~~Confidential~~

Helsinki, 22 September 2021

Addressees
Registrant(s) of kkkkkkkk as listed in the last Appendix of this decision

Date of submission of the dossier subject to this decision
04/11/2014

Registered substance subject to this decision ("the Substance")
Substance name: (1-methylethylidene)di-4,1-phenylene tetraphenyl diphosphate
EC number: 425-220-8
CAS number: NS

Decision number: Please refer to the REACH-IT message which delivered this communication (in format CCH-D-XXXXXXXXXX-XX-XX/F)

DECISION ON A COMPLIANCE CHECK

Under Article 41 of Regulation (EC) No 1907/2006 (REACH), you must submit the information listed below, by the deadline of ***27 June 2024***.

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

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

1. Long-term toxicity testing on fish also requested below (triggered by Annex VIII, Section 9.1.3., column 2)

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

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

*The requested above study (*Repeated dose toxicity oral 90 days test, Schroeder R.E., 2010)[1] *is already available in the jointly submitted registration for the Substance. Under Article 26(3) of REACH, you must not repeat a study involving vertebrate animals conducted on the same substance.*

2. Long-term toxicity testing on fish requested (Annex IX, Section 9.1.6.; test method: OECD TG 210)

The study (Fish, Early-life Stage Toxicity Test, Larron Tian, 2011) is already available in the jointly submitted registration for the Substance. Under Article 26(3) of REACH, you must not repeat a study involving vertebrate animals conducted on the same substance.

3. Identification of degradation products (Annex IX, 9.2.3.; test method: using an appropriate test method)

C. Information required from all the Registrants subject to Annex X of REACH

1. Pre-natal developmental toxicity study (Annex X, Section 8.7.2.; test method: OECD TG 414) by oral route, in a second species (rabbit)
2. Extended one-generation reproductive toxicity study (Annex X, Section 8.7.3.; test

[1] ECHA dissemination site: https://echa.europa.eu/fi/registration-dossier/-/registered-dossier/5460/7/6/2/?documentUUID=f83e8abd-c945-4dc6-b3a3-bdb8152b1f68

method: OECD TG 443) in rats, oral route, specified as follows:

- Ten weeks premating exposure duration for the parental (P0) generation;
- Dose level setting shall aim to induce systemic toxicity at the highest dose level;
- Cohort 1A (Reproductive toxicity); and
- Cohort 1B (Reproductive toxicity) without extension to mate the Cohort 1B animals to produce the F2 generation.

You must report the study performed according to the above specifications. Any expansions of the study design must be scientifically justified.

Reasons for the request(s) are explained in the following appendices:

- Appendices entitled "Reasons to request information required under Annexes VII to X of REACH", respectively.

Information required depends on your tonnage band

You must provide the information listed above for all REACH Annexes applicable to you, and in accordance with Articles 10(a) and 12(1) of REACH:

- the information specified in Annexes VII to X to REACH, for registration at more than 1000 tpa.

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 testing and reporting requirements provided under the Appendix entitled "Requirements to fulfil when conducting and reporting new tests for REACH purposes". In addition, you should follow the general recommendations provided under the Appendix entitled "General recommendations when conducting and reporting new tests for REACH purposes". For references used in this decision, please consult the Appendix entitled "List of references".

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[2] under the authority of Christel Schilliger-Musset, Director of Hazard Assessment

[2] 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 A: Reasons to request information required under Annex VIII of REACH

1. Long-term toxicity testing on fish

Short-term toxicity testing on fish is an information requirement under Annex VIII to REACH (Section 9.1.3.). Long-term toxicity testing on fish must be considered (Section 9.1.3., Column 2) if the substance is poorly water soluble.

You have provided an OECD TG 203 study on fish but no information on long-term toxicity on fish for the Substance.

We have assessed this information and identified the following issue:

Poorly water soluble substances require longer time to reach steady-state conditions. As a result, the short-term tests does not give a true measure of toxicity for this type of substances and the long-term test is required. A substance is regarded as poorly water soluble if, for instance, it has a water solubility below 1 mg/L or below the detection limit of the analytical method of the test material (ECHA Guidance R.7.8.5).

In the provided water solubility study (OECD TG 105), the saturation concentration of the Substance in water was determined to be 0.415 mg/L.

Therefore, the Substance is poorly water soluble and information on long-term toxicity on fish must be provided.

The examination of the information provided, as well as the selection of the requested test and the test design are addressed under section B.2.

Appendix B: Reasons to request information required under Annex IX of REACH

1. Sub-chronic toxicity study (90-day)

A Sub-chronic toxicity study (90 day) is a standard information requirement in Annex IX to REACH.

You have provided the following information under this endpoint:

(i) Short-term (28-day) repeated toxicity study in rat (key study, according to Method B7 of directive 92/69/EEC and MHW, 1997)

ECHA has assessed this information and identified the following issue(s):

To fulfil the information requirement, a study must comply with the OECD TG 408 (Article 13(3) of REACH). The specifications of this OECD TG include, among other elements, that dosing of the Substance should occur daily for a period of 90 days until the scheduled termination of the study.
The repeated dose oral toxicity (28-day) study you provided has an exposure duration of 28 days.

Based on the above, the information you provided do not fulfil the information requirement.

Information on the design of the study to be performed

Following the criteria provided in Annex IX, Section 8.6.2, Column 2, the oral route is the most appropriate route of administration to investigate repeated dose toxicity[3], the Substance is a liquid of very low vapour pressure (1.2 x 10^{-6} Pa at 25°C) and no uses with spray application are reported that could potentially lead to aerosols of inhalable size. Therefore, the sub-chronic toxicity study must be performed according to the OECD TG 408, in rats and with oral administration of the Substance.

Information on data sharing for studies involving vertebrate animals

The jointly submitted registration for the Substance contains data which is relevant for this endpoint (Repeated dose toxiicty oral 90 days test, [redacted] 2010). In accordance with Title III of the REACH Regulation, you must request it from the other registrant(s) and then make every effort to reach an agreement on the sharing of data and costs[4].

2. Long-term toxicity testing on fish

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

You have provided the following justification to omit the study: "A reliable report *named Flame Retardant Alternatives, which was conducted by* [redacted] *for the Washington State Departments of Ecology and Health, February 2006, indicates that Experimental fish NOEC values of BDP was 5 mg/L (*[redacted]*, 2006), which was much greater than the estimated water solubility for pure BDP. So it suggested that BDP has no effect to fish at saturation. Therefore, further studies on this endpoint will be unnecessary."*

[3] ECHA Guidance R.7a, Section R.7.6.2.3.2.
[4] https://echa.europa.eu/regulations/reach/registration/data-sharing

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

Although you do not explicitly claim an adaptation, ECHA understands that the information provided was submitted in order to meet the required information by way of adaptation under Annex XI, Section 1.1.2. This adaptation rule enables registrants to claim that the data from experiments not carried out according to GLP or the test methods referred to in Article 13(3) can be considered equivalent to data generated by those test methods where a number of cumulative conditions are met, in particular:

1. Adequate and reliable coverage of the key parameters foreseen to be investigated in the corresponding test methods referred to in Article 13(3), in this case long-term toxicity testing on fish according to OECD TG 210.
2. Exposure duration comparable to or longer than the corresponding test methods referred to in Article 13(3);
3. Adequate and reliable documentation of the study is provided;
4. Adequacy for the purpose of classification and labelling and/or risk assessment.

For independently assessing and establishing this for a study, a robust study summary must be provided (ECHA Guidance R.6, Section R.6.2.6; Art. 3(28) and 10(a)(vii) and Annex I, Section 3.1.5 of REACH).

Robust study summaries must provide a detailed summary of the objectives, methods, results and conclusions of a full study report providing sufficient information to make an independent assessment of the study (Article 3(28)).

In your justification you have referred to an existing report using the results from an existing study to conclude on the long-term toxicity testing on fish. You have only indicated the effect estimate from this study but provided no robust study summary.

Therefore, you have not provided detailed information on the objectives, methods, results and conclusions, allowing for an independent assessment of the study. Consequently, you have not demonstrated that any of the cumulative criteria indicated above are met.

Therefore, your adaptation is rejected.

Study design

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

<u>Information on data sharing for studies involving vertebrate animals</u>
The jointly submitted registration for the Substance contains data which is relevant for this endpoint (Fish, Early-life Stage Toxicity Test[redacted], 2011). In accordance with Title III of the REACH Regulation, you must request it from the other registrant and then make every effort to reach an agreement on the sharing of data and costs[5].

[5] https://echa.europa.eu/regulations/reach/registration/data-sharing

3. Identification of degradation products

Identification of degradation products is an information requirement under Annex IX to REACH (Section 9.2.3.).

You have not provided information nor an adaptation to fulfil this information requirement.

Therefore, this information requirement is not fulfilled.

This information is required for the purpose of the PBT/vPvB assessment (Annex I, Section 4) and the risk assessment (Annex I, Section 6) of the Substance.

Study design

Regarding the selection of appropriate and suitable test method(s), you are advised to consult ECHA Guidance R.7b (Section R.7.9.4) which describes the appropriate and suitable test methods for the determination of degradation products. You may obtain information on degradation/transformation products from the applicable simulation test OECD TG 309 "pathway part", OECD TG 308, OECD TG 307 or by some other measures such as enhanced screening level degradation test or modelling tools. You will need to provide a scientifically valid justification for the chosen method. The provided information should include, identification, stability, behaviour, molar quantity of transformation/degradation products relative to the parent compound. In addition, degradation half-life, log K_{ow} and potential toxicity of the transformation/degradation may need to be investigated.

Appendix C: Reasons to request information required under Annex X of REACH

1. Pre-natal developmental toxicity study in a second species

Pre-natal developmental toxicity (PNDT) studies (OECD TG 414) in two species is a standard information requirement under Annex X to REACH.

You have provided a study conducted with the Substance according to the test guideline OECD TG 414 (Prenatal Developmental Toxicity Study) in the rat as a first species ([redacted] 2006).

You have not provided information on a second species. Therefore the information requirement is not fulfilled.

Information on study design
A PNDT study according to the OECD TG 414 study should be performed in the rabbit or rat as the preferred species. The test in the first species was carried out by using a rodent species (rat). Therefore, a PNDT study in a second species must be performed in the rabbit as preferred non-rodent species.

2. Extended one-generation reproductive toxicity study

The basic test design of an Extended one-generation reproductive toxicity (EOGRT) study (OECD TG 443) is a standard information requirement under Annex X to REACH. Furthermore Column 2 of Section 8.7.3. defines when the study design needs to be expanded.

You did not provide any experimental data for this endpoint. Instead, you sought to adapt this information requirement in accordance with column 2 of Annex X, section 8.7.

ECHA has evaluated the provided information and identified the following issues:

According to Annex X, Section 8.7., Column 2, third indent, the study does not need to be conducted if the substance is of low toxicological activity. This needs to be demonstrated with three concomitant criteria, two of them being:

i. that it can be proven from toxicokinetic data that no systemic absorption occurs via relevant routes of exposure.
ii. there is no or no significant human exposure

In your registration dossier you have not provided any toxicokinetic data to prove no systemic absorption via relevant routes of exposure. To the contrary, in your Chemical Safety Report (CSR) you acknowledge that systemic absorption occurs, as you have assumed the following absorption values for the calculation of the DNEL for systemic toxicity: "*83 %, 20 % and 100 % absorption by the oral, dermal and inhalation route respectively*".

With regards to the human exposure, you state in your CSR: "*As the existing information indicates that BDP is used as flame-retardant and incorporated into matrix of many types of products. The exposure can be negligible because the low vapour pressure (less than 1.2 × 10-6 kPa at 25 °C, involatile) and former technical process*". Further, you have reported a number of consumer uses of articles, in which your Substance is incorporated, among others: larger articles (plastic chair, PVC-flooring, lawn mower, PC), Toys (doll, car, animals, teething rings), Plastic, small articles (ball pen, mobile phone).

Based on the information provided criterion (i) is not fulfilled, as systemic exposure to the Substance after oral administration does occur and you have not provided any toxicokinetic data to demonstrate otherwise.

As regard the criterion (ii), you claim that your substance is incorporated in articles and you assume that the exposure is negligible. However, you have not provided any evidence that there is no release of the substance from the articles during the whole life cycle.
According to ECHA Guidance R. 5 (section R.5.1.1.5.3.3), for substances incorporated in articles, the following, among others, should be considered to justify 'no release':

- Proof that no emissions from the article occur, including disposal and recovery of article waste.
- If the substance is embedded in the matrix of the article: a description of the stability of the article matrix and the bonds between the substance and the matrix during the different life cycle stages of the article. Proof that the substance remains fully immobile inside the article and does not migrate to the surface and out of it (e.g. due to the inherent physicochemical properties of the substance, or a special coating of the article).

You have not an provided acceptable justification to confirm that there are no releases from articles during the uses or during the disposal and waste stage. Therefore, the absence of or no significant human exposure cannot be excluded.

In conclusion, based on the above, your adaptation according to Annex X, Section 8.7., Column 2, third indent is rejected, therefore the information requirement is not fulfilled.

<u>The specifications for the study design</u>

ECHA considered the 90-day study on the Substance (available on the ECHA dissemination site[6]) for the assessment of the appropriate study design for EOGRTS.

Premating exposure duration and dose-level setting

The length of premating exposure period must be ten weeks to cover the full spermatogenesis and folliculogenesis before the mating, allowing meaningful assessment of the effects on fertility.

Ten weeks premating exposure duration is required to obtain results adequate for classification and labelling and /or risk assessment. There is no substance specific information in the dossier supporting shorter premating exposure duration.

Therefore, the requested premating exposure duration is ten weeks.

In order to be compliant and not to be rejected due to too low dose levels, the highest dose level shall aim to induce systemic toxicity, but not death or severe suffering of the animals, to allow comparison of reproductive toxicity and systemic toxicity. The dose level selection should be based upon the fertility effects. A descending sequence of dose levels should be selected in order to demonstrate any dose-related effect and to establish NOAELs.

If there is no relevant data to be used for dose level setting, it is recommended that range-finding results are reported with the main study.

[6] https://echa.europa.eu/fi/registration-dossier/-/registered-dossier/5460/7/6/2/?documentUUID=f83e8abd-c945-4dc6-b3a3-bdb8152b1f68

You have to provide a justification with your study results that demonstrates that the dose level selection meets the conditions described above.

Cohorts 1A and 1B

Cohorts 1A and 1B belong to the basic study design and must be included.

Species and route selection

The study must be performed in rats with oral[7] administration. In addition, based on the PNDT study provided in rats, oral gavage dosing is suitable for the Substance. Therefore, the study should be conducted using oral gavage dosing.

Further expansion of the study design

The conditions to include the extension of Cohort 1B are currently not met. Furthermore, no triggers for the inclusion of Cohorts 2A and 2B (developmental neurotoxicity) and Cohort 3 (developmental immunotoxicity) were identified. However, you may expand the study by including the extension of Cohort 1B, Cohorts 2A and 2B and/or Cohort 3 if relevant information becomes available from other studies or during the conduct of this study. Inclusion is justified if the available information meets the criteria and conditions which are described in Column 2, Section 8.7.3., Annex X. You may also expand the study due to other scientific reasons in order to avoid a conduct of a new study. The study design, including any added expansions, must be fully justified and documented. Further detailed guidance on study design and triggers is provided in ECHA Guidance[8].

[7] ECHA Guidance R.7a, Section R.7.6.2.3.2.
[8] ECHA Guidance R.7a, Section R.7.6.

Appendix D: Requirements to fulfil when conducting and reporting new tests for REACH purposes

A. 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[9].

B. 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[10].

[9] https://echa.europa.eu/practical-guides
[10] https://echa.europa.eu/manuals

Appendix E: General recommendations when conducting and reporting new tests for REACH purposes

A. Strategy for the PBT/vPvB assessment

Under Annex XIII, the information must be based on data obtained under conditions relevant for the PBT/vPvB assessment. You must assess the PBT properties of all relevant transformation/degradation products. Alternatively, you would have to justify why you consider these not relevant for the PBT/vPvB assessment.

You are advised to consult ECHA Guidance R.7b (Section R.7.9.), R.7c (Section R.7.10) and R.11 on PBT assessment for advice on the interpretation of results in concluding whether the Substance, including the relevant transformation and degradation products, fulfils the PBT/vPvB criteria of Annex XIII.

You must revise your PBT assessment when the new information is available.

Appendix F: 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 01 February 2021.

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

ECHA did not receive any comments within the commenting period.

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 G: List of references - ECHA Guidance[11] and other supporting documents

Evaluation of available information
Guidance on information requirements and chemical safety assessment, Chapter R.4 (version 1.1., December 2011), referred to as ECHA Guidance R.4 where relevant.

QSARs, read-across and grouping
Guidance on information requirements and chemical safety assessment, Chapter R.6 (version 1.0, May 2008), referred to as ECHA Guidance R.6 where relevant.

Read-across assessment framework (RAAF, March 2017)[12]

RAAF - considerations on multiconstituent substances and UVCBs (RAAF UVCB, March 2017)[13]

Physical-chemical properties
Guidance on information requirements and chemical safety assessment, Chapter R.7a (version 6.0, July 2017), referred to as ECHA Guidance R.7a in this decision.

Toxicology
Guidance on information requirements and chemical safety assessment, Chapter R.7a (version 6.0, July 2017), referred to as ECHA Guidance R.7a in this decision.

Guidance on information requirements and chemical safety assessment, Chapter R.7c (version 3.0, June 2017), referred to as ECHA Guidance R.7c in this decision.

Environmental toxicology and fate
Guidance on information requirements and chemical safety assessment, Chapter R.7a (version 6.0, July 2017), referred to as ECHA Guidance R.7a in this decision.

Guidance on information requirements and chemical safety assessment, Chapter R.7b (version 4.0, June 2017), referred to as ECHA Guidance R.7b in this decision.

Guidance on information requirements and chemical safety assessment, Chapter R.7c (version 3.0, June 2017), referred to as ECHA Guidance R.7c in this decision.

PBT assessment
Guidance on information requirements and chemical safety assessment, Chapter R.11 (version 3.0, June 2017), referred to as ECHA Guidance R.11 in this decision.

Guidance on information requirements and chemical safety assessment, Chapter R.16 (version 3.0, February 2016), referred to as ECHA Guidance R.16 in this decision.

Data sharing
Guidance on data-sharing (version 3.1, January 2017), referred to as ECHA Guidance on data sharing in this decision.

OECD Guidance documents[14]

[11] https://echa.europa.eu/guidance-documents/guidance-on-information-requirements-and-chemical-safety-assessment
[12] https://echa.europa.eu/support/registration/how-to-avoid-unnecessary-testing-on-animals/grouping-of-substances-and-read-across
[13] https://echa.europa.eu/documents/10162/13630/raaf_uvcb_report_en.pdf/3f79684d-07a5-e439-16c3-d2c8da96a316
[14] http://www.oecd.org/chemicalsafety/testing/series-testing-assessment-publications-number.htm

Guidance Document on aqueous–phase aquatic toxicity testing of difficult test chemicals – No 23, referred to as OECD GD 23.

Guidance document on transformation/dissolution of metals and metal compounds in aqueous media – No 29, referred to as OECD GD 29.

Guidance Document on Standardised Test Guidelines for Evaluating Chemicals for Endocrine Disruption – No 150, referred to as OECD GD 150.

Guidance Document supporting OECD test guideline 443 on the extended one-generation reproductive toxicity test – No 151, referred to as OECD GD 151.

Appendix H: Addressees of this decision and their corresponding information requirements

You must provide the information requested in this decision for all REACH Annexes applicable to you.

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.