~~Confidential~~

Helsinki, 05 May 2023

**Addressees**
Registrants of DMT_120-61-6_SIEF as listed in Appendix 3 of this decision

**Date of submission of the dossier subject to this decision**
25/04/2017

**Registered substance subject to this decision ("the Substance")**
Substance name: Dimethyl terephthalate
EC/List number: 204-411-8

**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 ***11 August 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. 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)

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

2. Sub-chronic toxicity study (90-day) (Annex IX, Section 8.6.2.; test method: OECD TG 408) by oral route, in rats

3. 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 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 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

**Reasons related to the information under Annex VII of REACH**

## 1. Ready biodegradability

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

### *1.1. Information provided*

2 You have provided the following information on the Substance:

(i) a ready biodegradability study according to a draft ISO guideline which you claim is now available as ISO 10708, (1993)

(ii) a ready biodegradability study according to OECD TG 301C (1980)

### *1.2. Assessment of the information provided*

#### *1.2.1. Study (i) does not meet the specifications of the ISO 10708*

3 To fulfil the information requirement, a study must comply with the test methods laid down in a Commission Regulation or in accordance with other international test methods recognised by the Commission or the Agency as being appropriate (Article 13(3) of REACH). As specified in the opinion from the Scientific Committee on Health and Environmental Risks (SCHER), ISO 10708 is considered adequate to inform on ready biodegradability. However, to fulfil the information requirement, the following conditions from the ISO 10708 must be met:

4 Technical specifications impacting the sensitivity/reliability of the test

a) the concentration of the test material is 100 mg ThOD/L.

5 In study (i) described as a ready biodegradability test according to ISO 10708:

6 Technical specifications impacting the sensitivity/reliability of the test

a) the concentration of the test material was 11.1 ± 0.2 mg/L wich corresponds to 19.2±0.35 mg ThOD/L.

7 Based on the above, there are critical methodological deficiencies resulting in the rejection of the study results for study (i). More, specifically the concentration of the test substance was over five times lower than the requirements of the ISO 10708. As a result the inoculum to test material ratio was higher than the specifications of the test method which may have created conditions that are too favourable. Therefore, the requirements of ISO 10708 are not met.

#### *1.2.2. Study (ii) does not meet the specifications of the OECD TG 301C*

8 To fulfil the information requirement, a study must comply with the OECD TG 301 or 310 (Article 13(3) of REACH). For a study according to OECD TG 301C, the following requirements must be met:

9 Reporting of the methodology and results

a) adequate information on the test material is provided (purity, composition including impurities);

b) the source of the inoculum, its concentration in the test (i.e., in cells/ml) and any pre-conditioning treatment are reported;

c) the test design (e.g. number of replicates, reference substance) is reported;

d) the test temperature and pH are reported;

e) the results of measurements at each sampling point in each replicate is reported in a tabular form;

f) the determination of primary biodegradation using a specific chemical analysis is reported.

10 For study (ii), none of the information in the above specifications list under a)-f) is reported.

11 Based on the above, the reporting of study (ii) is not sufficient to conduct an independent assessment of its reliability. More specifically, it is not possible to verify that the validity criteria of the test guideline were met, that the test was conducted under conditions that are consistent with the requirements of the OECD TG 301C and to assess the interpretation fof the results. Therefore, the requirements of OECD TG 301C are not met.

12 Therefore, for the reasons explained under sections 1.2.1. and 1.2.2., the information requirement is not fulfilled.

13 In your comments on the draft decision, you agree to perform the requested study.

**Reasons related to the information under Annex IX of REACH**

## 2. Sub-chronic toxicity study (90-day)

15 A sub-chronic toxicity study (90 day) is an information requirement under Annex IX, Section 8.6.2.

### *2.1. Information provided*

16 You have provided the following studies with the Substance:

(i) a dose range finding study (1947) oral in rat
(ii) a two-weeks study (1955) oral in rat
(iii) a 28-d study (1958) oral in rat
(iv) a 91-d key study (1972) oral in rat
(v) a 23-weeks study (1955) oral in dog
(vi) a whole body inhalation study (1972-1973) in rat similar to OECD 413
(vii) a 2- and 5-months whole body inhalation study (1963) in rat

### *2.2. Assessment of the information provided*

#### *2.2.1. Studies (i) to (iv) not adequate for the information requirement*

17 To fulfil the information requirement, the sub-chronic toxicity study (90 day) has to meet the requirements of the OECD TG 408. Therefore, the following specifications must be met:

a) at least 10 male and 10 female animals are used for each concentration and control group;
b) dosing of the Substance is performed daily for a minimum of 90 days;
c) haematological and clinical biochemistry tests are performed as specified in the test guideline (clinical biochemistry determinations to investigate major toxic effects in tissues and, specifically, for effects on kidney and liver, should be performed on blood samples obtained from each animal just prior to or as part of the procedure for killing the animals);
d) the oestrus cycle in females is examined at necropsy;
e) terminal organ and body weights are measured;
f) full histopathology is performed as specified in the test guideline.

18 In studies (i)- (iii) provided for this endpoint the exposure duration was limited to 10 or 11 days (i), 14 days (ii) and 28 days (iii) instead of a minimum of 90 days as specified under b) above.

19 In the study (iv) deficiencies were identified for the following specifications:

a) only males were included in each test and control group;
c) the clinical biochemistry investigations were performed "*on selected rats*" on the day 55 and 90 of feeding;
d) oestrus cyclicity was not assessed;
e) with the exception of liver and kidney, terminal organ weights and organ/body weight ratios were not recorded;
f) not reported which organs were studied for histopathology.

20 For these reasons the information provided in studies (i) – (iv) does not cover the specifications required by the OECD TG 408.

*2.2.2. Study (v) not performed in rodents, and it does not meet the requirements set out in the recognised test method*

21 Column 1 of Annex IX, 8.6.2. specifies a sub-chronic toxicity study (90-day) in one species, rodent, male and female as a standard information requirement. To fulfil the information requirement, a study must comply with the pertinent test methods laid down in a Commission Regulation or in accordance with other international test methods recognised by the Commission or the Agency as being appropriate (Article 13(3) of REACH).

22 Firstly, in study (v) dogs were used as test animals. This does not meet the REACH standard information requirement for a study in rodents.

23 Secondly, the study does not meet the requirements of a sub-chronic toxicity study (90 day) in dogs (EU Test Method B.27 / OECD TG 409). For a study to meet the requirements set out in the test method, the following specifications must be met:

a) there should be dogs of a defined breed;
b) dosing should begin preferably at 4-6 months and not later than 9 months of age;
c) at least 8 animals (four female and four male) should be used at each dose level;
d) at least three dose levels and a concurrent control shall be used, except where a limit test is conducted.

24 In study (v) deficiencies were identified for the following specifications:

a) this study employed different breeds: dog: 1 Gordon setter, 2 mongrels and 1 collie;
b) there is no information on dog's age;
c) only 4 animals, sex not specified;
d) no reporting on a limit test and two doses were used.

25 The information provided in study (v) does therefore not cover the specifications required by the recognised test method.

*2.2.3. Studies (vi) and (vii) not performed with the most appropriate route of administration, and they do not meet the requirements set out in the recognised test method*

26 Column 1 in Annex IX of REACH Regulation specifies that the sub-chronic toxicity study (90 day) has to be performed using the most appropriate route of administration, having regard to the likely route of exposure.

27 According to the criteria listed in Column 2 in Annex IX, 8.6.2., testing by the inhalation route is appropriate if exposure of humans via inhalation is likely taking into account the vapour pressure of the substance and/or the possibility of exposure to aerosols, particles or droplets of an inhalable size.

28 The substance is a solid with a water solubility limit of 31 mg/L and with a vapour pressure of 0.000139 kPa at 20 °C. According to data in the dossier "*Dimethyl terephthalate is not marketed or used in powder or granular form: it is commonly produced, transported and used in the molten state and as briquettes without respirable dust. If allowed to cool and solidify, the melt forms a rigid, solid cake.*"

29 As the vapour pressure of the substance is very low and the substance is only a slightly soluble solid not in powder form, the possibility of exposure to aerosols, particles or droplets of an inhalable size is unlikely. Thus, the information provided in studies (vi) and (vii) does

not show that the conditions for inhalation as the most appropriate route of administration are fulfilled.

30 Therefore, a study using the inhalation route is not considered appropriate to meet the standard information requirement.

31 In any case, the studies (vi) and (vii) have the following issue:

32 To fulfil the information requirement, the sub-chronic toxicity inhalation study (90-day) has to meet the requirements of the OECD TG 413. Therefore, the following specifications must be met:

a) testing is performed with at least three dose levels (unless conducted at the limit dose) and with concurrent controls;
b) at least 10 male and 10 female animals are used for each test and control group;
c) haematological and clinical biochemistry tests are performed as specified in the test guideline (determinations should be made for all exposed and control animals);
d) terminal organ and body weights are measured;
e) full histopathology is performed as specified in the test guideline;

33 In study (vi) described as equivalent or similar to OECD TG 413:

a) there were only two dose levels and a concurrent control;
b) 30 males only were reported for each concentration. However, only 10 animals/dose or even less were used for the main study, since the remaining 20 animals per group were observed for long-term effects and the study included two doses and a concurrent air control;
c) haematological and blood chemistry determinations were performed "*on 15 rats randomly selected from each group*" instead for all exposed and control animals;
d) with the exception of liver and kidney, terminal organ weights and organ/body weight ratios were not recorded;
e) you have not reported which organs were studied for histopathology.

34 In study (vii) described as 2- and 5-months studies:

a) there were only two dose levels and a concurrent control;
b) the sex and strain of animals was not specified;
c) clinical biochemistry was not performed; the type of haematological parameteres investigated were not described.

35 The information provided in studies (vi) and (vii) does not cover the specifications required by the OECD TG 413.

36 Therefore, for the reasons explained under sections 2.2.1. to 2.2.3., the information requirement is not fulfilled.

### *2.3. Specification of the study design*

37 Following the criteria provided in Annex IX, Section 8.6.2, Column 2, and considering the guidance on IRs and CSA, Section R.7.5.6.3.2, the oral route is the most appropriate route of administration to investigate repeated dose toxicity of the Substance.

38 According to the OECD TG 408, the rat is the preferred species.

39 Therefore, the study must be performed in rats according to the OECD TG 408 with oral administration of the Substance.

40 In your comments on the draft decision, you agree to perform the requested study.

## 3. Long-term toxicity testing on fish

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

### *3.1. Information provided*

42 You have adapted this information requirement by using Column 2 of Annex IX, Section 9.1. To support the adaptation, you have provided following information: "*The study does not need to be conducted as all identified uses of the substance are assessed as safe for the environment*".

### *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*

43 Annex IX, Section 9.1., Column 2 does not allow omitting the need to submit information on long-term toxicity to aquatic invertebrates under Column 1. It must be understood as a trigger for providing further information on aquatic invertebrates if the chemical safety assessment according to Annex I indicates the need (Decision of the Board of Appeal in case A-011-2018).

44 Your adaptation is therefore rejected.

45 Therefore, the information requirement is not fulfilled.

46 In your comments on the draft decision, you agree to perform the requested study.

### *3.3. Study design and test specifications*

47 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.).

**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

The information requirement for an Extended One-Generation Reproductive Toxicity Study (EOGRTS; Annexes IX or X, Section 8.7.3.) is not addressed in this decision. This may be addressed in a separate decision once the information from the sub-chronic toxicity study (90-day) requested in the present decision is provided; this is due to the fact that the results from the 90-day study are needed for the design of the EOGRTS. Similarly, the information requirement for a screening for reproductive/developmental toxicity (Annex VIII, Section 8.7.1.) is not addressed in this decision; as the EOGRTS will cover the same parameters.

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 14 March 2022.

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 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 requests.

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 |
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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

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