SUBSTANCE EVALUATION

CONCLUSION DOCUMENT

as required by REACH Article 48

for

diethyl phthalate (DEP)

EC No 201-550-6

CAS No 84-66-2

Evaluating Member States:

Germany

Portugal

Dated: 28 August 2015

Evaluating Member State Competent Authority

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Year of evaluation in CoRAP: 2014

DE / PT concluded the evaluation without the need to ask further information from the registrants under Article 46(1) decision.

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

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

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.

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

Diethyl phthalate was originally selected for substance evaluation in order to clarify suspected risks about:

- Suspected CMR (carcinogenic, mutagenic and/or reprotoxic effects)
- Suspected endocrine disruptor
- Relationship to consumer use (wide dispersive use)

The Substance Evaluation is targeted towards consumer health. During the evaluation, no further concerns were identified that need to be clarified under the substance evaluation process with regard to consumers.

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 *[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**

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

3.1. NEED FOR FOLLOW UP REGULATORY ACTION AT EU LEVEL

Not relevant.

3.2. NO FOLLOW-UP ACTION NEEDED

The concern could be removed because	**Tick box**
Hazard and exposure[1)] *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>	

[1)] Hazard on human health and consumer exposure

The existing information on diethyl phthalate (DEP) is sufficient to conclude that classification of DEP is not justified. In agreement with the CLP Regulation the changes in one out of eleven sperm parameters alone as seen in animals were not considered to warrant classification for fertility effects. According to 3.7.2.3.3 of Annex I, CLP Regulation effects of low or minimal toxicological significance (including small changes in semen parameters) should not lead to classification. The developmental findings such as reduced pup weight at weaning and reduced litter size occurred at doses above the limit dose of 1000 mg/kg bw/day. According to 3.7.2.5.8 and 3.7.2.5.9, Annex I of the CLP Regulation, effects at such high doses would normally not lead to classification unless expected human response indicate the need for a higher dose level.

Finally, the low molecular weight phthalate DEP and the shorter side chain (C2) do not support that DEP could act as a potent testicular toxin and could induce developmental changes in the male reproductive system as observed after prenatal exposure to mid molecular weight (so-called ‘transitional’) phthalates with critical lengths of carbon side chains (C4-C6).

Overall, by means of a weight of evidence approach the eMSCA considers the effects observed on male fertility and the observed developmental effects as not sufficient for classification as Repr. 2 according to Annex I, Part 3 of Regulation (EC) No 1272/2008 (CLP).

The existing information on DEP is sufficient to conclude that DEP does not exhibit endocrine disrupting effects in terms of human health similar to those observed with other phthalate diesters. Predominantly negative results on the oestrogenic or anti-androgenic potency of DEP are reported and an endocrine disrupting mechanism cannot be attributed to the DEP effects on the male reproductive system.

The registrants have also determined that DEP did not fulfil the CLP criteria. Consumer exposure is therefore not recorded in their Registration dossiers. The assessed data derived from publicly available literature do not indicate a concern based on consumer exposure to DEP via consumer uses.