EUROPEAN CHEMICALS AGENCY

~~Confidential~~

Helsinki, 6 May 2021

Addressees
Registrant of EC#253-781-7/CAS#38103-06-9 listed in the last Appendix of this decision

Date of submission for the jointly submitted dossier subject of a decision
05/11/2019

Registered substance subject to this decision, hereafter 'the Substance'
Substance name: 4,4'-[(isopropylidene)bis(p-phenyleneoxy)]diphthalic dianhydride
EC number: 253-781-7
CAS number: 38103-06-9

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

DECISION ON A TESTING PROPOSAL

Under Article 40 of Regulation (EC) No 1907/2006 (REACH), you must submit the information listed below, by the deadline of ***14 November 2022***.

A. Requirements applicable to all the Registrants subject to Annex IX of REACH

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

Reasons for the request(s) are explained in the appendix 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. Hence you have to comply with the requirements of Annexes VII to X of REACH, if you have registered a substance at above 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[1] under the authority of Christel Schilliger-Musset, Director of Hazard Assessment

[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 A: Reasons for the requirements applicable to all the Registrants subject to Annex IX of REACH

This decision is based on the examination of the testing proposals you submitted.

1. Sub-chronic toxicity study (90-day), oral route (Annex IX, Section 8.6.2.)

Examination of the testing proposal
A sub-chronic toxicity study (90 day) is a standard information requirement in Annex IX, Section 8.6.2. to REACH.

You have submitted a testing proposal for a sub-chronic toxicity study (90 day) in rats by the oral route according to OECD TG 408 with the Substance.

ECHA notes that you provided your considerations concluding that there were no alternative methods which could be used to adapt the information requirement(s) for which testing is proposed. ECHA has taken these considerations into account.

You proposed testing by the oral route, in rats. Given the physicochemical properties of the substance, ECHA agreed with your proposal.

Comments on the draft decision

Following receipt of the draft decision you submitted comments arguing that the testing proposal is no longer needed. You explained that since the initial registration of the substance in 2010, all of your tonnage has concerned the substance as a reacted monomer in imported polymers, but in 2019, in anticipation of an expected import of the unreacted monomer, you updated the substance registration to account for these additional uses including a testing proposal for a 90 days repeated dose toxicity study. However, you now indicate that due to a change of commercial activity, you did not import and do not intend to import the unreacted monomer substance.

However, based on your comments, we understand that you still import and intend to import the substance as a reacted monomer in imported polymers. In case of import of polymers, the monomer substance(s) and other substances of the polymers that have not already been registered by an actor up the supply chain, must be registered if both the conditions set out in Article 6(3) of REACH are met. You submitted a registration dossier for the Substance and this dossier must comply with the applicable information requirements, including the submission of a sub-chronic toxicity study (90 day).

This information requirement can be omitted only subject to the submission a valid adaptation under column 2, Section 8.6.2. of Annex IX or under Annex XI to REACH.

In that respect, you provided in your comment on the draft decision arguments for the lack of exposure covering the situation when the monomer is reacted into polymer. ECHA has examined the information in your comments and identified the following issue:

Exposure based adaptation under Annex XI, section 3

As stated in Annex XI, Section 3, testing in accordance with Sections 8.6 and 8.7 of Annex VIII and in accordance with Annexes IX and X may be omitted based on the exposure scenario(s) developed in the CSR, by providing an adequate and scientifically-supported justification based on a thorough and rigorous exposure assessment in accordance with Section 5 of Annex I and by communicating the specific conditions of use through the supply chain. Any one of the following criteria 3.2.(a),(b) or (c) shall be met. In particular:

- 3.2 (a) the manufacturer or importer demonstrates and documents that all of the following conditions are fulfilled,
  i. the results of the exposure assessment covering all relevant exposures throughout the life cycle of the substance demonstrate the absence of or no significant exposure in all scenarios of the manufacture and all identified uses as referred to in Annex VI section 3.5.;
  ii. a suitable DNEL or a PNEC can be derived from results of available test data for the Substance taking full account of the increased uncertainty resulting from the omission of the information requirement, and that DNEL or PNEC is relevant and appropriate both to the information requirement to be omitted and for risk assessment purposes; and
  iii. the comparison of the derived DNEL or PNEC with the results of the exposure assessment shows that exposures are always well below the derived DNEL or PNEC.
- 3.2 (b) where the substance is not incorporated in an article the manufacturer or the importer demonstrates and documents for all relevant scenarios that throughout the life cycle strictly controlled conditions as set out in Art 18(4)(a) to (f) apply; and/or
- 3.2 (c) where the substance is incorporated in an article in which it is permanently embedded in a matrix or otherwise rigorously contained by technical means, it is demonstrated and documented that all of the following conditions i) to (iii) are fulfilled, where the first condition is
  i. the substance is not released during its life cycle.
  ii. the likelihood that workers or the general public or the environment are exposed to the substance under normal or reasonably foreseeable conditions of use is negligible; and
  iii. the substance is handled according to the conditions set out in Article 18(4)(a) to (f) during all manufacturing and production stages including the waste management of the substance during these stages.

Firstly, you already indicate in your dossier that you have considered an exposure-based adaptation under section 3.2. (a) as not applicable for the reasons below

> *"Substance Tailored Exposure Driven testing is not appropriate in this case as the footnote to Section 3.2 (a) (ii) of Annex XI states the following... subparagraph 3.2(a)(ii), without prejudice to column 2 of section 8.6 of Annexes IX and X, a DNEL derived from a 28-day repeated dose toxicity study shall not be considered appropriate to omit a 90-day repeated dose toxicity study. As such it is deemed by the Regulation inappropriate to use a DNEL derived from a 28 day study to waive a 90 day study without other the grounds stated in Column 2 of Annex IX Section 8.6.2. In the absence of adequate justification for omitting the study the registrant has concluded that a sub-chronic toxicity study (90 days) (oral) is required"*

Secondly, with reference to Section 3.2 (b) for substances not incorporated into an article, you have not demonstrated and documented in your dossier or your comments (for all relevant scenarios) that throughout the life cycle strictly controlled conditions as set out in Article 18(4)(a) to (f) apply.

Finally, you indicate in your CSR that the substance is not incorporated into an Article which implies that Section 3.2 (c) is not applicable either.

Therefore, the information you provided in your comments on the draft decision and in the dossier does not meet any of the conditions set out for this adaptation in Annex XI, Section 3.

Under Article 40(3)(a) of REACH, you are requested to carry out the proposed test with the Substance.

Appendix B: 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[2].

B. Test material

1. Selection of the Test material(s)
   The Test Material used to generate the new data must be selected taking into account the following:
   - the 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

Appendix C: Procedure

ECHA started the testing proposal evaluation in accordance with Article 40(1) on 5 November 2019.

This testing proposal examination decision does not prevent ECHA from initiating compliance checks at a later stage on the registrations present.

ECHA held a third party consultation for the testing proposal from 27 January 2020 until 12 March 2020. ECHA did not receive information from third parties.

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.

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 D: List of references - ECHA Guidance[4] and other supporting documents

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 in this decision.

ECHA Read-across assessment framework (RAAF, March 2017)[5]

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.

OECD Guidance documents

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

[4] https://echa.europa.eu/guidance-documents/guidance-on-information-requirements-and-chemical-safety-assessment
[5] https://echa.europa.eu/support/registration/how-to-avoid-unnecessary-testing-on-animals/grouping-of-substances-and-read-across

Appendix E: 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) Data requirements to be fulfilled
[redacted]	[redacted]	[redacted]

Note: where applicable, the name of a third party representative (TPR) may be displayed in the list of recipients whereas the decision is sent to the actual registrant.