~~Confidential~~

Helsinki, 04 May 2023

Addressees
Registrants of Purified Terephthalic Acid-PMC as listed in Appendix 3 of this decision

Date of submission of the dossier subject to this decision
04/09/2020

Registered substance subject to this decision ("the Substance")
Substance name: Terephthalic acid
EC/List number: 202-830-0

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. Skin sensitisation (Annex VII, Section 8.3.)
   i. *in vitro/in chemico* skin sensitisation information on molecular interactions with skin proteins (OECD TG 442C), inflammatory response in keratinocytes (OECD TG 442D) and activation of dendritic cells (OECD TG 442E) (Annex VII, Section 8.3.1.); and
   ii. only if the *in vitro/in chemico* test methods specified under point i.) above are not applicable for the Substance or the results obtained are not adequate for classification and risk assessment, *in vivo* skin sensitisation (Annex VII, Section 8.3.2.; test method: EU B.42./OECD TG 429)

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

3. 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 VIII of REACH

4. In vitro gene mutation study in mammalian cells (Annex VIII, Section 8.4.3.; test method: OECD TG 476 or TG 490)

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

5. Pre-natal developmental toxicity study (Annex IX, Section 8.7.2.; test method: OECD TG 414) by oral route, in one species (rat or rabbit)

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

The reasons for the requests 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.

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 requests
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

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:

- Skin sensitisation (Annex VII, Section 8.3.)
- In vitro gene mutation study in bacteria (Annex VII, Section 8.4.1.)
- In vitro gene mutation study in mammalian cells (Annex VIII, Section 8.4.3.)
- Pre-natal developmental toxicity study (Annex IX, Section 8.7.2.)

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 13.

6 You predict the properties of the Substance from information obtained from the following source substances:

IPA	isophthalic acid, EC No. 204-506-4.
DEHT/DOTP	bis(2-ethylhexyl) terephthalate, EC No. 229-176-9.

7 Regarding IPA, you provide the following reasoning for the prediction of toxicological properties: "*Isophthalic acid (benzene-1,3-dicarboxylic acid, the source substance) and terephthalic acid (benzene-1,4-dicarboxylic acid, the Substance) are structurally very similar, differing only in the positioning of the carboxylic acid groups. IPA does not contain any additional structural groups compared to TPA. This slight structural difference is unlikely to affect the basic toxicological properties of the substances*".

8 For DEHT you state in the read-across justification document, under the toxicological data, the following reasoning for the prediction of toxicological properties: "*Data for DEHT show rapid absorption from the gastrointestinal tract and metabolism to liberate TPA and 2-ethylhexanol*".

9 ECHA understands that your read-across hypothesis for IPA assumes that different compounds have the same type of effects. ECHA also understands that your read-across hypothesis for DEHT is based on the formation of common (bio)transformation products. You predict the properties of your Substance to be quantitatively equal to those of the source substance.

10 We have identified the following issue with the prediction of ecotoxicological properties:

0.1.1.1. Inadequate read-across hypothesis for IPA

11 Annex XI, Section 1.5 requires that whenever read-across is used adequate and reliable documentation of the applied method must be provided. Such documentation must include an explanation why the properties of the Substance may be predicted from other substances in the group, i.e. a read-across hypothesis. This hypothesis should be based on recognition of the structural similarities and differences between the substances (Guidance on IRs and CSA, Section R.6.).It should explain why the differences in the chemical structures should not influence the toxicological properties or should do so in a regular pattern, taking into account that variations in chemical structure can affect both toxicokinetics (uptake and bioavailability) and toxicodynamics (e.g. interactions with receptors and enzymes) of substances (Guidance on IRs and CSA, Section R.6.2.1.3).

12 Your read-across hypothesis is only based on structural similarities and similarities in the physico-chemical properties of the source substance IPA. You consider that these elements are a sufficient basis for predicting the (eco)toxicological properties of the Substance.

13 You have not substantiated how structural and physico-chemical similarity alone would explain similarity in the predicted endpoint and thus be sufficient to justify the toxicological predictions.

14 Physico-chemical similarity alone does not necessarily lead to predictable or similar toxicological properties. You have not provided a well-founded hypothesis to establish a reliable prediction for a toxicological property, explaining why the structural differences do not influence toxicokinetics and toxicodynamics of the substances, and thus why the properties of the Substance may be predicted from information on the source substance.

0.1.1.2. Missing supporting information to compare the properties of the Substance and the source substance IPA

15 Annex XI, Section 1.5 requires that whenever read-across is used adequate and reliable documentation of the applied method must be provided. Such documentation must provide supporting information to scientifically justify the read-across explanation for prediction of properties. The set of supporting information should strengthen the rationale for the read-across in allowing to verify the crucial aspects of the read-across hypothesis and establishing that the properties of the Substance can be predicted from the data on the source substance(s) (Guidance on IRs and CSA R.6, Section R.6.2.2.1.f.).

16 For the read-across from IPA, supporting information must include bridging studies to compare and to confirm your claim that both the source substance and the Substance have similar properties.

17 As indicated above, your read-across hypothesis is based on the assumption that the structurally similar source substances cause the same type of effect(s). In this context, relevant, reliable and adequate information allowing to compare the properties of the source substance is necessary to confirm that the substances cause the same type of effects. Such information can be obtained, for example, from bridging studies of comparable design and duration for the Substance and of the source substance.

18 In the absence of such information, you have not established that the Substance and the source substance(s) are likely to have similar properties. Therefore you have not provided sufficient supporting information to scientifically justify the read-across.

0.1.1.3. Missing supporting information on the impact of non-common compound for the read-across from DEHT

19 Annex XI, Section 1.5 requires that whenever read-across is used adequate and reliable documentation of the applied method must be provided. Such documentation must provide

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

20 For the read-across from DEHT which is based on the formation of a common compound, supporting information must include toxicokinetic information on the formation of the common compound, bridging studies to compare properties of the Substance and the source substance and information to confirm that the exposure to the non-common compound will not impact the prediction.

21 As indicated above, your read-across hypothesis is based on the (bio)transformation of the Substance and the source substance to a common compound. In this context, exposure to the Substance and the source substance may also lead to exposure to other compounds than the common compound of interest. The impact of exposure to the non-common compound on the prediction of properties of the target needs to be assessed to ensure that a reliable prediction can be made.

22 You have not provided information characterising the exposure to the non-common compound resulting from exposure to the Substance and to the source substance. No experimental data or other adequate and reliable information addressing the impact of exposure to these non-common compounds is included in the documentation of your read-across approach.

23 Toxicokinetic information provided in the dossier of TPA indicate that DEHT is partially hydrolysed in the gastrointestinal tract of the rat to form terephthalic acid, and that there is systemic exposure to TPA, 2-ethylhexanol and its metabolites. This is supported by your statemebnt that *"The half-life for the disappearance of DEHT in rat gut homogenates was found to be 53.3 minutes".*

24 Therefore, you have not demonstrated that there is no exposure to the parent compound.

25 In the absence of such information, you have not established that a reliable prediction of the property under consideration of the Substance can be derived on the basis of your read-across hypothesis. Therefore, you have not provided sufficient supporting information to scientifically justify for the read-across.

0.1.1.4. Inadequate or unreliable studies on the source substance

26 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.

27 Specific reasons why the studies on the source substance do not meet these criteria are explained further below under the applicable information requirements (See Request 2 and 5). Therefore, no reliable predictions can be made for these information requirements.

0.1.2. Conclusion on the read-across approach

28 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. Skin sensitisation

29 Skin sensitisation is an information requirement under Annex VII, Section 8.3. Under Section 8.3., Column 1, the registrants must submit information allowing (1) a conclusion whether the substance is a skin sensitiser and (2) whether it can be presumed to have the potential to produce significant sensitisation in humans (Cat. 1A).

1.1. Information provided

30 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) An in vivo skin sensitisation study (Bueler test; 1991) with the source substance isophthalic acid, EC number 204-506-4

1.2. Assessment of the information provided

1.2.1. Read-across adaptation rejected

31 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.

1.2.2. No assessment of potency

32 To be considered compliant and enable a conclusion in cases where the substance is considered to cause skin sensitisation, the information provided must also allow a conclusion whether it can be presumed to have the potential to produce significant sensitisation in humans (Cat. 1A).

33 As the currently available data does not allow to conclude whether the Substance causes skin sensitisation (see section 1.2.1. above), this condition cannot be assessed.

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

1.3. Specification of the study design

35 To fulfil the information requirement for the Substance, information on molecular interaction with skin proteins and inflammatory response in keratinocytes and activation of dendritic cells (OECD TG 442C and OECD TG 442D and OECD TG 442E) must be provided. Furthermore an appropriate risk assessment is required if a classification of the Substance as a skin sensitiser (Cat 1A or 1B) is warranted.

36 In case no conclusion on the skin sensitisation potency can be made for the Substance based on the existing data or newly generated in vitro data, in vivo skin sensitisation study must be performed and the murine local lymph node assay (EU Method B.42/OECD TG 429) is considered as the appropriate study for the potency estimation.

2. In vitro gene mutation study in bacteria

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

2.1. Information provided

38 You have provided:

(i) An *in vitro* gene mutation study in bacteria (1979) with the Substance

2.2. Assessment of the information provided

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

39 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) triplicate plating is used at each dose level.

40 In study (i):

a) the test was performed with the strains S. typhimurium TA 1535, TA 1537, TA 98 and TA 100 (i.e., the strain E. coli WP2 uvrA, or E. coli WP2 uvrA (pKM101), or S. typhimurium TA102 is missing);
b) triplicate plating was not used at each dose level as only duplicate cultures (instead of triplicate) were included.

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

42 Therefore, the information requirement is not fulfilled.

2.3. Specification of the study design

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

3. Ready biodegradability

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

3.1. Information provided

45 You have provided:

(i) a ready biodegradability study, OECD TG 301B (1991) with the Substance;
(ii) a ready biodegradability study, OECD TG 301C (1975) with the Substance.

3.2. Assessment of information provided

3.2.1. The provided studies do not meet the specifications of the test guideline(s)

46 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, the following requirements must be met:

47 Technical specifications impacting the sensitivity/reliability of the test

a) determination is carried out at least in duplicate

48 Reporting of the methodology and results

b) the source of the inoculum, its concentration in the test are reported.

- For an OECD TG 301B, the concentration of the inoculum is set to reach a bacterial cell density of 10^7 to 10^8 cells/L in the test vessel. The suspended solid concentration is ≤ 30 mg/L.
- For an OECD TG 301C, the concentration of the inoculum is set to reach a bacterial cell density of 10^7 to 10^8 cells/L in the test vessel.

c) the test temperature and pH are reported.

d) the inorganic carbon content (IC) and total carbon content (TC) of the test material suspension in the mineral medium at the beginning of the test is reported (only for OECD TG 301B).

e) test design: number of replicate, reference substance, toxicity control, the oxygen uptake of the inoculum blank, the percentage degradation of the reference compound calculated from the oxygen consumption by day 7 and by day 14 (only for OECD TG 301C).

49 In study (i) described as a study on ready biodegradability (OECD TG 301B):

50 Technical specifications impacting the sensitivity/reliability of the test

a) determinations were not carried out in at least duplicate, as you have stated that "*two vessels dosed with TPA (i.e. the Substance): one at ca. 10 mg/L and the other at ca. 20 mg/L*."

Reporting of the methodology and results

b) You have not specified the concentration of the inoculum and the suspended solid concentration.

c) You have not reported pH.

d) You have not reported the inorganic carbon content (IC).

51 In study (ii) described as a study on ready biodegradability (OECD TG 301C):

b) You have not specified the concentration of the inoculum and the suspended solid concentration.

c) You have neither reported temperature nor pH.

f) You have not specified information on the test design, as specified f) above.

52 Based on the above,

- For study (i): there are critical methodological deficiencies resulting in the rejection of the study results. More specifically, as no replicate was used, the validity criteria of the test guideline cannot be verified.
- For both studies (i) and (ii): the reporting of the studies are not sufficient to conduct an independent assessment of their reliability.

53 Therefore, the requirements of OECD TG 301 B/C are not met and the information requirement is not fulfilled.

Reasons related to the information under Annex VIII of REACH

4. In vitro gene mutation study in mammalian cells

54 An in vitro gene mutation study in mammalian cells is an information requirement under Annex VIII, Section 8.4.3., in case of a negative result in the in vitro gene mutation test in bacteria and the in vitro cytogenicity test.

4.1. Information provided

55 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) an in vitro gene mutation study in mammalian cells (1994) with the source substance isophthalic acid, EC number 204-506-4

4.2. Assessment of the information provided

4.2.1. Read-across adaptation rejected

56 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.

4.3. Triggering of the information requirement

57 Your dossier contains (I) a negative result for *in vivo* micronucleus study, and (II) inadequate data for the other study (*in vitro* gene mutation study in bacteria).

58 The *in vitro* gene mutation study in bacteria provided in the dossier is rejected for the reasons provided in request 2.

59 The result of the request 2 will determine whether the present requirement for an *in vitro* mammalian cell gene mutation study in accordance with Annex VIII, Section 8.4.3 is triggered.

60 Consequently, you are required to provide information for this information requirement, if the *in vitro* gene mutation study in bacteria provides a negative result.

4.4. Specification of the study design

61 To fulfil the information requirement for the Substance, either the in vitro mammalian cell gene mutation tests using the hprt and xprt genes (OECD TG 476) or the thymidine kinase gene (OECD TG 490) are considered suitable.

Reasons related to the information under Annex IX of REACH

5. Pre-natal developmental toxicity study in one species

62 A pre-natal developmental toxicity (PNDT) study (OECD TG 414) in one species is an information requirement under Annex IX, Section 8.7.2.

5.1. Information provided

63 You have provided:

(i) a sexual differentiation study, no TG followed (2000) with the source substance DEHT

64 You have also adapted this information requirement by using Annex XI, Section 1.2. (weight of evidence) based on the following experimental data:

(ii) a developmental toxicity study similar to OECD TG 414 (1990) with the Substance
(iii) a developmental toxicity study according to OECD TG 414 (2005) with the source substance DEHT
(iv) a developmental toxicity study according to OECD TG 414 (2001) with the source substance DEHT

5.2. Assessment of the information provided

5.2.1. Study (i) not adequate for the information requirement

65 To fulfil the information requirement, a study must comply with OECD TG 414 (Article 13(3) of REACH). Therefore, the following specifications must be met:

a) at least 20 female animals with implantation sites are included for each test and control group to ensure a statistical power equivalent to OECD TG 414;
b) the foetuses are examined for external, skeletal and soft tissue alterations (variations and malformations).

66 The study (i) is described as a sexual differentiation study of male rats. This study has not been conducted under a specific test guideline.

67 The study does not cover the key parameters of OECD TG 414:

a) only 8 female animals (i.e., less than 20 female animals) with implementation sites are included in each group, and therefore the statistical power is not equivalent to OECD TG 414;
b) the foetuses are not examined for external, skeletal and soft tissue alterations (variations and malformations) are not investigated.

68 The study is not adequate for the information requirement and is therefore rejected.

5.2.2. Weight of evidence assessment (studies (ii), (iii) and (iv))

69 Annex XI, Section 1.2 states that there may be sufficient weight of evidence from several independent sources of information enabling, through a reasoned justification, a conclusion on the information requirement, while the information from each single source alone is insufficient to fulfil the information requirement.

70 The justification must have regard to the information that would otherwise be obtained from the study that must normally be performed for this information requirement.

71 According to ECHA Guidance R.4, a weight of evidence adaptation involves an assessment of the relative values/weights of the different sources of information submitted. The weight given is based on the reliability of the data, consistency of results/data, nature and severity of effects, and relevance and coverage of the information for the given regulatory information requirement. Subsequently, relevance, reliability, coverage, consistency and results of these sources of information must be balanced in order to decide whether they together provide sufficient weight to conclude on the corresponding information requirement.

72 Annex XI, section 1.2 requires that adequate and reliable documentation is provided to describe your weight of evidence approach. This documentation must include robust study summaries of the studies used as sources of information and a justification explaining why the sources of information together provide a conclusion on the information requirement.

73 You have not included a justification for your weight of evidence adaptation, which would include an adequate and reliable (concise) documentation as to why the sources of information provide sufficient weight to conclude on the information requirements under consideration.

74 In spite of this critical deficiency, ECHA has nevertheless assessed the validity of your adaptation. Your weight of evidence approach has deficiencies that are common to all information requirements under consideration and also deficiencies that are specific for these information requirements individually.

75 Relevant information that can be used to support weight of evidence adaptation for information requirement of Section 8.7.2 at Annex IX includes similar information that is produced by the OECD TG 414 on one species. The following aspects are covered: 1) prenatal developmental toxicity, 2) maternal toxicity, and 3) maintenance of pregnancy.

76 Developmental toxicity includes information after prenatal exposure on embryonic/foetal survivial(number of live foetuses; number of resorptions and dead foetuses, postimplantation loss), growth (body weights and size) and structural malformations and variations (external, visceral and skeletal).

77 Maternal toxicity includes information after gestational exposure on maternal survival, body weight and clinical signs.

78 Maintenance of pregnancy includes information on abortions or early delivery as a consequence of gestational exposure.

79 The sources of information (ii), (iii) and (iv) provide relevant information on developmental toxicity, maternal toxicity and maintenance of pregnancy. However, the reliability of the sources of information (iii) and (iv) is significantly affected by the deficiencies identified and explained under Appendix on Reasons common to several requests, and cannot contribute to the conclusion on this key element.

80 Information from source substance(s) can be used as part of weight of evidence adaptation if the read-across is accepted.

81 The information from (iii) and (iv) with a read across source substance is already rejected under Appendix 0.1. Therefore it cannot be used as part of the weight of evidence adaptation.

82 Therefore, no conclusion can be drawn on prenatal developmental toxicity as required by the information requirement.

83 In addition, according to ECHA Guidance[4] the highest dose level should be intended to produce some toxicity (or to reach the oral limit dose of 1000 mg/kg bw/day) to provide adequate information on reproductive toxicity for the purpose of both classification (including categorisation within the Reproductive toxicity hazard class) and risk

assessment. Dose level selection (and vehicle used) must be justified and documented to allow independent evaluation of the choice made.

84 The highest dose level in the source of information (ii) did not induce any toxicity and you have not shown that the aim was to induce toxicity. Therefore, the dose level selection was too low, and the studies do not fulfil the criterion set in OECD TG 414.

85 Finally, considering the route of exposure in the source of information (ii), OECD TG 414 states that "*The test chemical or vehicle is usually administered orally by intubation. If another route of administration is used, the tester should provide justification and reasoning for its selection*". You have not provided any justification why the inhalation route was chosen.

86 Taken together, the relevant information on prenatal developmental toxicity provided is not reliable.

87 Your weight of evidence adaptation does not include any relevant and reliable sources of information to conclude on the property of prenatal developmental toxicity on one species. Therefore your adaptation is rejectedand the information requirement is not fulfilled.

88 In your comments to the draft decision, you agree with ECHA's assessment. However, you state that "*The SIEF agrees that one additional OECD 414 study should be conducted in the rat on PTA or Isophthalic acid , EC No 204-506-4 (CAS No 121-91-5), further abbreviated as IPA"* and*. " it is envisaged that this study should be conducted on IPA. This study will serve as a bridging study for DART data between the substances (as IPA is currently data lacking for DART), which will also be read-across to PTA in a weight-of-evidence with the above data".* You also state that "*The SIEF is confident that the overall read-across justification, covering PTA, IPA, and DEHT, can be improved to a level of acceptance if the outcome of the studies is as expected. Should the read-across development be unfavourable, the registrants agree to commission a new OECD 414 study in the rat on PTA".*

89 ECHA takes note of your intentions to improve the toxicological profile of the Substance and your plans to refine your read-across approach. As indicated in your comments, this strategy relies essentially on data which is yet to be generated, therefore no conclusion on the compliance can currently be made. You remain responsible for complying with this decision by the set deadline.

5.3. Specification of the study design

90 A PNDT study according to the test method OECD TG 414 should be performed in rat or rabbit as preferred species.

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

92 Therefore, the study must be conducted in rats or rabbits with oral administration of the Substance.

6. Long-term toxicity testing on fish

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

6.1. Information provided

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

- All identified uses of the substance are assessed as safe for the environment.
- The Substance will not be directly applied to water and exposure to aquatic system is not expected to occur based on the use pattern.
- The Substance is not released from articles from polyesters following polymerisation.
- The Substance is readily biodegradable.

6.2. Assessment of the information provided

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

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

96 Your adaptation is therefore rejected and the information requirement is not fulfilled.

97 Therefore, the information requirement is not fulfilled.In your comments to the draft decision, you agree with ECHA's assessment. You indicate that you intend to adapt this information requirement by means of a grouping and read-across according toAnnex XI, Section 1.5. to REACH. You also explain that you intend to submit Qualitative or Quantitative-structure-activity relationship ((Q)SAR) to support the prediction. You specify that you intend to use the results of testing on either IPA or PTA for the prediction. You also state that, if neither of these options is applicable, you will conduct the requested study.

98 ECHA takes note of your intentions to improve the ecotoxicological profile of the Substance and to submit a read-across approach. As indicated in your comments, this strategy relies essentially on data which is yet to be generated, therefore no conclusion on the compliance can currently be made. You remain responsible for complying with this decision by the set deadline.

6.3. Study design and test specifications

99 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

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.

ECHA took into account your comments and did not amend the requests.

In the comments on the draft decision, you requested an extension of the deadline from 24 to 36 months from the date of adoption of the decision. However, you have provided no supporting document to justify your request. Therefore, ECHA has not amended the deadline.

ECHA took into account your comments and did not amend the requests or the deadline.

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]
[redacted]	[redacted]	[redacted]
[redacted]	[redacted]	[redacted]
[redacted]	[redacted]	[redacted]
[redacted]	[redacted]	[redacted]
[redacted]	[redacted]	[redacted]
[redacted]	[redacted]	[redacted]
[redacted]	[redacted]	[redacted]
[redacted]	[redacted]	[redacted]
[redacted]	[redacted]	[redacted]
[redacted]	[redacted]	[redacted]
[redacted]	[redacted]	[redacted]
[redacted]	[redacted]	[redacted]
[redacted]	[redacted]	[redacted]
[redacted]	[redacted]	[redacted]
[redacted]	[redacted]	[redacted]
[redacted]	[redacted]	[redacted]
[redacted]	[redacted]	[redacted]
[redacted]	[redacted]	[redacted]
[redacted]	[redacted]	[redacted]
[redacted]	[redacted]	[redacted]

[redacted]	[redacted]	[redacted]
[redacted]	[redacted]	[redacted]
[redacted]	[redacted]	[redacted]
[redacted]	[redacted]	[redacted]
[redacted]	[redacted]	[redacted]
[redacted]	[redacted]	[redacted]
[redacted]	[redacted]	[redacted]
[redacted]	[redacted]	[redacted]
[redacted]	[redacted]	[redacted]
[redacted]	[redacted]	[redacted]
[redacted]	[redacted]	[redacted]
[redacted]	[redacted]	[redacted]
[redacted]	[redacted]	[redacted]
[redacted]	[redacted]	[redacted]
[redacted]	[redacted]	[redacted]
[redacted]	[redacted]	[redacted]
[redacted]	[redacted]	[redacted]
[redacted]	[redacted]	[redacted]
[redacted]	[redacted]	[redacted]
[redacted]	[redacted]	[redacted]
[redacted]	[redacted]	[redacted]
[redacted]	[redacted]	[redacted]
[redacted]	[redacted]	[redacted]
[redacted]	[redacted]	[redacted]
[redacted]	[redacted]	[redacted]
[redacted]	[redacted]	[redacted]
[redacted]	[redacted]	[redacted]
[redacted]	[redacted]	[redacted]
[redacted]	[redacted]	[redacted]
[redacted]	[redacted]	[redacted]
[redacted]	[redacted]	[redacted]
[redacted]	[redacted]	[redacted]
[redacted]	[redacted]	[redacted]
[redacted]	[redacted]	[redacted]
[redacted]	[redacted]	[redacted]

[redacted]	[redacted]	[redacted]
[redacted]	[redacted]	[redacted]
[redacted]	[redacted]	[redacted]
[redacted]	[redacted]	[redacted]
[redacted]	[redacted]	[redacted]
[redacted]	[redacted]	[redacted]
[redacted]	[redacted]	[redacted]
[redacted]	[redacted]	[redacted]
[redacted]	[redacted]	[redacted]
[redacted]	[redacted]	[redacted]
[redacted]	[redacted]	[redacted]
[redacted]	[redacted]	[redacted]
[redacted]	[redacted]	[redacted]
[redacted]	[redacted]	[redacted]
[redacted]	[redacted]	[redacted]
[redacted]	[redacted]	[redacted]
[redacted]	[redacted]	[redacted]
[redacted]	[redacted]	[redacted]
[redacted]	[redacted]	[redacted]
[redacted]	[redacted]	[redacted]
[redacted]	[redacted]	[redacted]
[redacted]	[redacted]	[redacted]
[redacted]	[redacted]	[redacted]
[redacted]	[redacted]	[redacted]
[redacted]	[redacted]	[redacted]
[redacted]	[redacted]	[redacted]
[redacted]	[redacted]	[redacted]
[redacted]	[redacted]	[redacted]
[redacted]	[redacted]	[redacted]
[redacted]	[redacted]	[redacted]
[redacted]	[redacted]	[redacted]
[redacted]	[redacted]	[redacted]
[redacted]	[redacted]	[redacted]
[redacted]	[redacted]	[redacted]
[redacted]	[redacted]	[redacted]
[redacted]	[redacted]	[redacted]
[redacted]	[redacted]	[redacted]
[redacted]	[redacted]	[redacted]
[redacted]	[redacted]	[redacted]
[redacted]	[redacted]	[redacted]
[redacted]	[redacted]	[redacted]
[redacted]	[redacted]	[redacted]

[redacted]	[redacted]	[redacted]

~~Confidential~~

[redacted]	[redacted]	[redacted]
[redacted]	[redacted]	[redacted]
[redacted]	[redacted]	[redacted]
[redacted]	[redacted]	[redacted]
[redacted]	[redacted]	[redacted]
[redacted]	[redacted]	[redacted]
[redacted]	[redacted]	[redacted]
[redacted]	[redacted]	[redacted]
[redacted]	[redacted]	[redacted]

Where applicable, the name of a third party representative (TPR) may be displayed in the list of recipients whereas ECHA will send the decision to the actual registrant.

Appendix 4: Conducting and reporting new tests for REACH purposes

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

1.1. Test methods, GLP requirements and reporting

(1) Under Article 13(3) of REACH, all new data generated as a result of this decision must be conducted according to the test methods laid down in a European Commission Regulation or to international test methods recognised by the Commission or ECHA as being appropriate.

(2) Under Article 13(4) of REACH, ecotoxicological and toxicological tests and analyses must be carried out according to the GLP principles (Directive 2004/10/EC) or other international standards recognised by the Commission or ECHA.

(3) Under Article 10(a)(vi) and (vii) of REACH, all new data generated as a result of this decision must be reported as study summaries, or as robust study summaries, if required under Annex I of REACH. See ECHA Practical Guide on How to report robust study summaries[2].

(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