~~Confidential~~

Helsinki, 5 January 2023

Addressees
Registrant(s) of 112-47-0_NS as listed in Appendix 3 of this decision

Date of submission of the dossier subject to this decision
28/04/2017

Registered substance subject to this decision ("the Substance")
Substance name: Decane-1,10-diol
EC number: 203-975-2

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 ***14 April 2025***.

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

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

1. In vitro gene mutation study in bacteria (Annex VII, Section 8.4.1.; test method: OECD TG 471, 2020) using one of the following strains: E. coli WP2 uvrA, or E. coli WP2 uvrA (pKM101), or S. typhimurium TA102

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 repeated dose toxicity (28 days; Annex VIII, Section 8.6.1.) to be combined with the Screening for reproductive/developmental toxicity below

4. Screening for reproductive/developmental toxicity (Annex VIII, Section 8.7.1.; test method: EU B.64/OECD TG 422) by oral route, in rats

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

0. Reasons common to several requests

0.1. Assessment of the read-across approach

1 You have adapted the following standard information requirements by using grouping and read-across approach under Annex XI, Section 1.5:

i. Short-term repeated dose toxicity (28 day), (Annex VIII, Section 8.6.1.)

ii. Screening for reproductive/developmental toxicity (Annex VIII, Section 8.7.1.)

2 ECHA has considered the scientific and regulatory validity of your read-across approach(es) in general before assessing the specific standard information requirements in the following sections.

3 Annex XI, Section 1.5. specifies two conditions which must be fulfilled whenever a read-across approach is used. Firstly, there needs to be structural similarity between substances which results in a likelihood that the substances have similar physicochemical, toxicological and ecotoxicological properties so that the substances may be considered as a group or category. Secondly, it is required that the relevant properties of a substance within the group may be predicted from data for reference substance(s) within the group.

4 Additional information on what is necessary when justifying a read-across approach can be found in the Guidance on IRs and CSA, Chapter R.6. and related documents (RAAF, 2017; RAAF UVCB, 2017).

0.1.1. Predictions for toxicological properties

5 You provide a read-across justification document in IUCLID Section 7.8.1.

6 You predict the properties of the Substance from information obtained from the following source substance(s):

i. 1,6-hexanediol, EC No. 211-074-0.

7 You provide the following reasoning for the prediction of toxicological properties: ”In toxicology, the larger substances are considered to be less toxic because their absorption is lower than a small structure. In the present readacross approach, the data of 1,6-hexanediol (shorter structure) are used for the data gaps of 1,10-decanediol (longer structure). This read-across is considered to be valid, because the worst-case approach is followed.”

8 You also state that the Substance “has probably the same toxicity mechanism than 1,6-hexanediol (source substance).”

9 ECHA understands that your read-across hypothesis assumes that different compounds have the same type of effects. You predict the properties of your Substance based on a worst-case approach.

10 We have identified the following issue(s) with the prediction(s) of toxicological properties:

0.1.1.1. Missing supporting information

11 Annex XI, Section 1.5 of the REACH Regulation states that “physicochemical properties, human health effects and environmental effects or environmental fate may be predicted from data for reference substance(s)”. For this purpose “it is important to provide

supporting information to strengthen the rationale for the read-across" (Guidance on IRs and CSA R.6, Section R.6.2.2.1.f.). The set of supporting information should allow to verify the crucial aspects of the read-across hypothesis and establish that the properties of the Substance can be predicted from the data on the source substance(s).

12 Supporting information must include bridging studies to compare properties of the Substance and source substance or information to confirm your claimed worst-case prediction.

13 As indicated above, your read-across hypothesis is based on the assumption that the source substance constitutes a worst-case for the prediction of the property under consideration of the Substance. In this context, relevant, reliable and adequate information allowing to compare the properties of the Substance and of the source substance(s) is necessary to confirm a conservative prediction of the properties of the Substance from the data on the source substance(s). Such information can be obtained, for example, from bridging studies of comparable design and duration for the Substance and for the source substance(s).

14 No repeated dose toxicity or reproductive toxicity data are available on the Substance.

15 No studies investigating toxicokinetics or metabolism of the source substance and the Substance are available.

16 Therefore the available supporting information does not include relevant, reliable and adequate information for the Substance and of the source substance to support your read-across hypothesis.

17 In the absence of such information, you have not established that the source substance constitutes a worst-case for the prediction of the property under consideration of the Substance. Therefore, you have not provided sufficient supporting information to strengthen the rationale for the read-across.

0.1.1.2. Read-across hypothesis contradicted by existing data

18 Annex XI, Section 1.5. provides that "substances whose physicochemical, toxicological and eco-toxicological properties are likely to be similar or follow a regular pattern as result of structural similarity may be considered as a group or 'category' of substances". The Guidance on IRs and CSA, Section R.6.2.2.1.f. indicates that "it is important to provide supporting information to strengthen the rationale for the read-across". The set of supporting information should allow to verify the crucial aspects of the read-across hypothesis and establish that the properties of the Substance can be predicted from the data on the source substance.

19 The observation of differences in the toxicological properties between the source substance(s) and the Substance would contradict the hypothesis that the properties of the Substance can be predicted from the data on the source substances. An explanation why such differences do not affect the read-across hypothesis must be provided and supported by scientific evidence.

20 As indicated above, your read-across hypothesis is based on the assumption that the structurally similar Substance and source substances cause the same type of effect(s).

21 In the read-across justification document, you assume the source substance and the Substance have "the same physical and chemical properties, and a same toxicological profile" based on structural similarity, and based on OECD Toolbox toxicity and metabolism profiling.

22 Your OECD Toolbox toxicity profiling indicates a hepatotoxicity alert exclusively for the Substance.

23 The available OECD Toolbox profiler results on the Substance and on the source substance indicates differences in the toxicological properties of the substances. This contradicts your read-across hypothesis whereby the Substance and source substances cause the same type of effect(s). Therefore you have not demonstrated and justified that the properties of the source substance(s) and of the Substance are likely to be similar despite the observation of these differences.

0.1.1. Conclusion on the read-across approach

24 For the reasons above, you have not established that relevant properties of the Substance can be predicted from data on the source substance(s). Your read-across approach under Annex XI, Section 1.5. is rejected.

Reasons related to the information under Annex VII of REACH

1. In vitro gene mutation study in bacteria

25 In vitro gene mutation study in bacteria is a standard information requirement at Annex VII (Section 8.4.1.).

1.1. Information provided

26 You have provided:

i. In vitro gene mutation study in bacteria (1996) with the Substance.

1.2. Assessment of the information provided

27 We have assessed this information and identified the following issue(s):

1.2.1. Study not adequate for the information requirement

28 To fulfil the information requirement, the study must meet the requirements of OECD TG 471 (2020). Therefore, the following specifications must be:

i. The test must be performed with 5 strains: four strains of *S. typhimurium* (TA98; TA100; TA1535; TA1537 or TA97a or TA97) and one strain which is either *S. typhimurium* TA102 or *E. coli* WP2 uvrA or *E. coli* WP2 uvrA (pKM101)

29 The study i. is described as In vitro gene mutation study in bacteria. However, the following specifications are not according to the requirements of OECD TG 471 (2020):

i. results for the required fifth strain, S. typhimurium TA102 or E. coli WP2 uvrA or E. coli WP2 uvrA (pKM101).

30 The information provided does not cover one of the key parameters required by OECD TG 471.

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

1.3. Specification of the study design

32 To fulfil the information requirement for the Substance, the in vitro gene mutation study in bacteria (OECD TG 471, 2020) should be performed using one of the following strains: E. coli WP2 uvrA, or E. coli WP2 uvrA (pKM101), or S. typhimurium TA102.

2. Growth inhibition study aquatic plants

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

2.1. Information provided

34 You have provided a key study according to Commission Directive 92/69/EEC, on species Desmodesmus subspicatus, with the Substance.

2.2. Assessment of the information provided

35 We have assessed this information and identified the following issue(s):

36 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:

37 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 for species Desmodesmus subspicatus.

38 Technical specifications impacting the sensitivity/reliability of the test

- Three replicates at each test concentration and at least three replicates for controls (including solvent controls, if applicable) are included;
- 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;
- The initial biomass in the test cultures must be sufficiently low to allow exponential growth throughout the incubation period without risk of nutrient depletion. For test species *Desmodesmus subspicatus* the recommended initial cell density is 2-5 x10^3 cells/mL;
- the pH of the control medium does not increase by > 1.5 units.

39 Characterisation of exposure

- 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).

40 Your registration dossier provides a study showing the following issues:

41 Validity criteria

42 No information is provided on:

- the section-by-section growth rates in the control cultures;
- the biomass in the control at the end of the test;
- the mean coefficient of variation for section-by-section specific growth in the control;
- the coefficient of variation of average specific growth rates during the whole test period in replicate control cultures.

43 Technical specifications impacting the sensitivity/reliability of the test

44 No information is provided on:

- the number of replicates;
- the test medium.

45 Furthermore,

- the test was conducted on test species *Desmodesmus subspicatus* and the initial cell density was approximately $2x10^4$ cells/mL, higher than the recommended initial cell density of $2\text{-}5x10^3$ cells/mL;
- the pH increase in the controls was more than 1.5 units (beginning of the study: 8.0 - 8.1; end of the study: 7.8 - 10.3). The robust study summary indicates that the growth of algae was unaffected by this increase of pH, but no growth data has been provided to support that claim.

46 Characterisation of exposure

- the test media prepared specifically for analysis of exposure concentrations was not inoculated with algae, the reported measured values may not be representative of true exposure levels in the test vessels.

47 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. In particular, no information is provided regarding growth in the control. The high initial cell density may have caused a reduced growth in the controls and the excessive increase of pH.

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

Reasons related to the information under Annex VIII of REACH

3. Short-term repeated dose toxicity (28 days)

49 A short-term repeated dose toxicity study (28 days) is an information requirement under Annex VIII to REACH (Section 8.6.1.).

3.1. Information provided

50 You have adapted this information requirement by using a Grouping of substances and read-across approach based on experimental data from the following substances:

i. Sub-acute toxicity study (28-day) (1995) with 1,6-hexanediol (EC No. 211-074-0)

3.2. Assessment of the information provided

51 We have assessed this information and identified the following issue(s):

3.2.1. Read-across adaptation rejected

52 As explained in Section 0.1., your adaptation based on grouping of substances and read-across approach under Annex XI, Section 1.5 is rejected.

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

3.3. Specification of the study design

54 When there is no information available neither for the 28-day repeated dose toxicity endpoint (EU B.7, OECD TG 407), nor for the screening study for reproductive/developmental toxicity (OECD TG 421 or TG 422), the conduct of a combined repeated dose toxicity study with the reproduction/developmental toxicity screening test (OECD TG 422) is preferred to ensure that unnecessary animal testing is avoided. Such an approach offers the possibility to avoid carrying out a 28-day study according to OECD TG 407, because the OECD TG 422 can at the same time fulfil the information requirement of REACH Annex VIII, 8.6.1 and that of REACH Annex VIII, 8.7.1. (Guidance on IRs and CSA, Section R.7.6.2.3.2.).

55 For information on the study design see request for OECD TG 422 below.

4. Screening for reproductive/developmental toxicity

56 A screening for reproductive/developmental toxicity study (OECD 421 or OECD 422) is an information requirement under Annex VIII to REACH (Section 8.7.1.), if there is no evidence from analogue substances, QSAR or in vitro methods that the substance may be a developmental toxicant.

4.1. Information provided

57 You have adapted this information requirement by using a Grouping of substances and read-across approach based on experimental data from the following substances:

i. Screening for reproductive/developmental toxicity (1995) with 1,6-hexanediol (EC No. 211-074-0)

4.2. Assessment of the information provided

58 We have assessed this information and identified the following issue(s):

4.2.1. Read-across adaptation rejected

59 As explained in Section 0.1., your adaptation based on grouping of substances and read-across approach under Annex XI, Section 1.5 is rejected.

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

4.3. Specification of the study design

61 A study according to the test method EU B.64/OECD TG 422 must be performed in rats.

62 The study must be conducted with oral administration of the Substance (Guidance on IRs and CSA, Section R.7.6.2.3.2.).

63 Therefore, the study must be conducted in rats with oral administration of the Substance.

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.

In your comments you agreed to the draft decision. ECHA took your comments into account and did not amend the request(s).

In your comments on the draft decision, you requested an extension of the deadline to provide information from 12 to 24 months from the date of adoption of the decision. You justified your request with a letter from a testing laboratory.

On this basis, ECHA has 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 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]

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