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Helsinki, 11 September 2023

Addressee(s)
Registrant(s) of JS_Dimethylglutarate as listed in Appendix 3 of this decision

Date of submission of the dossier subject to this decision
20 July 2022

Registered substance subject to this decision ("the Substance")
Substance name: Dimethyl glutarate
EC/List number: 214-277-2

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 ***18 March 2026***.

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).

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

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

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

3. Long-term toxicity testing on aquatic invertebrates (Annex IX, Section 9.1.5.; test method: EU C.20./OECD TG 211).

4. Long-term toxicity testing on fish (Annex IX, Section 9.1.6.; test method: EU C.47./OECD TG 210).

The reasons for the request(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 addressee(s) 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 request(s)
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 request(s)

Reasons common to several requests

0.1. Read-across adaptation rejected

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

- Short-term toxicity testing on aquatic invertebrates (Annex VII, Section 9.1.1.)
- Short-term toxicity to fish (Annex VIII, Section 9.1.3.)

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 ecotoxicological properties

5 You provide a read-across justification document in IUCLID Section 13.

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

- DBE: Reaction Mass of dimethyl adipate, dimethyl glutarate and dimethyl succinate, EC/List number 906-170-0 (source substance);

7 You provide the following reasoning for the prediction of ecotoxicological/environmental fate properties: "DBE and DMG have almost identical measured values for short-term toxicity to fish. In addition, modeled values indicate that DMG is slightly less toxic to Daphnids (short-term) and to Alga.".

8 ECHA understands that your read-across hypothesis assumes that different compounds have the same type of effects. You predict the properties of your Substance to be quantitatively equal to those of the source substance.

0.1.1.1. Inadequate or unreliable studies on the source substance

9 According to Annex XI, Section 1.5., if the grouping concept is applied then in all cases the results to be read across must:

(1) be adequate for the purpose of classification and labelling and/or risk assessment;

(2) have adequate and reliable coverage of the key parameters addressed in the corresponding study that shall normally be performed for a particular information requirement;

(3) cover an exposure duration comparable to or longer than the corresponding study that shall normally be performed for a particular information requirement if exposure duration is a relevant parameter.

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10 Specific reasons why the studies on the source substance(s) do not meet these criteria are explained further below under the applicable information requirement sections 1 and 2. Therefore, no reliable predictions can be made for these information requirements.

0.1.2. Conclusion

11 Based on the 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. Short-term toxicity testing on aquatic invertebrates

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

1.1. Information provided

13 You have adapted this information requirement by using Annex XI, Section 1.5. (grouping of substances and read-across approach) based on experimental data from the following substances:

(i) a short-term toxicity study on *daphnia magna* (1982) with the source substance DBE: Reaction Mass of dimethyl adipate, dimethyl glutarate and dimethyl succinate, EC/List number 906- 170-0;

(ii) a short-term toxicity study on *daphnia magna* (1990) with the source substance DBE: Reaction Mass of dimethyl adipate, dimethyl glutarate and dimethyl succinate, EC/List number 906- 170-0.

1.2. Assessment of the information provided

1.2.1. Read-across adaptation rejected

14 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 based on information requirement-specific issue(s) which are addressed below.

1.2.1.1. Inadequate or unreliable studies on the source substance

15 Under Annex XI, Section 1.5., the results to be read across must have an adequate and reliable coverage of the key parameters addressed / cover an exposure duration comparable to or longer than the one specified in the test guideline for the corresponding study that shall normally be performed for a particular information requirement, in this case OECD TG 202. Therefore, the following specifications must be met:

Technical specifications impacting the sensitivity/reliability of the test

a) the test duration is 48 hours or longer;

Characterisation of exposure

b) 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.

16 In the studies:

Technical specifications impacting the sensitivity/reliability of the test

a) the test duration was 24 hours (only study ii.);

Characterisation of exposure

b) no analytical monitoring of exposure was conducted (both studies i. and ii.)

In your comments on the draft decision, you state that '*analytical monitoring is not necessary given that the test material is more than sufficiently soluble in water, is only negligibly volatile from water, has a low potential to adsorb*

to organic matter, and is not expected to hydrolyze or dissociate at neutral pH'. Thus, you suppose that nominal concentrations are expected to match measured concentrations very closely, within the margin of error of analytical sampling and measurement methods.

17 In your comments on the draft decision, you also state that '*these same studies were used in the registration of* [redacted] *and were accepted by ECHA without comment in its draft decision for that substance.'*

18 Based on the above,

- there are critical methodological deficiencies resulting in the rejection of the study results. More, specifically analytical monitoring was not conducted (both studies i. and ii.). Without analytical monitoring, it is not possible to determine whether and to what extent the tested organisms were exposed to the test material.

  Regarding your comments on the draft decision, you have not substantiated that the measured test material concentration remains within ± 20 % of the nominal concentration. For example, in the study on growth inhibition on aquatic plants (with the same source substance) the measured concentrations at the end of the test were 62 to 72% of the nominal values.

- As to the registration dossier on [redacted], the fact that these studies were not requested in a draft decision in that context does not imply that ECHA considered valid those studies.

19 On this basis, the specifications of OECD TG 202 are not met.

20 Based on the above, the studies submitted in your adaptation, as currently reported in your dossier, do not provide an adequate and reliable coverage of the key parameter(s) of the corresponding OECD TG (both studies) and do not cover an exposure duration comparable to or longer than the one specified in the corresponding OECD TG (study ii.).

21 Therefore, this information requirement is not fulfilled.

Reasons related to the information under Annex VIII of REACH

2. Short-term toxicity testing on fish

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

2.1. Information provided

23 You have provided:

(i) a short-term toxicity study on fish (1976) with the Substance.

24 In addition, you have adapted this information requirement by using Annex XI, Section 1.5. (grouping of substances and read-across approach) based on experimental data from the following substances:

(ii) a short-term toxicity study on fish (1982) with the source substance DBE: Reaction Mass of dimethyl adipate, dimethyl glutarate and dimethyl succinate, EC/List number 906- 170-0.

2.2. Assessment of the information provided

2.2.1. The provided study (i) does not meet the specifications of the test guideline(s)

25 To fulfil the information requirement, a study must comply with OECD TG 203 and the specifications of OECD GD 23 if the substance is difficult to test (Article 13(3) of REACH). Therefore, the following specifications must be met:

Validity criteria

a) the analytical measurement of test concentrations is conducted;

Characterisation of exposure

b) 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.

26 In study (i):

Validity criteria

a) no analytical measurement of test concentrations was conducted;

Characterisation of exposure

b) no analytical monitoring of exposure was conducted.

In your comments on the draft decision, you state that *"analytical monitoring is not necessary given that the test material is more than sufficiently soluble in water, is only negligibly volatile from water, has a low potential to adsorb to organic matter, and is not expected to hydrolyze or dissociate at neutral pH"*. Thus, you suppose that nominal concentrations are expected to match measured concentrations very closely, within the margin of error of analytical sampling and measurement methods.

27 In your comments on the draft decision, you also state that '*these same studies were used in the registration of* [redacted] *and were accepted by ECHA without comment in its draft decision for that substance.'*

28 Based on the above,

- the validity criteria of OECD TG 203 are not met
- there are critical methodological deficiencies resulting in the rejection of the study results. More, specifically analytical monitoring was not conducted. Without analytical monitoring, it is not possible to determine whether and to what extent the tested organisms were exposed to the test material.

  Regarding your comments on the draft decision, you have not substantiated that the measured test material concentration remains within ± 20 % of the nominal concentration. For example, in the study on growth inhibition on aquatic plants (with the same source substance) the measured concentrations at the end of the test were 62 to 72% of the nominal values.
- As to the registration dossier on [redacted], the fact that these studies were not requested in a draft decision in that context does not imply that ECHA considered valid those studies.

29 On this basis, the specifications of OECD TG 203 are not met and the information requirement is not fulfilled.

2.2.2. Read-across adaptation rejected

30 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 based on the information requirement-specific issue(s) addressed below.

2.2.2.1. Inadequate or unreliable study on the source substance

31 Under Annex XI, Section 1.5., the results to be read across must have an adequate and reliable coverage of the key parameters addressed in the test guideline for the corresponding study that shall normally be performed for a particular information requirement, in this case OECD TG 203. Therefore, the following specifications must be met:

Validity criteria

a) the analytical measurement of test concentrations is conducted;

Characterisation of exposure

b) 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.

32 In study (ii):

Validity criteria

a) no analytical measurement of test concentrations was conducted;

Characterisation of exposure

b) no analytical monitoring of exposure was conducted.

In your comments to the draft decision, you state that analytical monitoring is not an issue as nominal concentrations are expected to match measured within the margin of error of analytical sampling and measurement methods.

33 Based on the above,

- the validity criteria of OECD TG 203 are not met;
- there are critical methodological deficiencies resulting in the rejection of the study results. More, specifically analytical monitoring was not conducted. Without analytical monitoring, it is not possible to determine whether and to what extent the tested organisms were exposed to the test material.

Regarding your comments on the draft decision, and as already explained in section 1.3 and 2.2.1 you have not substantiated that the measured test material concentration remains within ± 20 % of the nominal concentration. Furthermore, in the case of short-term testing on fish, analytical monitoring is one of the validity criteria of the study and it must be conducted. Specifically, in static tests, if the concentrations of the test material are expected to remain within ± 20 % of the nominal, then the test material concentration is determined (in one replicate) in the highest and lowest test concentrations, and a concentration around the expected LC50 at the beginning and end of the test.

34 As explained above, without analytical monitoring, it is not possible to determine whether and to what extent the tested organisms were exposed to the test material.

35 On this basis, the specifications of OECD TG 203 are not met.

36 Based on the above, the study submitted in your adaptation, as currently reported in your dossier, does not provide an adequate and reliable coverage of the key parameter(s) of the corresponding OECD TG.

37 Therefore, the information requirement is not fulfilled.

Reasons related to the information under Annex IX of REACH

3. Long-term toxicity testing on aquatic invertebrates

38 Long-term toxicity testing on aquatic invertebrates is an information requirement under Annex IX to REACH (Section 9.1.5.).

3.1. Information provided

39 You have adapted this information requirement by using Column 2 of Annex IX, Section 9.1. To support the adaptation, you have provided the following information:

(i) Justification for data waiving: "In accordance with column 2 of REACH Annex IX, long term toxicity testing on aquatic invertebrates (required in section 9.1.5) shall be proposed by the registrant if the chemical safety assessment indicates the need to investigate further the effects on aquatic organisms. As the substance is not classified as dangerous for the environment, is readily biodegradable and has a low potential for bioaccumulation, no further testing is required".

3.2. Assessment of the information provided

3.2.1. Annex IX, Section 9.1., Column 2 is not a valid basis to omit the study

40 Under Annex IX, Section 9.1., Column 2 is not a basis for omitting information on long-term toxicity to aquatic invertebrates referred to under Column 1, Section 9.1.5.

41 Your adaptation is therefore rejected.

42 Therefore, the information requirement is not fulfilled.

3.3. Comments on the draft decision

43 In your comments to the draft decision, you do not agree to perform the requested study. Instead, you indicate that you intend to adapt this information requirement by means of grouping and read-across according to Annex XI, Section 1.5, of the REACH Regulation.

44 You refer to a group (category) of [redacted] substances which include branched or linear [redacted], with the general structure of [redacted].

45 You propose to predict the long-term toxicity on aquatic invertebrates property of the Substance from new studies on category member/source substance [redacted] or on [redacted].

46 In the comments, you present a strategy relying on the generation of additional "*common studies or bridging studies that will be necessary to support the category*", but provide no supporting information for ecotoxicological properties.

47 As this strategy relies on a category read-across approach that has not yet been fully described and justified, as well as on data which is yet to be generated for the proposed category members/source substances (including bridging studies and supporting information), no conclusion on the compliance of the proposed adaptation can be made. You remain responsible for complying with this decision by the set deadline.

4. Long-term toxicity testing on fish

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

4.1. Information provided

49 You have adapted this information requirement by using Column 2 of Annex IX, Section 9.1. To support the adaptation, you have provided the following information:

(i) Justification for data waiving: "In accordance with column 2 of REACH Annex IX, long term toxicity testing on fish (required in section 9.1.6) shall be proposed by the registrant if the chemical safety assessment indicates the need to investigate further the effects on aquatic organisms. As the substance is not classified as dangerous for the environment, is readily biodegradable and has a low potential for bioaccumulation, no further testing is required".

4.2. Assessment of the information provided

4.2.1. Annex IX, Section 9.1., Column 2 is not a valid basis to omit the study

50 Under Annex IX, Section 9.1., Column 2 is not a basis for omitting information on long-term toxicity to fish referred to under Column 1, Section 9.1.6.

51 Your adaptation is therefore rejected.

52 Therefore, the information requirement is not fulfilled.

4.3. Study design

53 To fulfil the information requirement for the Substance, the Fish, Early-life Stage Toxicity Test (test method OECD TG 210) is the most appropriate (Guidance on IRs and CSA, Section R.7.8.2.).

4.4. Comments on the draft decision

54 In your comments to the draft decision, you you do not agree to perform the requested study. Instead, you indicate that you intend to adapt this information requirement by means of grouping and read-across according to Annex XI, Section 1.5, of the REACH Regulation.

55 You refer to a group (category) of [redacted] substances which include branched or linear [redacted], with the general structure of [redacted].

56 You propose to predict the long-term toxicity on fish property of the Substance from new studies on category member/source substance [redacted] or on [redacted].

57 In the comments, you present a strategy relying on the generation of additional "*common studies or bridging studies that will be necessary to support the category*", but provide no supporting information for ecotoxicological propoerties.

58 As this strategy relies on a category read-across approach that has not yet been fully described and justified, as well as on data which is yet to be generated for the proposed category members/source substances (including bridging studies and supporting information), no conclusion on the compliance of the proposed adaptation can be made. You remain responsible for complying with this decision by the set deadline.

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).
Guidance for monomers and polymers; ECHA (2012).
***Guidance on intermediates*;** ECHA (2010).
All guidance documents are 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 09 December 2022.

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).

The deadline of the decision is set based on standard practice for carrying out OECD TG tests. It has been exceptionally extended by 12 months from the standard deadline granted by ECHA to take into account currently longer lead times in contract research organisations.

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: Addressee(s) 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 (https://echa.europa.eu/practical-guides).

(4) Under the introductory part of Annexes VII/VIII/IX/X to REACH, where a test method offers flexibility in the study design, for example in relation to the choice of dose levels or concentrations, the chosen study design must ensure that the data generated are adequate for hazard identification and risk assessment.

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.

With that detailed information, ECHA can confirm 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 (https://echa.europa.eu/manuals).