~~Confidential~~

Helsinki, 13 April 2022

Addressees
Registrants of JS_203_765_0 as listed in the last Appendix of this decision

Date of submission of the dossier subject to this decision
17/04/2019

Registered substance subject to this decision ("the Substance")
Substance name: 2-methylundecanal
EC number: 203-765-0
CAS number: 110-41-8

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 ***19 July 2024***.

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

B. Information required from all the Registrants subject to Annex IX of REACH

1. Long-term toxicity testing on fish (Annex IX, Section 9.1.6.; test method: OECD TG 210)

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

- Appendix/Appendices entitled "Reasons to request information required under Annexes VII to X of REACH", respectively.

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;
- the information specified in Annexes VII, VIII and IX to REACH, for registration at 100-1000 tpa;

You are only required to share the costs of information that you must submit to fulfil your information requirements.

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". 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 Mike Rasenberg, 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 to request information required under Annex VII of REACH

1. 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 the following information:

i. OECD TG 201, Aldehyde C12 MNA Pure: Inhibition of Growth to the Alga *Pseudokirchneriella subcapitata*, key study, 2013, [redacted].

We have assessed this information and identified the following issues:

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:

Validity criteria

- exponential growth in the control cultures is observed over the entire duration of the test.

  However, section-by-section growth rates in the control cultures were not reported (i.e. 0-24h, 24-48h and 48-72h).

- at least 16-fold increase in biomass is observed in the control cultures by the end of the test.

  However, the initial biomass and the biomass in the control at the end of the test were not reported.

- the mean coefficient of variation (CV%) 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%.

  However, calculated CV% of section-by-section specific growth rates are not reported.

- 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*.

  However, average specific growth rates during the whole test period in replicate control cultures were not reported.

Reporting of the methodology and results

- the results of algal biomass determined in each flask at least daily during the test period are reported in a tabular form.

  However, tabulated data on the algal biomass determined daily for each treatment group and control are not reported;

Based on the above, the validity criteria of OECD TG 201 are not met. More specifically, the exponential growth over entire test period cannot be confirmed, since the section-by-section growth rates in the control cultures are not reported. Further, 16-fold increase of biomass during the test and the required coefficient of variations cannot be confirmed, since the daily results of biomass determinations during the test are not reported. This means that the reliability of the test cannot be independently assessed. Therefore, the requirements of OECD TG 201 are not met.

In your comments on the draft decision, you submitted tabulated biomass data at 0, 24, 48 and 72 hours of the test and the required coefficients of variations, supported by documents Appendix A and Attachments I and II. ECHA has assessed the information against the requirement in OECD TG 201. The information you have provided in your comments addresses the incompliances identified in this decision for this information requirement. However, as the information is currently not available in your registration dossier, the data gap remains. You should therefore submit this information in an updated registration dossier by the deadline set out in the decision.

On this basis, the information requirement is not fulfilled.

Study design

The Substance is difficult to test due to the low water solubility (1.6 mg/L) and adsorptive properties (logKow = 4.9). OECD TG 201 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 201. 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.

Appendix B: Reasons to request information required under Annex IX of REACH

1. Long-term toxicity testing on fish

Long-term toxicity testing on fish is an information requirement under Annex IX to REACH (Section 9.1.6.).

You have provided the following information:

i. a justification to omit the study which you consider to be based on Annex IX, Section 9.1., Column 2. In support of your adaptation, you provided the following justification:

Long-term fish toxicity testing as described in Annex IX of Regulation (EC) No 1907/2006 is not considered to be necessary as the chemical safety assessment demonstrates safe use of 2-methylundecanal.

We have assessed this information and identified the following issue:

Annex IX, Section 9.1., Column 2 does not allow omitting the need to submit information on long-term toxicity to fish under Column 1. It must be understood as a trigger for providing further information on long-term toxicity to fish if the chemical safety assessment according to Annex I indicates the need (Decision of the Board of Appeal in case A-011-2018).

Your adaptation is therefore rejected.

In the comments to the draft decision, you refer to the ECHA guidance R.7b: Endpoint specific guidance, Version 4.0 June 2017, section R.7.8.2 (p. 15) and section R.7.8.4.3, and also to R.5: Adaptation of information requirements, Version 2.1, December 2011, R.5.1.3.2 (p. 11). Based on these you argue that *"the ECHA guidance suggest that long term testing on invertebrates (preferably daphnia) and fish are not a requirement for Annex IX substances, if the chemical safety assessment does NOT indicate the need to investigate further the effects on aquatic organisms (e.g. if the results from a quantitative assessment give PEC/PNEC < 1), meaning that an exposure based adaptation may be applied"*.

We understand that with your comment, you intend to refer to an adaptation under Annex IX, Section 9.1., Column 2.

We have assessed this information and identified the following issue:

The Board of Appeal's decision (A-011-2018) from 4 May 2020 states that REACH Annex IX (section 9.1, column 2) does not allow registrants to omit information on long term toxicity to fish under column 1. Instead, it must be understood as a trigger for providing further information on long-term aquatic toxicity if the chemical safety assessment according to Annex I indicates such a need. In practice, this means that further long-term fish toxicity tests than those described in Annex IX, column 1, may be required depending on the properties of the substance. As explained on ECHA's website (https://echa.europa.eu/standard-information-requirements-recommendations), The Board of Appeal decision on case A-011-2018 overrides advice given in the ECHA Guidance. This means that the as a consequence, information on aquatic toxicity described in ECHA's Guidance on Information Requirements and Chemical Safety Assessment related to REACH Annex IX, section 9.1, Column 2 as a waiver for the information requirement under Column 1 is no longer valid. In situations where exposure is absent or so low that additional hazard information will not lead to improved risk management, the registrant may consider using an exposure-based adaptation (Annex XI, Section 3; ECHA Guidance R.5).

However, you have provided the adaptation according to Annex IX, Section 9.1., Column 2 and also referred to ECHA guidance to support the adaptation. As explained above, the applied adaptation is not acceptable.

Please note that this decision does not consider 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). You remain responsible for complying with this decision by the set deadline.

On this basis, the information requirement is not fulfilled.

Study design

OECD TG 210 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.

Appendix C: 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

Before generating new data, you must agree within the joint submission on the chemical composition of the material to be tested (Test Material) which must be relevant for all the registrants of the Substance.

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 variation in compositions reported by all members of the joint submission,
   - 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 and whether it is suitable for use by all members of the joint submission.

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

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 04 May 2021.

ECHA notified you of the draft decision and invited you to provide comments.

ECHA took into account your comments and did not amend the requests.

In your comments on the draft decision, you requested an extension of the deadline to provide information from 9 to 24 months (best case) or up to 40 months (worst case) from the date of adoption of the decision. You justify the extension by referring to lab capacities of main Contract Research Organisations (CROs) and also to the fact that the substance is difficult to test. You further justify the need to extent the deadline to 40 months by referring to the ECHA Guidance on Registration, Section 7.2. You consider that "*an additional deadline of 12 month (after the final testing reports are received) should be applied as the requested data would trigger the rework of the current CSR*". However, the above section of the ECHA Guidance on Registration refers to relevant maximum deadlines for spontaneous update in relation to the conditions set out under Article 22(1) of REACH. Under Article 22(2) of REACH, an update of the registration dossier to provide the information required by the decision made in accordance with Artcile 40 must be provided within the deadline specified in that decision. Therefore, your request for an additional extension of 12 months is irrelevant.

ECHA has assessed the information provided as part of your justification and has granted the request and extended the deadline to 24 months.

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)[6]

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[7]

[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] https://echa.europa.eu/documents/10162/13630/raaf_uvcb_report_en.pdf/3f79684d-07a5-e439-16c3-d2c8da96a316
[7] http://www.oecd.org/chemicalsafety/testing/series-testing-assessment-publications-number.htm

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

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.

~~Confidential~~

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]
[redacted]	[redacted]	[redacted]
[redacted]	[redacted]	[redacted]
[redacted]	[redacted]	[redacted]
[redacted]	[redacted]	[redacted]
[redacted]	[redacted]	[redacted]
[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.