

Annex XV report

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

Substance Name: 2,2-bis(4'-hydroxyphenyl)-4-methylpentane

EC Number: 401-720-1

CAS Number: 6807-17-6

Submitted by: Sweden

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CONTENTS

PROPOSAL FOR IDENTIFICATION OF A SUBSTANCE OF VERY HIGH CONCERN ON THE BASIS OF THE CRITERIA SET OUT IN REACH ARTICLE 57	4
PART I	5
JUSTIFICATION	5
1. IDENTITY OF THE SUBSTANCE AND PHYSICAL AND CHEMICAL PROPERTIES	5
1.1 Name and other identifiers of the substance	5
1.2 Composition of the substance	6
1.3 Physicochemical properties	6
2. HARMONISED CLASSIFICATION AND LABELLING	6
3. ENVIRONMENTAL FATE PROPERTIES	7
4. HUMAN HEALTH HAZARD ASSESSMENT	7
5. ENVIRONMENTAL HAZARD ASSESSMENT	7
6. CONCLUSIONS ON THE SVHC PROPERTIES	8
6.1 CMR assessment	8
PART II	9
7. REGISTRATION AND C&L NOTIFICATION STATUS	9
7.1 Registration status	9
7.2 CLP notification status	9
8. TOTAL TONNAGE OF THE SUBSTANCE	9
9. INFORMATION ON USES OF THE SUBSTANCE	9
10. INFORMATION ON STRUCTURE OF THE SUPPLY CHAIN	10
11. ADDITIONAL INFORMATION	10
11.1 Substances with similar hazard and use profiles on the Candidate List	10
11.2 Existing EU legislation	11
REFERENCES FOR PART I	12
REFERENCES FOR PART II	12

TABLES

Table 1: Substance identity	5
Table 2: Classification according to Annex VI, Table 3.1 (list of harmonised classification and labelling of hazardous substances) of Regulation (EC) No 1272/2008.....	6
Table 3: CLP notifications.....	9
Table 4: Tonnage status.....	9

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Substance Name: 2,2-bis(4'-hydroxyphenyl)-4-methylpentane

EC Number: 401-720-1

CAS number: 6807-17-6

- The substance is proposed to be 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 toxic for reproduction category 1B¹.

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

2,2-bis(4'-hydroxyphenyl)-4-methylpentane (4,4'-isobutylethylidenediphenol)² is covered by index number 604-024-00-8 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 toxic for reproduction category 1B (hazard statement H360F: 'May damage fertility').

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

- Toxic for reproduction category 1B in accordance with Article 57 (c) of REACH.

Registration dossiers submitted for the substance? Yes (NONS registration)

¹ H360F: 'May damage fertility'

² Synonym name in Annex VI, Table 3.1 of Regulation (EC) No 1272/2008.

PART I

Justification

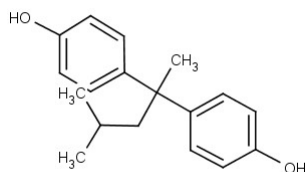
1. Identity of the substance and physical and chemical properties

1.1 Name and other identifiers of the substance

Table 1: Substance identity

EC number:	401-720-1
EC name:	2,2-bis(4'-hydroxyphenyl)-4-methylpentane
CAS number (in the EC inventory):	6807-17-6
CAS number: Deleted CAS numbers:	
CAS name:	
IUPAC name:	4-[2-(4-hydroxyphenyl)-4-methylpentan-2-yl]phenol
Index number in Annex VI of the CLP Regulation	604-024-00-8
Molecular formula:	C ₁₈ H ₂₂ O ₂
Molecular weight range:	270.372 g/mol
Synonyms:	4,4-isobutylethylidenediphenol

Structural formula:



1.2 Composition of the substance

Name: 2,2-bis(4'-hydroxyphenyl)-4-methylpentane

Description: organic

Substance type: mono-constituent

1.3 Physicochemical properties

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

2. Harmonised classification and labelling

2,2-bis(4'-hydroxyphenyl)-4-methylpentane (4,4-isobutylethylidenediphenol*) is covered by Index number 604-024-00-8 in part 3 of Annex VI to the CLP Regulation as follows:

Table 2: Classification according to Annex VI, Table 3.1 (list of harmonised classification and labelling of hazardous substances) of Regulation (EC) No 1272/2008

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)		
604-024-00-8	4,4-isobutylethylidenediphenol	401-720-1	6807-17-6	Repr. 1B Eye Irrit. 2 Aquatic Acute 1 Aquatic Chronic 1	H360F** H319 H400 H410	GHS08 GHS09 Dgr	H360F** H319 H410			

*Synonym name used in Annex VI, Table 3.1 of Regulation (EC) No 1272/2008.

**Harmonised classifications for fertility and developmental effects under Directive 67/548/EEC.

3. Environmental fate properties

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

4. Human health hazard assessment

See sections 2 and 6.1 of this Annex XV report.

5. Environmental hazard assessment

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

6. Conclusions on the SVHC Properties

6.1 CMR assessment

2,2-bis(4'-hydroxyphenyl)-4-methylpentane (4,4-isobutylethylidenediphenol)³ is covered by index number 604-024-00-8 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 toxic for reproduction category 1B (H360F 'May damage fertility').

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

- Toxic for reproduction category 1B in accordance with Article 57 (c) of REACH.

³ Synonym used in Annex VI, Table 3.1 of Regulation (EC) No 1272/2008.

Part II

7. Registration and C&L notification status

7.1 Registration status

There are two NONS registrations for this substance.

7.2 CLP notification status

Table 3: CLP notifications

	CLP Notifications ⁴
Number of aggregated notifications	1
Total number of notifiers	1

8. Total tonnage of the substance

Table 4: Tonnage status

Total tonnage band for the registered substance (excluding the volume registered under Art 17 or Art 18) ⁵	There are no data on current tonnage.
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9. Information on uses of the substance

So far, no company has claimed the two NONS registrations for 2,2-bis(4'-hydroxyphenyl)-4-methylpentane that were notified under Directive 67/548/EEC. No registration according to Article 10 or Article 17 and/or 18 was submitted by registration deadline 2018-05-31⁵.

Potential use in thermal paper

The chemical structure of 2,2-bis(4'-hydroxyphenyl)-4-methylpentane suggests that the substance may be used in the manufacture of thermal paper. In the SinList, the non-governmental organisation ChemSec lists thermal printing paper as a possible use for the substance⁶. However, neither the U.S. EPA nor ANSES have mentioned the substance as an alternative to BPA in thermal papers^{7,8,9}.

Patents

⁴ C&L Inventory database, <http://echa.europa.eu/web/guest/information-on-chemicals/cl-inventory-database> (accessed 19 June 2018)

⁵ <https://echa.europa.eu/registration-dossier/-/registered-dossier/9410> (accessed 28 June 2018)

⁶ Chemsec Sinlist. Available at: <http://chemsec.org/business-tool/sin-list/>

⁷ http://www2.epa.gov/sites/production/files/2015-08/documents/bpa_final.pdf (accessed 28 June, 2018)

⁸ <https://www.anses.fr/en/system/files/CHIM2009sa0331Ra-3.pdf> (accessed 28 June, 2018)

⁹ <https://echa.europa.eu/documents/10162/c6a8003c-81f3-4df6-b7e8-15a3a36baf76> (accessed 28 June, 2018)

According to the PubChem database, 777 patents submitted from 1976 to 2017 are linked to the use of 2,2-bis(4'-hydroxyphenyl)-4-methylpentane. The majority of patents are for use in polymers. Twenty-seven percent of the submitted patents indicate potential use in thermal papers. The screening of patents cannot give an answer to the relevance of the use or if the use is linked to the function as a developer in thermal papers, but rather an indication of current and future uses of the substance. Other minor uses include drugs/biocides, surface coatings, inks, adhesives etc.

10. Information on structure of the supply chain

No information available.

11. Additional information

11.1 Substances with similar hazard and use profiles on the Candidate List

Bisphenols are chemical substances consisting of two phenols (two ring structures of carbon) linked in the 4th-position of the ring structures. Hence, 2,2-bis(4'-hydroxyphenyl)-4-methylpentane is structurally similar to several bisphenols with known or suspected reproductive and endocrine disrupting effects, for example bisphenol A (BPA). *In vivo* and *in vitro* studies show that several bisphenols (such as BPF and BPS) are hormonally active with similar potency and mode of action (Rochester and Bolden 2015). BPA is already included in the Candidate List based on its reprotoxic and endocrine disrupting properties.

Endocrine disrupting properties/concern

2,2-bis(4'-hydroxyphenyl)-4-methylpentane is included on the European Commission priority list for endocrine disruptors¹⁰ as a Group 3 substance, which means that there is no evidence of endocrine disrupting activity or there is no data available. However, in a study from 2007 on updating the ED priority list¹¹, 2,2-bis(4'-hydroxyphenyl)-4-methylpentane was included because of positive effects observed in *in vivo* and *in vitro* assays¹². However, endocrine disrupting effects have not been considered in this SVHC proposal.

Similar uses

2,2-bis(4'-hydroxyphenyl)-4-methylpentane is structurally similar to BPA and reports indicate that 2,2-bis(4'-hydroxyphenyl)-4-methylpentane might have similar uses as BPA, e.g., in the manufacturing of thermal paper. A screening of 2,2-bis(4'-hydroxyphenyl)-4-methylpentane patents further indicates that as many as 27 percent of these patents may be linked to potential use in thermal paper. Thus, a grouping approach with BPA is considered appropriate.

Identification of 2,2-bis(4'-hydroxyphenyl)-4-methylpentane as an SVHC and subsequent authorisation based on a grouping approach, would help to prevent inappropriate substitution of

¹⁰ http://ec.europa.eu/environment/chemicals/endocrine/strategy/substances_en.htm (accessed 29 June 2018).

¹¹ http://ec.europa.eu/environment/chemicals/endocrine/pdf/final_report_2007.pdf (accessed 29 June 2018).

¹² Study on enhancing the ED priority list with a focus on low production volume chemicals ENV.D4/ETUR/2005/0028r (May 2007) Available at: http://ec.europa.eu/environment/chemicals/endocrine/pdf/final_report_2007.pdf (accessed 16 August 2018).

BPA (or other BPA analogues that may become regulated in the future).

If the uses of 2,2-bis(4'-hydroxyphenyl)-4-methylpentane are similar to BPA it can be expected that the content of 2,2-bis(4'-hydroxyphenyl)-4-methylpentane will occur as residues below 0.1% w/w in most articles. An exception would be thermal papers in which the levels can amount to 1-2 percent by weight¹³.

11.2 Existing EU legislation

2,2-bis(4'-hydroxyphenyl)-4-methylpentane is listed in Annex II of the Cosmetics Regulation (EC) 1223/2009 (List Of Substances Prohibited In Cosmetic Products), reference number 1079¹⁴.

¹³ Anses 2014: <https://www.anses.fr/en/system/files/REACH2013re0004EN.pdf> (accessed 29 June, 2018)

¹⁴ http://www.saponemopera.com/en/Cosmetic%20Products%20Regulation%201223_2009.pdf (accessed 29 June, 2018)

REFERENCES

References for Part I

EU (2006). Regulation (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/

EU (2008). 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.

References for Part II

Rochester, J.R. and A.L. Bolden (2015): Bisphenol S and F: A Systematic Review and Comparison of the Hormonal Activity of Bisphenol A Substitutes. *Environ Health Perspect*, 123(7): 643-650.