baua:
Bundesanstalt für Arbeitsschutz
und Arbeitsmedizin

# SUBSTANCE EVALUATION

# CONCLUSION DOCUMENT

## as required by REACH Article 48

## for

# 4,4'-[(isopropylidene)bis(p-phenyleneoxy)]diphthalic dianhydride (BPA-DA)

## EC No 253-781-7

## CAS No 38103-06-9

**Evaluating Member State:**

Germany

Dated: 19 November 2015

DISCLAIMER

The Conclusion document has been prepared by the evaluating Member State as a part of the substance evaluation process under the REACH Regulation (EC) No 1907/2006. The information and views set out in this document are those of the author and do not necessarily reflect the position or opinion of the European Chemicals Agency or other Member States. The Agency does not guarantee the accuracy of the information included in the document. Neither the Agency nor the evaluating Member State nor any person acting on either of their behalves may be held liable for the use which may be made of the information contained therein. Statements made or information contained in the document are without prejudice to any further regulatory work that the Agency or Member States may initiate at a later stage.

## Evaluating Member State Competent Authority

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## Year of evaluation in CoRAP: 2013

The substance evaluation was concluded without requesting further information from the Registrant(s) under an Article 46(1) decision due to the Registrant(s) demonstrating that the substance is only imported as a reacted monomer and that the percentage of the monomer is below the threshold to identify the polymer as a PBT substance.

**Please find (search for) further information on registered substances here:**

http://echa.europa.eu/de/information-on-chemicals/registered-substances

# Foreword

Substance evaluation is an evaluation process under REACH Regulation (EC) No. 1907/2006. Under this process the Member States perform the evaluation and ECHA secretariat coordinates the work.

In order to ensure a harmonised approach, ECHA in cooperation with the Member States developed risk-based criteria for prioritising substances for substance evaluation. The list of substances subject to evaluation, the Community rolling action plan (CoRAP), is updated and published annually on the ECHA web site[1].

Substance evaluation is a concern driven process, which aims to clarify whether a substance constitutes a risk to human health or the environment. Member States evaluate assigned substances in the CoRAP with the objective to clarify the potential concern and, if necessary, to request further information from the registrant(s) concerning the substance. If the evaluating Member State concludes that no further information needs to be requested, the substance evaluation is completed. If additional information is required, this is sought by the evaluating Member State. The evaluating Member State then draws conclusions on how to use the existing and obtained information for the safe use of the substance.

This Conclusion document, as required by the Article 48 of the REACH Regulation, provides the final outcome of the Substance Evaluation carried out by the evaluating Member State. In this conclusion document, the evaluating Member State shall consider how the information on the substance can be used for the purposes of identification of substances of very high concern (SVHC), restriction and/or classification and labelling. With this Conclusion document the substance evaluation process is finished and the Commission, the registrants of the substance and the competent authorities of the other Member States are informed of the considerations of the evaluating Member State. In case the evaluating Member State proposes further regulatory risk management measures, this document shall not be considered initiating those other measures or processes.

[1] http://echa.europa.eu/regulations/reach/evaluation/substance-evaluation/community-rolling-action-plan

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# 1. CONCERN(S) SUBJECT TO EVALUATION

BPA-DA was originally selected for substance evaluation in order to clarify suspected risk about PBT and high aggregated tonnage.

During the evaluation no further concerns to be clarified under substance evaluation process were identified.

# 2. CONCLUSION OF SUBSTANCE EVALUATION

The available information on the substance and the evaluation conducted has led the evaluating Member State to the following conclusions, as summarised in the table below.

| **Conclusions** | **Tick box** |
|---|---|
| Need for follow up regulatory action at EU level<br>*[if a specific regulatory action is already identified then, please, select one or more of the specific follow up actions mentioned below]* | |
| *Need for Harmonised classification and labelling* | |
| *Need for Identification as SVHC (authorisation)* | |
| *Need for Restrictions* | |
| *Need for other Community-wide measures* | |
| No need for regulatory follow-up action | x |

The evaluating Member State Competent Authority (eMSCA) concluded first that further information was required to clarify the concerns regarding PBT. However, during the substance evaluation decision making process, the registrant demonstrated that the substance is only imported as a reacted monomer and that the percentage of the residual monomer is below the threshold to identify the polymer as a PBT substance. For the same reason it is concluded that exposure to the environment is of no relevance.

As the potential verification of the PBT-status of the monomer by means of a substance evaluation would not lead to further regulatory measures, the decision-making process was terminated and substance evaluation concluded.

# 3. JUSTIFICATION FOR THE CONCLUSION ON THE NEED OF REGULATORY RISK MANAGEMENT

## 3.1. NEED FOR FOLLOW UP REGULATORY ACTION AT EU LEVEL

Not required.

## 3.2. NO FOLLOW-UP ACTION NEEDED

| **The concern could be removed because** | **Tick box** |
|---|---|
| *Exposure was verified to be not relevant* and/or | ***x*** |
| *Hazard and /or exposure was verified to be under appropriate control* and/or | |
| *The registrant modified the applied risk management measures.* | |
| *other: <Please specify>* | |

The eMSCA concluded first that further information was required to clarify the concerns regarding PBT. However, during the substance evaluation decision making process, the registrant demonstrated that the substance is only imported as a reacted monomer and that the percentage of the residual monomer is <0.1% w/w.

The eMSCA considers that the concern for potential PBT properties remains unverified since no additional information was requested to clarify the concern. However, since the percentage of the residual monomer is below the threshold to identify the polymer as a PBT substance, verification of the monomer's PBT-status would not lead to further regulatory measures. Consequently, the substance evaluation was concluded.

If new uses would be registered for BPA-DA, the evaluating MSCA recommends considering the re-inclusion of this substance in the CoRAP for further clarification of the concerns regarding PBT.

# 4. TENTATIVE PLAN FOR FOLLOW-UP ACTIONS (IF NECESSARY)

Not required.