

**Substance Name(s): 4,4'-isopropylidenediphenol
(bisphenol A)**

EC Number: 201-245-8

CAS Number: 80-05-7

MEMBER STATE COMMITTEE

**SUPPORT DOCUMENT FOR IDENTIFICATION OF
4,4'-ISOPROPYLIDENEDIPHENOL (BISPHENOL A)
AS A SUBSTANCE OF VERY HIGH CONCERN
BECAUSE OF ITS TOXIC FOR REPRODUCTION
(ARTICLE 57 C) PROPERTIES**

Adopted on 2 December 2016

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IDENTIFICATION OF A SUBSTANCE OF VERY HIGH CONCERN ON THE BASIS OF THE CRITERIA SET OUT IN REACH ARTICLE 57

Substance Name: 4,4'-isopropylidenediphenol (Bisphenol A)

EC Number: 201-245-8

CAS number: 80-05-7

- The substance is identified as a substance meeting the criteria of Article 57 (c) of Regulation (EC) No 1907/2006 (REACH) owing to its classification in the hazard class reproductive toxicity category 1B¹.

Note – throughout this report the substance 4,4'-isopropylidenediphenol is also referred to as bisphenol A and/or the abbreviation BPA.

Summary of how the substance meets the criteria set out in Article 57 of the REACH Regulation

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.

Registration dossiers submitted for the substance: Yes

¹ Classification in accordance with section 3.1 of Annex I to Regulation (EC) no 1272/2008 as amended by Commission Regulation (EU) 2016/1179 (9th ATP of the CLP)

Justification

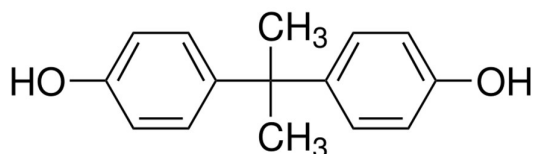
1. Identity of the substance and physical and chemical properties

1.1 Name and other identifiers of the substance

Table 1: Substance identity

EC number:	201-245-8
EC name:	4,4'-isopropylidenediphenol
CAS number (in the EC inventory):	80-05-7
Deleted CAS numbers:	27360-89-0; 28106-82-3; 37808-08-5; 137885-53-1; 146479-75-6; 1429425-26-2
CAS name:	phenol, 4,4'-(1-methylethylidene)bis-
IUPAC name:	4,4'-propane-2,2-diyldiphenol
Index number in Annex VI of the CLP Regulation	604-030-00-0
Molecular formula:	C ₁₅ H ₁₆ O ₂
Molecular weight range:	228.29 g/mol
Synonyms:	Bisphenol A BPA 2,2-bis(4-hydroxyphenyl)propane

Structural formula:



1.2 Composition of the substance

Name: 4,4'-isopropylidenediphenol (Bisphenol A)

Description: 80-100%

Substance type: mono-constituent

Table 2: Constituents other than impurities/additives

Constituents	Typical concentration	Concentration range	Remarks
4,4'-isopropylidenediphenol (<i>bisphenol A</i>) (EC 201-245-8)	80-100%	No information	

Table 3: Impurities

Impurities	Typical concentration	Concentration range	Remarks
<i>None relevant for SVHC identification</i>			

Table 4: Additives

Additives	Typical concentration	Concentration range	Remarks
<i>None relevant for SVHC identification</i>			

1.3 Identity and composition of degradation products/metabolites relevant for the SVHC assessment

Not relevant for the identification of the substance as SVHC in accordance with Article 57 (c) of REACH.

1.4 Identity and composition of structurally related substances (used in a grouping or read-across approach)

Not relevant for the identification of the substance as SVHC in accordance with Article 57 (c) of REACH.

1.5 Physicochemical properties

Not relevant for the identification of the substance as SVHC in accordance with Article 57 (c) of REACH.

2. Harmonised classification and labelling

Bisphenol A is covered by Index number 640-030-00-0 in part 3 of Annex VI to the CLP Regulation as follows as amended by Commission Regulation (EU) 2016/1179 (9th ATP)²:

Table 5: Classification according to Annex VI, Table 3.1 (list of harmonised classification and labelling of hazardous substances) of Regulation (EC) No 1272/2008 (as amended by Commission Regulation (EU) 2016/1179)

Index No	International Chemical Identification	EC No	CAS No	Classification		Labelling			Spec. Conc. Limits, M-factors	Notes
				Hazard Class and Category code(s)	Hazard statement code(s)	Pictogram, Signal Word code(s)	Hazard statement code(s)	Suppl. Hazard statement code(s)		
604-030-00-0	bisphenol A; 4,4'-isopropylidenediphenol	201-245-8	80-05-7	Repr. 1B STOT SE 3 Eye Dam. 1 Skin Sens. 1	H360F H335 H318 H317	GHS08 GHS07 GHS05 Dgr	H360F H335 H318 H317			

3. Environmental fate properties

Not relevant for the identification of the substance as SVHC in accordance with Article 57 (c) of REACH.

4. Human health hazard assessment

Bisphenol A has been classified Repr. 1B – H360F in agreement with the opinion adopted by RAC³ on 14 March 2014, on the basis of effects on female reproductive capacity, on female reproductive organs and male reproductive organs. The opinion can be found on <http://echa.europa.eu/documents/10162/777918ff-33b5-46ff-be89-2bdc406d34fa>.

This classification has been integrated into Regulation (EC) No 1272/2008 in Annex VI, part 3, Table 3.1 (the list of harmonised classification and labelling of hazardous substances) in its 9th Adaptation to Technical Progress (ATP) (Commission Regulation (EU) 2016/1179).

ED-related properties of bisphenol A in relation to its reproductive toxicity as well as to other toxic effects will be addressed in a separate Annex XV dossier for identification as SVHC under Article 57 (f) to be submitted in early 2017.

5. Environmental hazard assessment

Not relevant for the identification of the substance as SVHC in accordance with Article 57 (c) of REACH.

² COMMISSION REGULATION (EU) 2016/1179 of 19 July 2016 amending, for the purposes of its adaptation to technical and scientific progress, Regulation (EC) No 1272/2008 of the European Parliament and of the Council on classification, labelling and packaging of substances and mixtures

³ Opinion of the Risk Assessment Committee proposing harmonised classification and labelling at EU level of Bisphenol A; 4,4'-isopropylidenediphenol (ECHA 2014).

6. Conclusions on the SVHC Properties

6.1 CMR assessment

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.

6.2 PBT and vPvB assessment

Not relevant for the identification of the substance as SVHC in accordance with Article 57 (c) of REACH.

6.3 Assessment under Article 57(f)

Not relevant for the identification of the substance as SVHC in accordance with Article 57 (c) of REACH.

ED-related properties of bisphenol A in relation to its reproductive toxicity as well as to other toxic effects will be addressed in a separate Annex XV dossier for identification as SVHC under Article 57 (f) to be submitted in early 2017.

References

ECHA (2014). Committee for Risk Assessment (RAC). Opinion proposing harmonised classification and labelling at EU level of Bisphenol A; 4,4'-isopropylidenediphenol. Adopted 14 March 2014. ECHA. Available at <http://echa.europa.eu/documents/10162/777918ff-33b5-46ff-be89-2bdc406d34fa> (accessed on 6 June 2016).

Commission Regulation (EU) 2016/1179 of 19 July 2016 amending, for the purposes of its adaptation to technical and scientific progress, Regulation (EC) No 1272/2008 of the European Parliament and of the Council on classification, labelling and packaging of substances and mixtures. Available at <http://eur-lex.europa.eu/legal-content/EN/TXT/?uri=uriserv%3AOJ.L.2016.195.01.0011.01.ENG> (accessed on 25 August 2016).