europa.eu/manuals
[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

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]

Note: where applicable, the name of a third party representative (TPR) may be displayed in the list of recipients whereas the decision is sent to the actual registrant.