~~Confidential~~

Helsinki, 5 January 2023

Addressees
Registrant(s) of 1,12-DODECANDIOL as listed in Appendix 3 of this decision

Date of submission of the dossier subject to this decision
05/05/2020

Registered substance subject to this decision ("the Substance")
Substance name: Dodecane-1,12-diol
EC number: 227-133-9

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 ***11 April 2024***.

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

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)

Information required from all the Registrants subject to Annex VIII of REACH

3. Short-term toxicity testing on fish (Annex VIII, Section 9.1.3.; test method: EU C.1./OECD TG 203)

The reasons for the decision(s) are explained in Appendix 1.

Information required depends on your tonnage band

You must provide the information listed above for all REACH Annexes applicable to you in accordance with Articles 10(a) and 12(1) of REACH. The addressees of the decision and their corresponding information requirements based on registered tonnage band are listed in Appendix 3.

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 requirements for testing and reporting new tests under REACH, see Appendix 4.

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

Appendix 1: Reasons for the decision
Appendix 2: Procedure
Appendix 3: Addressees of the decision and their individual information requirements
Appendix 4: Conducting and reporting new tests under REACH

[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 1: Reasons for the decision

Contents

Reasons related to the information under Annex VII of REACH

1. Short-term toxicity testing on aquatic invertebrates

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

1.1. Information provided

2 You have provided a study according to OECD TG 202.

1.2. Assessment of the information provided

3 We have assessed this information and identified the following issues:

4 To fulfil the information requirement, a study must comply with OECD TG 202 (Article 13(3) of REACH). Therefore, the following specifications must be met:

5 Validity criteria

a) the percentage of immobilised daphnids is ≤ 10% at the end of the test in the controls (including the solvent control, if applicable);
b) the dissolved oxygen concentration is ≥ 3 mg/L in all test vessels at the end of the test;

6 Technical specifications impacting the sensitivity/reliability of the test

c) young daphnids, aged less than 24 hours at the start of the test, are used;
d) test animals are not fed during the test;
e) at least 20 animals are used at each test concentration and for the controls;
f) the dilution water does not induce signs of stress to the test animals over the duration of the test;
g) the test medium fulfils the following condition(s): particulate matter ≤ 20 mg/L, total organic carbon (TOC) ≤ 2 mg/L, hardness between 140 and 250 mg/L (as $CaCO_3$), pH between 6 and 9;
h) if the dilution water is from a natural source, conductivity and total organic carbon (TOC) or chemical oxygen demand (COD) are measured whenever these characteristics may have changed significantly;
i) the pH variation is < 1.5 units;
j) at least five concentrations are tested. If less than five concentrations are included in the test design a justification must be provided;
k) test concentrations follow a geometric series with a spacing factor < 2.2;
l) the test concentrations are below the limit of solubility of the test material in the dilution water;

7 Characterisation of exposure

m) analytical monitoring must be conducted. 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;
n) the concentrations of the test material are measured at least at the highest and lowest test concentration, at the beginning and end of the test;

8 Your registration dossier provides an OECD TG 202 showing the following:

9 Validity criteria

10 No information is provided on:

a) the percentage of immobilised daphnids at the end of the test in the controls;
b) the dissolved oxygen concentration;

11 Technical specifications impacting the sensitivity/reliability of the test

12 No information is provided on:

c) the age of the test animals;
d) whether they were not fed during the test;
e) the number of animals used for each test concentration and for the controls;
f) whether signs of stress were not observed in the test animals of the dilution water control during the test;
g) the test medium;
h) the pH and pH variation;
i) the concentrations tested;

13 Characterisation of exposure

14 No information is provided on:

j) the analytical method applied (specificity, recovery efficiency, precision, limits of determination (i.e. detection and quantification) and working range);
k) what test concentrations were measured and when.

15 Based on the above, you have not provided an adequate and reliable documentation of the study. The reporting of the study is not sufficient to conduct an independent assessment of its validity and reliability.

16 Therefore, the requirements of OECD TG 202 are not met.

1.3. Information provided in your comments

17 In your comments to the draft decision, you acknowledge the shortcomings reported above. You agree to update the robust study summary by providing detailed information on: the validity criteria, the technical specifications impacting the sensitivity/reliability of the study, the characterisation of exposure.

18 However, as that information is currently not available in your registration dossier, the data gap remains. You should submit this information in an updated registration dossier by the deadline set in the decision.

1.4. Conclusion

19 On this basis, the information requirement is not fulfilled.

2. Growth inhibition study aquatic plants

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

2.1. Information provided

21 You have provided a study according to OECD TG 201 on test species Desmodesmus subspicatus.

2.2. Assessment of the information provided

22 We have assessed this information and identified the following issues:

23 To fulfil the information requirement, a study must comply with OECD TG 201 (Article 13(3) of REACH). Therefore, the following specifications must be met:

24 Validity criteria

a) exponential growth in the control cultures is observed over the entire duration of the test;
b) at least 16-fold increase in biomass is observed in the control cultures by the end of the test;
c) 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%;
d) 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*;

25 Technical specifications impacting the sensitivity/reliability of the test

e) three replicates at each test concentration and at least three replicates for controls (including solvent controls, if applicable) are included;
f) at least 6 treatment replicates are included if a limit test (at 100 mg/L or at the limit of solubility of the test substance) is conducted;
g) one of the two alternative growth medium (*i.e.* the OECD or the AAP medium) is used;
h) for *Desmodesmus subspicatus* the initial cell density is 2-5 x10^3 cells/mL;
i) the pH of the control medium does not increase by > 1.5 units;
j) the test concentrations are arranged in a geometric series with a spacing factor ≤ 3.2, unless a higher factor is justified by a flat concentration response curve;
k) the test concentrations are below the limit of solubility of the test material in the dilution water;
l) if a solvent is used, its concentration is ≤ 100 µg/L;

26 Characterisation of exposure

m) analytical monitoring is conducted. Adequate information on the analytical method (including performance parameters of the method) is provided;
n) the test media prepared specifically for analysis of exposure concentrations during the test is treated identically to those used for testing (*i.e.* inoculated with algae and incubated under identical conditions);
o) the concentrations of the test material are measured at least at the beginning and end of the test:
    i. at the highest, and
    ii. at the lowest test concentration, and
    iii. at a concentration around the expected EC_{50}.

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

28 Validity criteria

29 No information is provided on:

a) growth in the control cultures;
b) the biomass at the start and end of the test or biomass increase;
c) the mean coefficient of variation for section-by-section specific growth in the control;
d) the coefficient of variation of average specific growth rates during the whole test period in replicate control cultures;

30 Technical specifications impacting the sensitivity/reliability of the test

31 No information is provided on:

e) the number of replicates for each test concentration and for the controls;

f) the test medium;
g) the initial cell density;
h) the pH and pH variation in the controls;
i) the concentrations tested;
j) whether a solvent was used;

32 Characterisation of exposure

33 No information is provided on:

k) the analytical method applied and its performance parameters;
l) whether the test media prepared specifically for analysis of exposure concentrations was inoculated with algae;
m) what test concentrations were measured and when.

34 Based on the above, you have not provided an adequate and reliable documentation of the study. The reporting of the study is not sufficient to conduct an independent assessment of its validity and reliability.

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

2.3. Information provided in your comments

36 In your comments to the draft decision, you acknowledge the shortcomings reported above. You agree to update the robust study summary by providing detailed information on: the validity criteria, the technical specifications impacting the sensitivity/reliability of the study, the characterisation of exposure.

37 However, as that information is currently not available in your registration dossier, the data gap remains. You should submit this information in an updated registration dossier by the deadline set in the decision.

2.4. Conclusion

38 On this basis, the information requirement is not fulfilled.

Reasons related to the information under Annex VIII of REACH

3. Short-term toxicity testing on fish

39 Short-term toxicity testing on fish is an information requirement under Annex VIII to REACH (Section 9.1.3.).

3.1. Information provided

40 You have provided the following information:

41 You have provided a key study according to OECD TG 203.

3.2. Assessment of the information provided

42 We have assessed this information and identified the following issues:

43 To fulfil the information requirement, a study must comply with OECD TG 203 (Article 13(3) of REACH). Therefore, the following specifications must be met:

44 Validity criteria

a) mortality in the control(s) is ≤ 10% (or one fish, if fewer than 10 control fish are tested) at the end of the test;
b) the dissolved oxygen concentration is ≥ 60% of the air saturation value in all test vessels throughout the exposure;
c) the analytical measurement of test concentrations is conducted;

45 Technical specifications impacting the sensitivity/reliability of the test

d) all fish are held in the laboratory for at least 9 days before being used for testing (including a 48 hours settling-in period and a 7 days acclimation period);
e) only batches showing mortalities below 5% of the population in seven days and with no diseases or abnormalities are used;
f) the test is conducted on juveniles of similar age (or size);
g) the test duration is 96 hours or longer;
h) the dilution water does not induce signs of stress to the test animals over the duration of the test;
i) the test medium fulfils the following condition(s): particulate matter ≤ 5 mg/L, total organic carbon (TOC) ≤ 2 mg/L or carbon oxygen demand (COD) ≤ 5 mg/L;
j) if natural water is used, the following condition(s) are fulfilled: DOC or TOC and nitrate-content (NO_3) is measured once prior to the test. Analyses of nitrate and chlorine is performed on each batch of dilution water. Quality parameters of the dilution water are determined at least biannually, including heavy metals, major anions and cations, pesticides and total organic carbon and suspended solids.
k) although not generally recommended, if a solvent is used, its concentration in the test water is below its critical micelle concentration (if relevant) and, in all case, ≤ 100 mg/L (or 0.1 mL/L);
l) the fish-to-water loading rate is ≤ 0.8 g of fish (wet weight) per litre of water for static and semi-static tests, it is ≤ 0.5 g of fish (wet weight) per litre of water per day and 5 g/L at any time for flow-through tests.
m) the photoperiod is adequate for the selected test species;
n) the fish are not be fed during the exposure period;
o) at least 7 fish are used at each test concentration and in the control(s);

46 Characterisation of exposure

p) analytical monitoring must be conducted. 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.

47 Your registration dossier provides an OECD TG 203 showing the following:

48 Validity criteria

49 No information is provided on:

a) mortality in the control(s);
b) the dissolved oxygen concentration;
c) whether analytical measurement of the test concentrations was conducted;

50 Technical specifications impacting the sensitivity/reliability of the test

d) The test duration is reported to be only 48 hours;

51 Furthermore, no information is provided on:

e) whether the fish were acclimatised before the start of the test;
f) the mortality in the batch of fish used for testing;
g) the size or age of fish used for testing;
h) whether signs of stress were not observed in the test animals of the dilution water control during the test;
i) particulate matter, total organic carbon (TOC) or carbon oxygen demand (COD) in the test medium;
j) the source and characteristics of the dilution water;
k) whether a solvent was used;
l) the test design (static, semi-static or flow-through) and the fish-to-water loading rate;
m) the photoperiod;
n) whether the fish were fed during the exposure period;
o) the number of fish tested for each test concentration;

52 Characterisation of exposure

53 No information is provided on:

p) whether analytical monitoring of exposure was conducted.

54 Based on the above, you have not provided an adequate and reliable documentation of the study. The reporting of the study is not sufficient to conduct an independent assessment of its validity and reliability.

55 Therefore, the requirements of OECD TG 203 are not met.

3.3. Information provided in your comments

56 In your comments to the draft decision, you acknowledge the shortcomings reported above. You also provide the study report in a file attached to your comments.

57 The study report does provide information that addresses some of the issues listed above, e.g., on some of the test conditions and on the fact that the dissolved oxygen concentration was ≥ 60% of the air saturation value.

58 However, it seems that no analytical measurement of the test concentrations was conducted in this study.

59 You claim that "the study was conducted in 1985 to the state of the art available at that time". However, you have not provided an adaptation under Annex XI, Section 1.1.2 of the REACH Regulation nor attempted to demonstrate that all the conditions of that adaptation

are met, in particular adequate and reliable coverage of the key parameters of OECD TG 203.

60 As an aside, ECHA notes that the version of OECD TG 203 adopted on 4 April 1984, applicable at the time the study was conducted, indicated as one of its validity criteria "evidence that the concentration of the substance being tested has been satisfactorily maintained […] over the test period". In your comments, you explain that the maximum dissolved concentration of 18.6 mg/L observed in the solubility study can be assumed also for the fish study. However, your explanation does not constitute actual evidence that the concentration of the substance has been satisfactorily maintained over the test period.

61 You also invoke article 13.2 of REACH as a justification for not conducting a new test on vertebrate animals. However, minimisation of vertebrate animal testing is not on its own a legal ground for adapting the information requirement.

3.4. Conclusion

62 On this basis, the information requirement is not fulfilled.

References

The following documents may have been cited in the decision.

Guidance on information requirements and chemical safety assessment (Guidance on IRs & CSA)

Chapter R.4 Evaluation of available information; ECHA (2011).
Chapter R.6 QSARs, read-across and grouping; ECHA (2008).
Appendix to Chapter R.6 for nanoforms; ECHA (2019).
Chapter R.7a Endpoint specific guidance, Sections R.7.1 – R.7.7; ECHA (2017).
Appendix to Chapter R.7a for nanomaterials; ECHA (2017).
Chapter R.7b Endpoint specific guidance, Sections R.7.8 – R.7.9; ECHA (2017).
Appendix to Chapter R.7b for nanomaterials; ECHA (2017).
Chapter R.7c Endpoint specific guidance, Sections R.7.10 – R.7.13; (ECHA 2017).
Appendix to Chapter R.7a for nanomaterials; ECHA (2017).
Appendix R.7.13-2 Environmental risk assessment for metals and metal compounds; ECHA (2008).
Chapter R.11 PBT/vPvB assessment; ECHA (2017).
Chapter R.16 Environmental exposure assessment; ECHA (2016).

Guidance on data-sharing; ECHA (2017).

All Guidance on REACH is available online: https://echa.europa.eu/guidance-documents/guidance-on-reach

Read-across assessment framework (RAAF)

RAAF, 2017 Read-across assessment framework (RAAF), ECHA (2017)
RAAF UVCB, 2017 Read-across assessment framework (RAAF) – considerations on multi- constituent substances and UVCBs), ECHA (2017).

The RAAF and related documents are available online:
https://echa.europa.eu/support/registration/how-to-avoid-unnecessary-testing-on-animals/grouping-of-substances-and-read-across

***OECD Guidance documents* (OECD GDs)**

OECD GD 23 Guidance document on aquatic toxicity testing of difficult substances and mixtures; No. 23 in the OECD series on testing and assessment, OECD (2019).
OECD GD 29 Guidance document on transformation/dissolution of metals and metal compounds in aqueous media; No. 29 in the OECD series on testing and assessment, OECD (2002).
OECD GD 150 Revised guidance document 150 on standardised test guidelines for evaluating chemicals for endocrine disruption; No. 150 in the OECD series on testing and assessment, OECD (2018).
OECD GD 151 Guidance document supporting OECD test guideline 443 on the extended one-generation reproductive toxicity test; No. 151 in the OECD series on testing and assessment, OECD (2013).

Appendix 2: 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 4 March 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 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.

The deadline of the decision is set based on standard practice for carrying out OECD TG tests. It has been exceptionally extended by 6 months from the standard deadline granted by ECHA to take into account currently longer lead times in contract research organisations.

Appendix 3: Addressees of this decision and their corresponding information requirements

In accordance with Articles 10(a) and 12(1) of REACH, the information requirements for individual registrations are defined as follows:

- 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;
- the information specified in Annexes VII to X to REACH, for registration at more than 1000 tpa.

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]

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.

Appendix 4: Conducting and reporting new tests for REACH purposes

1. Requirements when conducting and reporting new tests for REACH purposes

1.1. 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].

1.2. 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