

AGREEMENT OF THE MEMBER STATE COMMITTEE

ON THE IDENTIFICATION OF

1,2-Benzenedicarboxylic acid, di-C6-10-alkyl esters; 1,2-Benzenedicarboxylic acid, mixed decyl and hexyl and octyl diesters with ≥ 0.3% of dihexyl phthalate (EC No. 201-559-5)

AS SUBSTANCES OF VERY HIGH CONCERN

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

Adopted on 29 May 2015

This agreement concerns

Substance name:	1,2-Benzenedicarboxylic acid, di-C6-10-alkyl esters with $\geq 0.3\%$ of dihexyl phthalate (EC No. 201-559- 5)	hexyl and octyl diesters
EC number:	271-094-0	272-013-1
CAS number (in the EC inventory):	68515-51-5	68648-93-1
Molecular formula:	Unspecified	Unspecified
Structural formula:	$C_{6-10} = 0$	R = decyl, hexyl or octyl

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 (2 February 2015, submission number DX007073-31) on identification of 1,2-benzenedicarboxylic acid, di-C6-10-alkyl esters; 1,2-benzenedicarboxylic acid, mixed decyl and hexyl and octyl diesters with $\geq 0.3\%$ of dihexyl phthalate (EC No. 201-559-5) as substances of very high concern due to their toxic for reproduction properties.

The Annex XV dossier was circulated to Member States on 2 March 2015 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 18 May 2015 and agreed in the written procedure of the Member State Committee with closing date of 29 May 2015.

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

1,2-Benzenedicarboxylic acid, di-C6-10-alkyl esters²; 1,2benzenedicarboxylic acid, mixed decyl and hexyl and octyl diesters² are identified as substances meeting the criteria of Article 57 (c) of Regulation (EC) 1907/2006 (REACH) as these substances meet the criteria for classification as toxic for reproduction category 1B in accordance with Regulation (EC) No 1272/2008³ when they contain \geq 0.3 % (wt/wt) of dihexyl phthalate (EC No. 201-559-5).

² The substances are identified as SVHC only where they contain ≥ 0.3 % (wt/wt) of dihexyl phthalate (EC No. 201-559-5).

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:

1,2-Benzenedicarboxylic acid, di-C6-10-alkyl esters; 1,2-benzenedicarboxylic acid, mixed decyl and hexyl and octyl diesters with $\geq 0.3\%$ of dihexyl phthalate (EC No. 201-559-5) meet the criteria of Article 57 (c) of Regulation (EC) 1907/2006 (REACH) owing to their classification as Repr. 1B (H360FD: May damage fertility. May damage the unborn child). This is due to the fact that dihexyl phthalate is covered by Index number 607-702-00-1 in part 3 of Annex VI to the CLP Regulation, and that no specific concentration limits are set in Annex VI of the CLP Regulation and therefore the generic concentration limit is to be used for the purpose of determining the classification of substances (or mixtures) containing dihexyl phthalate.

Therefore, 1,2-benzenedicarboxylic acid, di-C6-10-alkyl esters; 1,2benzenedicarboxylic acid, mixed decyl and hexyl and octyl diesters with \geq 0.3% of dihexyl phthalate (EC No. 201-559-5) meet the criteria of Article 57(c) of Regulation (EC) 1907/2006 (REACH Regulation).

Reference:

Support Document for 1,2-benzenedicarboxylic acid, di-C6-10-alkyl esters; 1,2benzenedicarboxylic acid, mixed decyl and hexyl and octyl diesters with $\geq 0.3\%$ of dihexyl phthalate (EC No. 201-559-5) (Member State Committee, 29 May 2015)