

**AGREEMENT OF THE MEMBER STATE COMMITTEE
ON THE IDENTIFICATION OF
BIS(2-ETHYLHEXYL) PHTHALATE (DEHP)
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

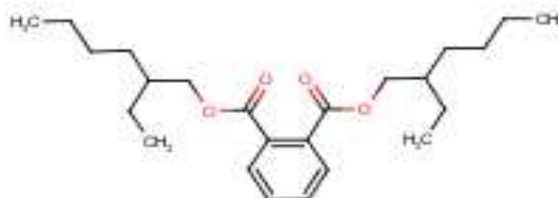
Substance name: Bis(2-ethylhexyl) phthalate (DEHP)

EC number: 204-211-0

CAS number: 117-81-7

Molecular formula: C₂₄H₃₈O₄

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 presented a proposal in accordance with Article 59(3) and Annex XV of the REACH Regulation (26 August 2014, submission number DU002194-36) on identification of *Bis(2-ethylhexyl) phthalate (DEHP)* 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 DEHP to human health. In accordance with Article 59 (9) of the REACH Regulation, a MSC opinion with majority and minority views is to be prepared, adopted by MSC and sent to the Commission for taking a final decision in accordance with the procedure outlined in Article 133 (3) of the REACH Regulation.

Agreement of the Member State Committee in accordance with Article 59(8):

***Bis(2-ethylhexyl) phthalate (DEHP)* is identified as a substance of very high concern 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 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.**

UNDERLYING ARGUMENTATION FOR IDENTIFICATION OF SUBSTANCE OF VERY HIGH CONCERN

Endocrine disrupting properties – Article 57(f):

In relation to the environment, adverse effects concerning development and reproduction are generally regarded as endpoints of particular relevance because such effects are likely to manifest themselves at the population level. The effects observed in rats are of particular concern for mammalian wildlife species with a natural low reproductive output (including endangered species) as negative effects on reproduction have an even higher potential for causing long term negative effect at the population level for such taxa.

Adverse effects caused by exposure to DEHP have also been identified in non-mammalian species where the sex ratio and reproductive output was affected in fish. Furthermore, several studies in fish indicate that DEHP has an estrogenic MoA which may cause the sex reversal of male fish to female fish and / or affect the reproductive output. Hence the current data indicates also in fish that DEHP has endocrine disruptive properties leading to adverse effects related to sexual development and reproduction.

In summary, when available information from mammalian and ecotoxicological studies are combined, DEHP can be considered an endocrine disruptor for the environment as it fulfils the WHO/IPCS definition of an endocrine disruptor and the recommendations from the European Commission's Endocrine Disruptors Expert Advisory Group for a substance to be identified as an endocrine disruptor.

DEHP 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 wildlife species, 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 population relevant endpoints of concern, and as such frequently used for regulatory hazard and risk assessment for environmental species.

Conclusion: Taking into account all available information on the intrinsic endocrine disrupting properties of DEHP and its adverse effects, it is concluded that DEHP is a substance with endocrine disrupting properties for which there is scientific evidence of probable serious effects to the environment 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 *Bis(2-ethylhexyl) phthalate (DEHP)* (Member State Committee, 11 December 2014)