

AGREEMENT OF THE MEMBER STATE COMMITTEE

**ON THE IDENTIFICATION OF 1,2-BENZENEDICARBOXYLIC ACID,
DIHEXYL ESTER, BRANCHED AND LINEAR**

AS A SUBSTANCE OF VERY HIGH CONCERN

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

Adopted on 30 May 2014

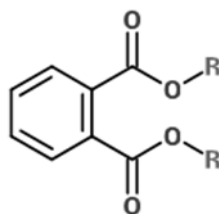
This agreement concerns

**Substance name: 1,2-Benzenedicarboxylic acid, dihexyl ester, branched
and linear**

EC number: 271-093-5

CAS number: 68515-50-4

Molecular formula: C₂₀H₃₀O₄



Structural formula:

R = C₆H₁₃, branched and linear

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 (26 February 2014, submission number DN005315-49) on identification of *1,2-Benzenedicarboxylic acid, dihexyl ester, branched and linear* as a substance of very high concern due to its toxic for reproduction properties.

The Annex XV dossier was circulated to Member States on 3 March 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 20 May 2014 and agreed in the written procedure of the Member State Committee with closing date of 30 May 2014.

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

***1,2-Benzenedicarboxylic acid, dihexyl ester, branched and linear* is identified as a substance meeting the criteria of Article 57 (c) of Regulation (EC) 1907/2006 (REACH) owing to the adopted opinion² by the Committee for Risk Assessment (RAC) which has agreed that the substance meets the criteria for classification as toxic for reproduction category 1B in accordance with Regulation (EC) No 1272/2008³**

² Committee for Risk Assessment RAC Opinion proposing harmonised classification and labelling at EU level of 1,2-Benzenedicarboxylic acid, dihexylester, branched and linear EC number: 271-093-5 CAS number: 68515-50-4 CLH-O-0000002695-67-03/F Adopted 7 June 2013 <http://echa.europa.eu/documents/10162/18d3ed6d-91c5-48d0-844a-8383ab5723b3>

³ Regulation (EC) No 1272/2008 of the European Parliament and of the Council of 16 December 2008 on classification, labelling and packaging of substances and mixtures, amending and repealing Directives 67/548/EEC and 1999/45/EC, and amending Regulation (EC) No 1907/2006.

UNDERLYING ARGUMENTATION FOR IDENTIFICATION OF SUBSTANCE OF VERY HIGH CONCERN

Toxicity for reproduction:

In accordance with Article 37(4) of the Regulation (EC) No 1272/2008⁴, the Committee for Risk Assessment (RAC) has adopted an opinion for harmonised classification and labelling of *1,2-benzenedicarboxylic acid, dihexyl ester, branched and linear* in June 2013. At RAC-25 the RAC adopted the opinion that *1,2-benzenedicarboxylic acid, dihexyl ester, branched and linear* meets the criteria for classification as toxic for reproduction Repr. 1B, H360FD ("May damage fertility. May damage the unborn child."). The corresponding classification in accordance with Directive 67/548/EEC would be toxic for reproduction Repr. Cat.2, R60-61 ("May impair fertility. May cause harm to the unborn child."). After decision of the European Commission, confirming the classification as Repr. 1B, the new classification will be included in the list of harmonised classifications (Annex VI to the CLP Regulation).

Therefore, *1,2-benzenedicarboxylic acid, dihexyl ester, branched and linear* meets the criteria of Article 57(c) of Regulation (EC) 1907/2006 (REACH Regulation).

Reference:

Support Document *1,2-Benzenedicarboxylic acid, dihexyl ester, branched and linear* (Member State Committee, 30 May 2014)

⁴ Regulation (EC) No 1272/2008 of the European Parliament and of the Council of 16 December 2008 on classification, labelling and packaging of substances and mixtures, amending and repealing Directives 67/548/EEC and 1999/45/EC, and amending Regulation (EC) No 1907/2006.