

AGREEMENT OF THE MEMBER STATE COMMITTEE ON THE IDENTIFICATION OF

4,4'-ISOPROPYLIDENEDIPHENOL (BISPHENOL A)

AS A SUBSTANCE OF VERY HIGH CONCERN

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

Adopted on 2 December 2016

This agreement concerns

Substance name: 4,4'-isopropylidenediphenol (bisphenol A)

EC number: 201-245-8

CAS number: 80-05-7

Molecular formula: C₁₅H₁₆O₂

Structural formula:

 $HO - CH_3 - OH$

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

France presented a proposal in accordance with Article 59(3) and Annex XV of the REACH Regulation (30 August 2016, submission number SPS-012444-16) on identification of *4,4'-isopropylidenediphenol* (bisphenol A) as a substance of very high concern due to its toxic for reproduction properties.

The Annex XV dossier was circulated to Member States on 6 September 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 22 November 2016 and agreed in the written procedure of the Member State Committee with closing date of 2 December 2016.

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

4,4'-isopropylidenediphenol (bisphenol A) is identified as a substance meeting the criteria of Article 57 (c) of Regulation (EC) 1907/2006 (REACH) as this substance meets the criteria for classification as toxic for reproduction category 1B in accordance with Regulation (EC) No 1272/2008².

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² 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 A SUBSTANCE OF VERY HIGH CONCERN

Toxicity for reproduction:

4,4'-isopropylidenediphenol (Bisphenol A) is covered by index number 604-030-00-0 of Regulation (EC) No 1272/2008 in Annex VI, part 3, Table 3.1 (the list of harmonised classification and labelling of hazardous substances) and it is classified in the hazard class reproductive toxicity category 1B (H360F 'May damage fertility') since its 9th Adaptation to Technical Progress (ATP) (Commission Regulation (EU) 2016/1179).

Therefore, this classification of the substance in Regulation (EC) No 1272/2008 shows that it meets the criteria for classification in the hazard class:

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

Reference:

Support Document (Member State Committee, 2 December 2016)