

**OPINION OF THE MEMBER STATE COMMITTEE
ON THE IDENTIFICATION OF**

Dicyclohexyl phthalate

AS A SUBSTANCE OF VERY HIGH CONCERN

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

Adopted on 9 June 2016

This opinion concerns

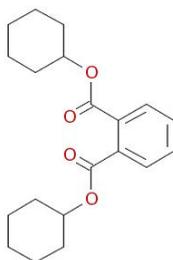
Substance name: Dicyclohexyl phthalate

EC number: 201-545-9

CAS number: 84-61-7

Molecular formula: C₂₀H₂₆O₄

Structural formula:



¹Regulation (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

Sweden presented a proposal in accordance with Article 59(3) and Annex XV of the REACH Regulation (17 February 2016, submission number SPS-011978-16-1) on identification of *dicyclohexyl phthalate* as a substance of very high concern due to its toxic for reproduction (CMR) and endocrine disruptive 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 29 February 2016 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 May 2016 and was discussed in the meeting on 6-9 June 2016 of the Member State Committee.

MSC **did not reach** unanimous agreement on the part of the proposal related to effects of DCHP 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.

Five 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 DCHP 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 DCHP 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):

***Dicyclohexyl phthalate (DCHP)* should be identified as a substance of very high concern because:**

- **it meets the criteria of Article 57 (c) of Regulation (EC) 1907/2006 (REACH) owing to its classification as toxic for reproduction category 1B³**
- **it meets 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 of other substances listed in paragraphs (a) to (e) of Article 57 of REACH.**

³ DCHP is included in the 9th ATP to Regulation (EC) No 1272/2008 Annex VI, part 3, Table 3.1 List of harmonised classification and labelling of hazardous substances [as amended and adapted to technical and scientific progress by Commission Regulation (EU) No 944/2013, OJ No L 235, p.5 , 3.10.2013], as agreed at the 44th meeting of the REACH Committee 3-4 February 2016

UNDERLYING ARGUMENTATION FOR IDENTIFICATION OF SUBSTANCE OF VERY HIGH CONCERN

Toxicity for reproduction:

DCHP should be identified as a substance of very high concern in accordance with Article 57 (c) of Regulation (EC) 1907/2006 (REACH) because it meets the classification criteria for reproductive toxicity, category 1B.

In accordance with Article 37(4) of the Regulation (EC) No 1272/2008, the Committee for Risk Assessment (RAC) has adopted an opinion for harmonised classification and labelling of dicyclohexyl phthalate. At RAC-31 (December 2014) the RAC adopted the opinion that dicyclohexyl phthalate meets the criteria for classification as toxic for reproduction Repr. 1B, H360D ("May damage the unborn child."). DCHP is included in the 9th ATP to Regulation (EC) No 1272/2008 in accordance with the agreement of the REACH Committee taken at the 44th meeting (3-4 February 2016).

Therefore, this harmonised classification of DCHP shows that the substance meets the criteria for classification in the hazard class:

- Reproductive toxicity category 1B in accordance with Article 57 (c) of REACH.

Endocrine disrupting properties – Article 57(f):

DCHP should be identified as a substance of very high concern in accordance with 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 of other substances listed in points (a) to (e) of Article 57 of REACH.

DCHP has been shown to adversely affect the endocrine system of mammals primarily through *in vivo* findings on reduced fetal testosterone production. These findings are further substantiated by mechanistic findings of inhibitory effects on enzymes in the steroidogenic biosynthesis pathway. The spectrum of effects observed in rats include increased areola mammae retention, decreased anogenital distance, prolonged preputial separation, genital malformations associated with small testis, signs of reduced sperm quality, atrophic tubules in prostate, prostatic intraepithelial neoplasia and testicular changes including tubular atrophy of which almost all can be considered adverse.

In conclusion, DCHP is considered an endocrine disruptor for human health as it fulfils the World Health Organisation/International Programme on Chemical Safety (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.

The endocrine disrupting properties of DCHP give rise to an equivalent level of concern to those of other substances listed in points (a) to (e) of Article 57 of REACH because scientific evidence shows that exposure during sensitive time windows of development are likely to cause irreversible developmental programming effects leading to severe effects on development and reproduction. This is regarded as particularly serious in relation to human health, also because these adverse effects may first manifest themselves in later life stages because of exposure during early life stages and it may be difficult to establish a toxicological threshold for such effects with sufficient certainty. A reduced ability to reproduce

considerably reduces the quality of life for the individuals affected, and it has a negative impact on society as it contributes to an increased financial burden.

Taking into account the available information on the intrinsic toxic for reproduction and endocrine disrupting properties of DCHP and its adverse effects to human health, it is concluded that DCHP should be identified as a substance of very high concern in accordance with Article 57 (c) and 57 (f) of Regulation (EC) 1907/2006 (REACH) 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 the MSC opinion for *Dicyclohexyl phthalate (DCHP)* (Member State Committee, 6-9 June 2016)