EUROPEAN CHEMICALS AGENCY

~~Confidential~~

Helsinki, 27 January 2021

Addressees
Registrants of JS 201-898-9 / 89-32-7 as listed in the last Appendix of this decision

Date of submission of the dossier subject to this decision
23/04/2018

Registered substance subject to this decision ("the Substance")
Substance name: Benzene-1,2:4,5-tetracarboxylic dianhydride
EC number: 201-898-9
CAS number: 89-32-7

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 ***2 November 2021***.

Requested information must be generated using the Substance or alternatively the analogue substance pyromellitic acid (benzene-1,2,4,5-tetracarboxylic acid, EC: 201-879-5).

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 // EU C.26./OECD TG 221])

The reasons for the request(s) are explained in the following 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;
- the information specified in Annexes VII and VIII to REACH, for registration at 10-100 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". 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 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. An OECD TG 201 study conducted on the analogue benzene-1,2,4,5-tetracarboxylic acid (EC: 201-879-5).

We have assessed this information and identified the following issue:

Tests on substances must be conducted in accordance with the OECD test guidelines or other internationally recognised test methods (Article 13(3) of REACH).

OECD TG 201 require(s) that the following conditions are met (among others):

Validity criteria

- exponential growth in the control cultures is observed over the entire duration of the test;
- at least 16-fold increase in biomass is observed in the control cultures by the end of the test;
- 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%;
- the coefficient of variation of average specific growth rates during the whole test period in replicate control cultures is ≤ 7% in tests with *Desmodesmus subspicatus*.

Technical specifications impacting the sensitivity/reliability of the test

- one of the two alternative growth medium (*i.e.* the OECD or the AAP medium) is used. Any deviations from recommended test media must be described and justified.

Characterisation of exposure

- a reliable analytical method for the quantification of the test material in the test solutions with reported specificity, recovery efficiency, precision, limits of determination (*i.e.* detection and quantification) and working range must be available.

Reporting of the methodology and results

- the method for determination of biomass and evidence of correlation between the measured parameter and dry weight are reported;
- detailed results including growth data in tabular form, graphical presentation of the concentration/effect relationship and estimates of toxicity for response variables e.g., EC_{50} and associated confidence intervals should be reported.

Your registration dossier provides an OECD TG 201 showing the following:

Validity criteria

- section-by-section growth rates (i.e. 0-24 h; 24-48 h and 48-72 h) in the control cultures were not reported;
- the initial biomass and the biomass at the end of the test were not reported;
- the mean coefficient of variation for section-by-section specific growth was not reported;
- the coefficient of variation of average specific growth rates during the whole test period in replicate control cultures was not reported.

Technical specifications impacting the sensitivity/reliability of the test

- the test medium is described as a reconstituted freshwater culture medium. You have not provided a justification as why you did not use one of the two alternative growth medium of the OECD TG 201;

Characterisation of exposure

- you have not provided performance parameters of the analytical method;

Reporting of the methodology and results

- the method used to determine algal biomass is not reported;
- detailed results were not reported including growth data in tabular form, graphical presentation of the concentration/effect relationship and confidence intervals of the response variable (EC_{50}).

Based on the above, the validity criteria of OECD TG 201 are not met as the growth rates in the control culture, biomass development, the specified coefficients of variation were not reported. All of these are considered as necessary information in assessing that the used algae strain's growth rate meets the requirements of the test guideline.

In addition, the properties of the applied test medium are not described and there is no reasoning available why this medium was selected. The standard test media specified in the test guideline are normally applied to guarantee sufficient nutrition environment for the algae and if there are deviations, they should be reported. In this case it is not possible to assess how the selected medium affected the algal growth and sensitivity of the test.

Also the performance parameters of the reported analytical method, to measure test substance concentrations in the test solutions, were not reported. Therefore, the reliability of the applied method and reported measured concentrations cannot be independently assessed.

The reporting of the methods and results has also some deficiencies, for example the method to determine algal biomass and detailed results such as concentration/effect relationship of the study were not reported. Due to these deficiencies it is not possible assess the reliability of the reported effect concentrations.

Therefore, the requirements of OECD TG 201 are not met.

On this basis, the information requirement is not fulfilled.

In your comments on the draft decision you provided information showing that the algae test reported in the technical dossier is valid. You supported this with the full study report.

ECHA has assessed this new information against the requirements in OECD TG 201 and concludes that it is adequate to resolve the deficiencies identified above. The information you have provided in your comments therefore addresses the incompliances identified in this draft decision for this information requirement. However, until this information becomes available in your registration dossier, the data gap remains. You should therefore submit this information in an updated registration dossier by the deadline set in the decision.

Study design

The Substance is unstable in water and hydrolyses quickly in contact with water to pyromellitic acid (benzene-1,2,4,5-tetracarboxylic acid, EC: 201-879-5). Its half-life time $t_{(1/2)}$ in purified water is less than 20 minutes at 25°C. Therefore, the requested OECD TG 201 test can be performed with the hydrolysis product, i.e. pyromellitic acid.

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

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

Testing strategy for aquatic toxicity testing

You are advised to consult ECHA Guidance R.7b, (Section R.7.8.5) which describes the Integrated Testing Strategy, to determine the sequence of aquatic toxicity tests and testing needed.

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 20 March 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. However, the requested test do not need to be performed if you include the required information in an updated version of the technical dossier by the deadline set in the decision.

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.

[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

OECD Guidance documents[7]
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.

[7] http://www.oecd.org/chemicalsafety/testing/series-testing-assessment-publications-number.htm

Appendix F: Addressees of this decision and the corresponding information requirements applicable to them

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.