~~Confidential~~

Helsinki, 20 June 2023

Addressee
Registrant of JS_131-11-3 as listed in Appendix 3 of this decision

Date of submission of the dossier subject to this decision
23/05/2018

Registered substance subject to this decision ("the Substance")
Substance name: Dimethyl phthalate
EC/List number: 205-011-6

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 ***25 September 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. In vitro gene mutation study in bacteria (Annex VII, Section 8.4.1.; test method: OECD TG 471, 2020)

2. Short-term toxicity testing on aquatic invertebrates (Annex VII, Section 9.1.1.; test method: EU C.2./OECD TG 202)

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

4. Ready biodegradability (Annex VII, Section 9.2.1.1.; test method: EU C.4. A/B/C/D/E/F/OECD TG 301A/B/C/D/E/F or EU C.29./OECD TG 310)

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 addressee of the decision and its corresponding information requirements based on registered tonnage band are listed in Appendix 3.

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)

Contents

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Reasons related to the information under Annex VII of REACH

1. In vitro gene mutation study in bacteria

1 An in vitro gene mutation study in bacteria is an information requirement under Annex VII, Section 8.4.1.

1.1. Information provided

2 You have provided:

(i) An in vitro gene mutation study in bacteria (1982) with the Substance

1.2. Assessment of the information provided

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

3 To fulfil the information requirement, a study must comply with the OECD TG 471 (Article 13(3) of REACH). Therefore, the following specifications must be met:

a) the test is 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);
b) the maximum dose tested induces a reduction in the number of revertant colonies per plate compared to the negative control, or the precipitation of the tested substance. If no precipitate or limiting cytotoxicity is observed, the highest test dose corresponds to 5 mg/plate or 5 µl/plate;
c) at least 5 doses are evaluated, in each test condition;
d) triplicate plating is used at each dose level;
e) one positive control is included in the study and the positive control substance produces a statistically significant increase in the number of revertant colonies per plate compared with the concurrent negative control;
f) the number of revertant colonies per plate for the concurrent negative control is inside the historical control range of the laboratory;
g) the mean number of revertant colonies per plate is reported for the treated doses and the controls.

4 In study (i) described as an in vitro gene mutation study on bacteria:

a) the test was performed with the strains S. typhimurium TA 1535, TA 1537, TA 98 and TA 100 (i.e., the strains *S. typhimurium* TA102 or *E. coli* WP2 uvrA or *E. coli* WP2 uvrA (pKM101)are missing);
b) the maximum dose tested did not induced a reduction in the number of revertant colonies per plate compared to the negative control, or the precipitation of the tested substance and it was less than 5 mg/plate or 5 ml/plate;
c) not reported how many doses were evaluated in absence and in presence of metabolic activation (i.e., less than 5 doses);
d) triplicate plating was not used at each dose level;
e) the positive control substance did not produce a statistically significant increase in the number of revertant colonies per plate compared with the concurrent negative control;
f) the number of revertant colonies per plate for the concurrent negative control was not inside the historical control range of the laboratory;

g) the mean number of revertant colonies per plate for the treated doses and the controls was not reported.

5 The information provided does not cover the specification(s) required by the OECD TG 471.

6 Therefore, the information requirement is not fulfilled.

1.3. Specification of the study design

7 To fulfil the information requirement for the Substance, the in vitro gene mutation study in bacteria (OECD TG 471, 2020) is considered suitable.

1.4. Information regarding data sharing

8 The jointly submitted registration for the Substance contains in vitro gene mutation studies (1993 and 2022) which are adequate for this information requirement. In accordance with Title III of the REACH Regulation, you may request it from the other registrants and then make every effort to reach an agreement on the sharing of data and costs (Guidance on data-sharing).

2. Short-term toxicity testing on aquatic invertebrates

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

2.1. Information provided

10 You have provided:

(i) a short-term toxicity study to daphnia (1980) with the Substance.

2.2. Assessment of the information provided

2.2.1. The provided study does not meet the information requirement

11 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:

12 Characterisation of exposure:

a) 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.

13 Reporting of the methodology and results:

b) Test design is reported (*e.g.* test concentrations used, number of replicates).
c) Test procedure is reported (*e.g.* composition of the test medium, loading in number of *Daphnia* per test vessel).
d) Number of immobilised daphnids is determined at 24 and 48 hours. Data are summarised in tabular form, showing for each treatment group and control, the number of daphnids used, and immobilisation at each observation.

14 In study (i) described as short-term toxicity study on daphnids.

15 Characterisation of exposure:

a) No analytical monitoring of exposure was conducted.

16 Reporting of the methodology and results

b)-d) You did not provide any information listed above.

17 Based on the above,

- there are critical methodological deficiencies resulting in the rejection of the study results. More specifically in the absence of analytical monitoring, you have not demonstrated that the test material has been satisfactorily maintained throughout the test.
- the reporting of the study is not sufficient to conduct an independent assessment of its reliability. More specifically, it is not possible to confirm the requirements of the test guideline and the validity of the study based on the information provided in the dossier.

18 Therefore, the requirements of OECD TG 202 are not met, and the information requirement is not fulfilled.

3. Growth inhibition study aquatic plants

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

3.1. Information provided

20 You have provided:

(i) a growth inhibition study to algae (1997) with the Substance.

3.2. Assessment of the information provided

3.2.1. The provided study does not meet the information requirement

21 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:

22 Characterisation of exposure:

a) Analytical monitoring must be conducted.
b) The results can be based on nominal or measured initial concentration only if the concentration of the test material has been maintained within ±20 % of the nominal or measured initial concentration throughout the test.

23 Reporting of the methodology and results:

c) Test design is reported (*e.g.*, number of replicates, number of test concentrations and geometric progression used).
d) Test conditions are reported (*e.g.*, composition of the test medium, test temperature, test species, biomass density at the beginning of the test).
e) Method for determination of biomass and evidence of correlation between the measured parameter and dry weight are reported.
f) Results of algal biomass determined in each flask at least daily during the test

period are reported in a tabular form.

g) Microscopic observation performed to verify a normal and healthy appearance of the inoculum culture are reported. Any abnormal appearance of the algae at the end of the test is reported.

h) Adequate information on the analytical method (including performance parameters of the method) and on the results of the analytical determination of exposure concentrations is provided.

In study (i) described as *growth inhibition study on aquatic plants/algae*:

24 Characterisation of exposure:

a) You have not specified whether analytical monitoring of exposure was conducted.

b) You have expressed the effect values based on nominal concentrations. However, you neither reported measured concentrations nor demonstrated that the concentration of the test material has been maintained within ±20 % of the nominal or measured initial concentration throughout the test.

25 Reporting of the methodology and results:

c)-h) You did not provide any information listed above.

Based on the above,

- there are critical methodological deficiencies resulting in the rejection of the study results. More specifically you have not demonstrated that the test material has been satisfactorily maintained throughout the test.
- the reporting of the study is not sufficient to conduct an independent assessment of its reliability. More specifically, it is not possible to confirm the requirements of the test guideline and the validity of the study based on the information provided in the dossier.

26 Therefore, the requirements of OECD TG 201 are not met, and the information requirement is not fulfilled.

4. Ready biodegradability

27 Ready biodegradability is an information requirement in Annex VII to REACH (Section 9.2.1.1.).

4.1. Information provided

28 You have provided:

(i) a semicontinuous activated sludge (SCAS) study (1985) with the Substance.

4.2. Assessment of information provided

4.2.1. The provided study does not meet the information requirement

29 To fulfil the information requirement, a study must comply with the OECD TG 301 or 310 (Article 13(3) of REACH). Therefore, for a study according to OECD TG 301 or 310 must be provided.

30 You described the study (i) as "*semicontinuous activated sludge (SCAS) test*".

31 You indicated that the conducted study is a SCAS test, which is not a ready biodegradability test but an inherent biodegradability test. According to ECHA Guidance Document R7.9.5.1, "*the optimum conditions in inherent biodegradability tests stimulate adaptation of the microorganisms thus increasing the biodegradation potential, compared to natural environments. Therefore, positive results in these tests should not be interpreted as evidence for rapid degradation in the environment*".

32 Based on above, the study (i) cannot be used to conclude on ready biodegradability for the Substance.

33 Therefore, the requirements of OECD TG 301 or 310 are not met, and 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).
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 12 April 2022.

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

ECHA did not receive any comments within the commenting period.

The deadline of the decision is set based on standard practice for carrying out OECD TG tests. It has been exceptionally extended to 36 months from the standard deadline granted by ECHA to take into account currently longer lead times in contract research organisations. Furthermore, the information requested in the draft decision has also been requested in a decision send to other registrants of the same substance. The deadlines of both decisions were aligned in order to allow data sharing between the registrants of the Substance.

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 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;

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.

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]

(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

(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 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.

Technical instructions on how to report the above is available in the manual on How to prepare registration and PPORD dossiers[3].

References to Guidance on REACH and other supporting documents can be found in Appendix 1.

[2] https://echa.europa.eu/practical-guides
[3] https://echa.europa.eu/manuals