

OPINION OF THE MEMBER STATE COMMITTEE
ON THE IDENTIFICATION OF DIBUTYL PHTHALATE (DBP)
AS A SUBSTANCE OF VERY HIGH CONCERN

**According to Articles 57 and 59 of
Regulation (EC) 1907/2006¹**

Adopted on 11 December 2014

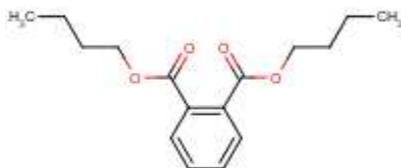
This agreement concerns

Substance name: Dibutyl phthalate (DBP)

EC number: 201-557-4

CAS number: 84-74-2

Molecular formula: C₁₆H₂₂O₄



Structural formula:

¹ Regulation (EC) No 1907/2006 of the European Parliament and of the Council of 18 December 2006 concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH), establishing a European Chemicals Agency, amending Directive 1999/45/EC and repealing Council Regulation (EEC) No 793/93 and Commission Regulation (EC) No 1488/94 as well as Council Directive 76/769/EEC and Commission Directives 91/155/EEC, 93/67/EEC, 93/105/EC and 2000/21/EC

Denmark (Dossier submitter) presented a proposal in accordance with Article 59(3) and Annex XV of the REACH Regulation (28 August 2014, submission number DU002407-33) on identification of *Dibutyl phthalate (DBP)* as a substance of very high concern due to its endocrine disrupting properties for which there is scientific evidence of probable serious effects to **human health** and the **environment** which give rise to an equivalent level of concern to those of other substances listed in paragraphs (a) to (e) of Article 57 of REACH.

The Annex XV dossier was circulated to Member States on 1 September 2014 and the Annex XV report was made available to interested parties on the ECHA website on the same day according to Articles 59(3) and 59(4).

Comments were received from both Member States and interested parties on the proposal.

The dossier was referred to the Member State Committee on 17 November 2014 and was discussed in the meeting on 8-11 December 2014 of the Member State Committee.

MSC **did not reach** unanimous agreement on the part of the proposal related to effects of DBP to **human health**².

Pursuant to Articles 59 (9) and 85(8) of REACH in order for the Commission to draft a proposal on the identification of the substance in accordance with the procedure outlined in Article 133 (3) of the REACH Regulation, the Member State Committee provides this opinion, consisting of the position of the majority of its members, including its grounds.

Four MSC members expressed a minority position, including their grounds, that is made available in a separate document.

In accordance with Article 59 (9), a final decision on the identification of DBP shall be taken in accordance with the procedure referred to in Article 133(3).

² At the meeting, the dossier submitter informed MSC of its decision to **withdraw** its proposal for identification of DBP under Article 57 (f) as giving rise to an equivalent level of concern due to endocrine disrupting properties in relation to the **environment** in order to further elaborate on the justifications provided in the documentation.

OPINION OF THE MEMBER STATE COMMITTEE IN ACCORDANCE WITH ARTICLE 59(8):

Dibutyl phthalate (DBP) should be identified as a substance meeting the criteria of Article 57 (f) of Regulation (EC) 1907/2006 (REACH) because it is a substance with endocrine disrupting properties for which there is scientific evidence of probable serious effects to human health which give rise to an equivalent level of concern to those for other substances listed in paragraphs (a) to (e) of Article 57 of REACH.

UNDERLYING ARGUMENTATION FOR IDENTIFICATION OF SUBSTANCE OF VERY HIGH CONCERN

Endocrine disrupting properties - Article 57(f):

Human Health: DBP has been shown to adversely affect the endocrine system of mammals primarily through in vivo findings on reduced foetal testosterone. These findings are further substantiated by mechanistic findings, also in vivo, of down-regulation of genes in the steroidogenic biosynthesis pathway. The spectrum of adverse effects observed in rats include increased nipple retention, decreased anogenital distance, genital malformations, reduced number of spermatocytes and testicular changes including multinucleated gonocytes, tubular atrophy and Leydig cell hyperplasia.

In summary, when available information from toxicological studies is combined, DBP can be considered an endocrine disruptor for both the environment and for human health as it fulfils the WHO/IPCS definition of an endocrine disruptor and the recommendations from the European Commission's Endocrine Disrupters Expert Advisory Group for a substance to be identified as an endocrine disruptor.

DBP is considered as a substance giving rise to an equivalent level of concern because scientific evidence shows that exposure during sensitive time windows of development may cause irreversible developmental programming effects leading to severe effects on development and reproduction, regarded as particularly serious in relation to human health, also because these adverse effects may first manifest themselves in later life stages as a consequence of exposure during early life stages. Adverse effects on development and reproduction are in addition generally regarded as endpoints of concern, and as such frequently used for regulatory hazard and risk assessment both for human health.

In conclusion and taking into account all available information on the intrinsic endocrine disrupting properties of DBP and its adverse effects, it is concluded that DBP is a substance for which there is scientific evidence of probable serious effects to humans which gives rise to an equivalent level of concern to those of other substances listed in points (a) to (e) of Article 57 of REACH.

Reference:

Support Document to MSC opinion *Dibutyl phthalate (DBP)* (Member State Committee, provided to MSC on 19 November 2014 and adopted on 11 December 2014)