EUROPEAN CHEMICALS AGENCY

Helsinki, 13 May 2020

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

Date of submission for the jointly submitted dossier subject of this decision
26/03/2018

Registered substance subject to this decision, hereafter 'the Substance'
Substance name: N-(2-hydroxypropyl)oleamide
EC number: 203-828-2
CAS number: 111-05-7

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

DECISION ON A COMPLIANCE CHECK

Based on Article 41 of Regulation (EC) No 1907/2006 (REACH), ECHA requests that you submit the information listed below by the deadline of ***22 February 2021***.

A. Requirement applicable to the Registrant subject to Annex IX of REACH

Long-term toxicity testing on aquatic invertebrates (Annex IX, Section 9.1.5.; test method EU C.20./OECD TG 211) with the Substance;

Conditions to comply with the requests
You are bound by the request for information corresponding to the REACH Annex 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, VIII and 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. The timeline has been set to allow for sequential testing where relevant.

ECHA
EUROPEAN CHEMICALS AGENCY

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 request to comply with Annex IX of REACH

Under Articles 10(a) and 12(1) of REACH, a technical dossier registered at 100 to 1000 tonnes or more per year must contain, as a minimum, the information specified in Annexes VII to IX to REACH.

Long-term toxicity testing on aquatic invertebrates (Annex IX, Section 9.1.5.)

Long-term toxicity testing on aquatic invertebrates is a standard information requirement in Annex IX to the REACH Regulation.

You have provided a key study: OECD TG 211 (2014).

We have assessed this information and identified the following deficiencies:

Under Articles 3(28) and 10(a)(vii) and Annex I, Section 3.1.5. of REACH, a robust study summary must be provided for the study/ies giving rise to the highest concern. A robust study summary must cover critical information and allow an assessment of the validity and reliability of the study. For a study conducted according to OECD 211, information necessary for the assessment of its validity and reliability includes:

- For semi-static tests, where the concentrations do not remain within 80-120% of nominal, the effect concentrations should be expressed relative to the mean concentration over the whole exposure period, calculated from the geometric mean of the measured concentrations at the start and end of each media renewal period;
- Where a measured concentration at the end of the exposure period is absent or where it indicates that the substance is not detected, the validity of the test should be reconfirmed. In order to calculate a mean exposure concentration, the final concentration may be taken as the limit of detection for the method if the substance is not detected. When the substance is detected but not quantified, it is good practice to use half of the limit of quantification. Since there may be various methods for determining that, the method selected to determine mean measured concentrations should be made explicit in the reporting of test results;
- State a limit of quantification (LoQ) of the analytical method used.
- The possibility of losses during sampling, sample treatment and analysis must be considered and documented.

In the provided study, there is analytical monitoring demonstrating that the test substance concentration during the test was not maintained within the required 20% of the measured initial measured concentrations.

You have reported effect concentrations expressed as initial measured concentrations.

In addition, the measured initial concentration was not maintained and in most of the old medium, the Substance could not be quantified.

You did not state a LoQ of the analytical method used.

You have provided following possible explanations of the loss of the Substance;

- A reaction between the test item and the test medium, leading to a modification of the molecular mass and to a lack of detection by the analysis method;
- An adsorption of the test item on daphnia and/or algae.

However, you have not analysed further the extent of each of the potential loss processes.

For difficult to test substances, including poorly water soluble substances tested at low chemical concentrations, OECD GD 23 is applicable. As indicated there you may express the toxicity based on the mean initial measured concentrations if the initial test concentrations were below 80 % of the nominal and this concentrations was maintained (within ±20% of the initial) throughout the test including the final sampling (OECD DG 23, paragraph 177). Therefore the actual effect concentrations may be much lower than the current values based on the initial measured concentration. As you have not reported the limit of quantification of the analytical method, it is not possible for ECHA to calculate the effect concentrations.

Regarding, the possibility of losses during sampling, sample treatment and analysis, you have suggested that the loss of the Substance from the test solution may be due to 1) complexation between the Substance with the test mesium and/or 2) the adsorption of the Substance onto daphnia/algae. In terms of complexation, OECD DG 23 states that data from tests in which complexation has been judged to have had a significant bearing on the result are likely to be of questionable value for classifying test chemicals and for extrapolating to a predicted no effect concentration for risk assessment unless additional tests are conducted to attempt to determine the nature and extent of the effect. The extent to which complexation affects toxicity therefore should be determined where possible (paragraph 113).

For possible adsorption to the organisms, OECD DG 23 states that adsorption may also be a problem in chronic daphnid studies where test chemical adsorbed to the food algae can lead to apparent reduction in the freely dissolved concentration (when algae are separated prior to analysis), but would still provide a secondary exposure route via ingestion. In such cases it may be desirable to determine how much chemical is in both phases (test solution and algae) to explain observed toxicity to daphnids (paragraph 110).

You have not attempted to determine the nature and extent of complexation nor adsorption. Therefore, ECHA considered that you have not considered and documented the possibility of losses during sampling, sample treatment and analysis.

Because of this incorrect reporting and the missing analytical monitoring data (i.e. the limit of quantification for the method), the data provided do not allow an independent assessment of the validity and reliability of this study and its results for use in hazard assessment.

Currently as long as the missing elements are not provided and the incorrect reporting is not corrected, the information provided does not fulfil the information requirement.

In your comments to the draft decision, you have provided the following:

- Raw data
- Recalculated effect concentrations based on the geometric mean concentrations.
- the limit of quantification (LoQ) of the analytical method used.
- an analysis of the extent of each of the potential loss processes.
- Revised PNEC value

In addition, you indicate that you intend to update the technical dossier including the CSR to fulfil the requirements of this endpoint. ECHA has assessed the provided information. ECHA agrees that the submitted information is sufficient to fulfil the information requirement. However, you must provide this information in an updated dossier by the deadline of this decision. ECHA will assess the latest dossier update after the deadline in the decision has passed.

Appendix B: Procedural history

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 compliance check was initiated on 22 February 2019.

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(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.

ECHA
EUROPEAN CHEMICALS AGENCY

Appendix C: Observations and technical guidance

1. This compliance check decision does not prevent ECHA from initiating further 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 the Member States.

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 shall 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 registrants of the Substance are responsible for agreeing on the composition of the test material to be selected for carrying out the tests required by the present decision. 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.

   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.

   Technical instructions are available in the manual "How to prepare registration and PPORD dossiers"[3].

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

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

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 in this decision.

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]

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.

OECD Guidance documents[6]
Guidance Document on aqueous-phase aquatic toxicity testing of difficult test chemicals – No 23, referred to as OECD GD23.
Guidance Document supporting the OECD TG 443 on the extended one-generation reproductive toxicity test – No 151, referred to as OECD GD151.

[4] https://echa.europa.eu/guidance-documents/guidance-on-information-requirements-and-chemical-safety-assessment
[5] https://echa.europa.eu/support/registration/how-to-avoid-unnecessary-testing-on-animals/grouping-of-substances-and-read-across
[6] http://www.oecd.org/chemicalsafety/testing/series-testing-assessment-publications-number.htm

Appendix D: List of the registrant to which the decision is addressed and the corresponding information requirement applicable

Registrant Name	Registration number	(Highest) Data requirements to be fufilled
[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.