~~Confidential~~

Helsinki, 20 September 2021

Addressees
Registrant(s) of JS_AG8REAL as listed in the last Appendix of this decision

Date of submission of the dossier subject to this decision
05/09/2018

Registered substance subject to this decision ("the Substance")
Substance name: Reaction mass of L-Glutamic acid, N-(1-oxooctyl)-, sodium salt and N-L-glutamyl-L-glutamic acid, N'-(1-oxooctyl)-, sodium salt
EC number: [redacted]
CAS number: NS

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

DECISION ON A COMPLIANCE CHECK

Under Article 41 of Regulation (EC) No 1907/2006 (REACH), you must submit the information listed below, by the deadline of ***27 September 2022***.

The scope of this compliance check is limited to physical chemistry, environmental fate and behaviour and aquatic environment.

Requested information must be generated using the Substance unless otherwise specified.

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

1. Short-term toxicity testing on aquatic invertebrates (Annex VII, Section 9.1.1.; test method: EU C.2./OECD TG 202)

2. Growth inhibition study aquatic plants (Annex VII, Section 9.1.2.; test method: EU C.3./OECD TG 201)

3. Ready biodegradability (Annex VII, Section 9.2.1.1.; test method: OECD TG 301A/B/C/D/E/F or OECD TG 310)

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

- Appendix entitled "Reasons common to several requests";
- Appendix entitled "Reasons to request information required under Annex VII of REACH".

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 Annex VII to REACH, for registration at 1-10 tonnes per year (tpa), or as a transported isolated intermediate in quantity above 1000 tpa.

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, when adopted under Article 51 of REACH, may be appealed to the Board of Appeal of ECHA within three months of its notification to you. Please refer to http://echa.europa.eu/regulations/appeals for further information.

Failure to comply

If you do not comply with the information required by this decision by the deadline indicated above, ECHA will notify the enforcement authorities of your Member State.

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 on Reasons common to several requests

1. Assessment of the identity of the test material

The following issue concerns all the studies conducted for the following standard information requirements:

1. Short-term toxicity testing on aquatic invertebrates (Annex VII, Section 9.1.1.)
2. Growth inhibition study aquatic plants (Annex VII, Section 9.1.2.)
3. Ready biodegradability (Annex VII, Section 9.2.1.1.)

You have provided studies for the above listed endpoints (1 – 3) conducted with test material L-glutamic acid, N-(1-oxooctyl)-, sodium salt [redacted]. However, you indicated that the Substance is a reaction mass of L-Glutamic acid, N-(1-oxooctyl)-, sodium salt and N-L-glutamyl-L-glutamic acid, N'-(1-oxooctyl)-, sodium salt.

To comply with these information requirements, the test material in a study must be representative for the Substance (Art. 10 and Recital 19 of REACH; ECHA Guidance R.4.1). Therefore, the unambiguous characterisation of the composition of the Substance and test material used to generate the data is required to evaluate the representativeness 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, and include details on the composition, including quantitative and qualitative information on all constituents present in the test material.

To identify the test materials in all the studies for the endpoints 1 – 3, you have provided the test material name, and the purity of the test substance in water. Information on EC/CAS number and the detailed composition, including quantitative and qualitative information on all constituents present in the test material has not been provided.

In your comments to the initial draft decision, you outline the need to change the Substance's name in order to register it under REACH. You outline the communication details with the Registration team within ECHA. You outline whilst the current name in the dossier under the Substance identity is correct and in line with REACH, the Substance's previous name outlined in the environmental testing could not be changed. However, you confirm the environmental testing was done on the Substance. You indicate you will update your dossier to prove the identity of the substance tested with the Substance registered.

ECHA outlines that in the robust study summaries of the environmental testing, the identity of the substance tested with the Substance should be explicitly cross referenced.

In summary you provided your intentions for future data. No information could be assessed.

So this information does not change the outcome of ECHA's assessment.

Without comprehensive reporting of all constituents present in the test material (including their identity and concentrations) ECHA is unable to confirm that the test material(s) are representative of the Substance.

Please note that this decision does not take into account updates of the registration dossiers after the date on which you were notified of the draft decision according to Article 50(1) of REACH (see section 5.4. of ECHA's Practical Guide "How to act in Dossier Evaluation)."

Therefore, the provided information is rejected. In addition to this critical deficiency, further endpoint specific issues are described in the sections A1-A3, below.

Appendix A: Reasons to request information required under Annex VII of REACH

1. Short-term toxicity testing on aquatic invertebrates

Short-term toxicity testing on aquatic invertebrates is an information requirement under Annex VII to REACH (Section 9.1.1.).

You have provided an OECD TG 202 study (2016) with L-glutamic acid, N-(1-oxooctyl)-, sodium salt [redacted].

We have assessed this information and identified the following issues:

A. the identity of the test material

In the dossier assessed for this decision and in your comments to the initial draft decision, as explained in Section 1 of the Appendix on Reasons common to several requests, the test material currently cannot be considered representative for the Substance.

B. OECD 202 study

To fulfil the information requirement, a study must comply with OECD TG 202 and the requirements of OECD GD 23 (ENV/JM/MONO(2000)6/REV1) if the substance is difficult to test (Article 13(3) of REACH). Therefore, the following specifications must be met:

1. a reliable analytical method for the quantification of the test material in the test solutions with information on performance parameters (reported specificity, recovery efficiency, precision, limits of determination (i.e. detection and quantification) and working range) must be available;
2. the effect values can only be based on nominal or measured initial concentration if the concentration of the test material has been satisfactorily maintained within 20 % of the nominal or measured initial concentration throughout the test (see also ECHA Guidance R.7b, Section R.7.8.4.1).

Regarding point 1 above, in the dossier assessed for the initial draft decision, you stated that analytical total organic carbon (TOC) was measured during the study. However, you have not provided performance parameters of the analytical method (such as limit of determination).

Regarding point 2 above, in the dossier assessed for the initial draft decision, you reported the effect concentration based on the measured initial concentration and indicated that the test material has been stable throughout the test period. However, you did not provide measured concentrations to verify this. In addition, in the ready biodegradability endpoint, you reported that the test material degrades rapidly (i.e. 20% after 1 day and 87% after 6 days), suggesting that significant loss could have occurred, especially under static experimental set-up. Therefore, measured concentrations are needed to verify the stability of the test material and justify the reporting of the effect concentration.

In your comments to the initial draft decision, you indicate your intentions:

1. TOC evaluation method and measured concentration will be better specified as these parameters were evaluated by the laboratory and are available on the test report and its attachments.
2. An update of the IUCLID dataset to provide the missing details will be sent.
3. We will demonstrate that biodegradability doesn't affect the concentrations tested as time are shorter.

No information was provided to allow assessment. This information does not change the outcome of ECHA's assessment.

In addition to all the endpoints, you indicate a proposal to ECHA as follows:

1. Although you agree that the level of detail in study summaries is crucial, you consider that the concerns of ECHA are not well founded.
2. To reinforce further the information submitted in the registration dossiers, all data requested will be provided with detailed discussion.
3. You kindly request that ECHA takes in consideration an update of the dossier with all the requested information before deciding reports data are not sufficient.

In summary you provided your intentions for future data. No information was provided to allow assessment. This information does not change the outcome of ECHA's assessment.

Please note that this decision does not take into account updates of the registration dossiers after the date on which you were notified of the draft decision according to Article 50(1) of REACH (see section 5.4. of ECHA's Practical Guide "How to act in Dossier Evaluation)."

Based on the above,

- the reporting of the study is not sufficient to conduct an independent assessment of its reliability. Therefore, the requirements of OECD TG 202 are not met.

On this basis, the information requirement is not fulfilled.

Study design

The Substance is difficult to test due to the surface active properties and potential ready biodegradability. OECD TG 202 specifies that, for difficult to test substances, you must consider the approach described in OECD GD 23 or other approaches, if more appropriate for your substance. In all cases, the approach selected must be justified and documented. Due to the properties of Substance, it may be difficult to achieve and maintain the desired exposure concentrations. Therefore, you must monitor the test concentration(s) of the Substance throughout the exposure duration and report the results. If it is not possible to demonstrate the stability of exposure concentrations (i.e. measured concentration(s) not within 80-120% of the nominal concentration(s)), you must express the effect concentration based on measured values as described in OECD TG 202. In case a dose-response relationship cannot be established (no observed effects), you must demonstrate that the approach used to prepare test solutions was adequate to maximise the concentration of the Substance in the test solution.

2. Growth inhibition study aquatic plants

Growth inhibition study aquatic plants is an information requirement under Annex VII to REACH (Section 9.1.2.).

You have provided an OECD TG 201 study (2016) with L-glutamic acid, N-(1-oxooctyl)-, sodium salt [redacted].

We have assessed this information and identified the following issues:

A. the identity of the test material

In the dossier assessed for this decision and in your comments to the initial draft decision, a explained in Section 1 of the Appendix on Reasons common to several requests, the test

material currently cannot be considered representative for the Substance.

B. OECD TG 201 study

To fulfil the information requirement, a study must comply with OECD TG 201 and the requirements of OECD GD 23 (ENV/JM/MONO(2000)6/REV1) if the substance is difficult to test (Article 13(3) of REACH). Therefore, the following specifications must be met:

1. exponential growth in the control cultures is observed over the entire duration of the test;
2. at least 16-fold increase in biomass is observed in the control cultures by the end of the test;
3. the mean coefficient of variation for section-by-section specific growth rates (days 0-1, 1-2 and 2-3, for 72-hour tests) in the control cultures is ≤ 35%;
4. the coefficient of variation of average specific growth rates during the whole test period in replicate control cultures is ≤ 7% in tests with *Pseudokirchneriella subcapitata*;
5. the results can be based on nominal or measured initial concentration only if the concentration of the test material has been maintained within 20 % of the nominal or measured initial concentration throughout the test.

In the technical dossier, you indicated that the validity criteria were fulfilled. However, you did not provide any raw data to verify the validity criteria as outlined points 1-4 above.

Regarding point 5 above, you reported the effect concentration based on the measured initial concentration and indicated that the test material has been stable throughout the test period. However, you did not provide measured concentrations to verify this. In addition, in the ready biodegradability endpoint, you reported that the test material degrades rapidly (i.e. 20% after 1 day and 87% after 6 days), suggesting that significant loss could have occurred, especially under static experimental set-up. Therefore, measured concentrations are needed to verify the stability of the test material and justify the reporting of the effect concentration.

In your comments to the initial draft decision, you indicate your intentions:

1. The information requested is already present in the report and in its attachments.
2. An update of the IUCLID dataset to provide the missing details will be sent.
3. You will demonstrate that biodegradability doesn't affect the concentrations tested as time are shorter.

No information was provided to allow an assessment. This information does not change the outcome of ECHA's assessment.

Please note that this decision does not take into account updates of the registration dossiers after the date on which you were notified of the draft decision according to Article 50(1) of REACH (see section 5.4. of ECHA's Practical Guide "How to act in Dossier Evaluation)."

Based on the above,

- the reporting of the study is not sufficient to conduct an independent assessment of its reliability. Therefore, the requirements of OECD TG 201 are not met.

On this basis, the information requirement is not fulfilled.

Study design

OECD TG 201 specifies that for difficult to test substances OECD GD 23 must be followed. As already explained above, the Substance is difficult to test. Therefore, you must fulfil the requirements described in 'Study design' under Appendix [A.1].

3. Ready biodegradability

Ready biodegradability is an information requirement in Annex VII to REACH (Section 9.2.1.1.).

You have provided an OECD TG 310 study (2016) with L-glutamic acid, N-(1-oxooctyl)-, sodium salt (1:2).

We have assessed this information and identified the following issues:

A. the identity of the test material

In the dossier assessed for this decision and in your comments to the initial draft decision, as explained in Section 1 of the Appendix on Reasons common to several requests, the test material currently cannot be considered representative for the Substance.

B. OECD 310 study

To fulfil the information requirement, a study must comply with the OECD TG 301 or 310 (Article 13(3) of REACH). Therefore, for a study according to OECD TG 301, the following requirements must be met:

- The inoculum is not be pre-adapted to the test material;
- If activated sludge or a secondary effluent is used, it must be taken from a treatment plant or laboratory-scale unit receiving predominantly domestic sewage;
- For substances that are widely used and continuously emitted to waste water treatment plants (WWTPs), e.g. if they are ubiquitous in consumer products, it is acknowledged that pre-exposure of the degrading microorganisms may not be avoided. In this case, use of such inocula can be acceptable provided that the level of pre-exposure remains low. However, inocula from WWTPs influenced by point sources must not be used, e.g. if effluents from an industrial site using the substance are connected to the municipal WWTP.
- The concentration of the inoculum is set to reach a bacterial cell density of 10^2 to 10^5 cells/L in the test vessel.

In the technical dossier, you did not specify whether the inoculum is pre-adapted to the test material. In addition, you stated that the inoculum was "*aerobic sludge that has been selected by the mixed treatment plant of urban (about 66%) and industrial (about 34%)*". You did not provide information on the concentration of the inoculum.

You have not demonstrated that the inoculum is not pre-adapted to the test material nor inocula was not taken from the industrial site using the Substance. In addition, you did not demonstrate that the inocula meets the specification of the TG 310.

In your comments to the initial draft decision, you indicate your intentions:

1. The information requested is already present in the report and in its attachments.
2. An update of the IUCLID dataset to provide the missing details will be sent.

In summary you provided your intentions for future data. No information was provided to allow an assessment. This information does not change the outcome of ECHA's assessment.

Please note that this decision does not take into account updates of the registration dossiers after the date on which you were notified of the draft decision according to Article 50(1) of REACH (see section 5.4. of ECHA's Practical Guide "How to act in Dossier Evaluation)."

Therefore, there are critical methodological deficiencies affecting the reliability of the test results, we are not in a position to conduct an independent assessment of the study reliability.

On this basis, the information requirement is not fulfilled.

Appendix B: 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[2].

B. Test material

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 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.

Technical instructions on how to report the above is available in the manual on How to prepare registration and PPORD dossiers[3].

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

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Appendix C: General recommendations when conducting and reporting new tests for REACH purposes

A. Environmental testing for substances containing multiple constituents

Your Substance contains multiple constituents and, as indicated in ECHA Guidance R.11 (Section R.11.4.2.2), you are advised to consider the following approaches for persistency, bioaccumulation and aquatic toxicity testing:

- the "known constituents approach" (by assessing specific constituents), or
- the "fraction/block approach, (performed on the basis of fractions/blocks of constituents), or
- the "whole substance approach", or
- various combinations of the approaches described above

Selection of the appropriate approach must take into account the possibility to characterise the Substance (i.e. knowledge of its constituents and/or fractions and any differences in their properties) and the possibility to isolate or synthesize its relevant constituents and/or fractions.

Appendix D: Procedure

This decision does not prevent ECHA from initiating further compliance checks at a later stage on the registrations present.

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

The compliance check was initiated on 9 April 2020 .

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.

Appendix E: List of references - ECHA Guidance[4] 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)[5]

RAAF - considerations on multiconstituent substances and UVCBs (RAAF UVCB, March 2017)

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.

OECD Guidance documents[6]
Guidance Document on aqueous–phase aquatic toxicity testing of difficult test chemicals – No 23, referred to as OECD GD 23.

[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

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.

Appendix F: Addressees of this decision and their corresponding information requirements

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]

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.