

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: Bis(α,α -dimethylbenzyl) peroxide

EC Number: 201-279-3

CAS Number: 80-43-3

Submitted by: Norwegian Environment Agency

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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 Identity and composition of degradation products/metabolites relevant for the SVHC assessment.....	6
1.4 Identity and composition of structurally related substances (used in a grouping or read-across approach).....	6
1.5 Physicochemical properties	6
2. HARMONISED CLASSIFICATION AND LABELLING	7
3. ENVIRONMENTAL FATE PROPERTIES	8
4. HUMAN HEALTH HAZARD ASSESSMENT	8
5. ENVIRONMENTAL HAZARD ASSESSMENT	8
6. CONCLUSIONS ON THE SVHC PROPERTIES	8
6.1 CMR assessment.....	8
6.2 PBT and vPvB assessment.....	8
6.3 Assessment under Article 57(f)	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.....	12
11. ADDITIONAL INFORMATION.....	13
11.1 Substances with similar hazard and use profiles on the Candidate List	13
11.2 Alternatives.....	13
11.3 Existing EU legislation.....	13
11.4 Previous assessments by other authorities/ongoing regulatory activities.....	13
REFERENCES FOR PART I	14
REFERENCES FOR PART II	14

TABLES

Table 1: Substance identity	5
Table 2: Constituents other than impurities/additives	6
Table 3: Classification according to Annex VI, Table 3 (list of harmonised classification and labelling of hazardous substances) of Regulation (EC) No 1272/2008	7
Table 4: Registration status	9
Table 5: CLP notifications	9
Table 6: Tonnage status	9
Table 7: Uses	10

ABBREVIATIONS

AC: Article Category
 ARN: Assessment of regulatory needs
 CLH: Harmonised classification and labelling
 ERC: Environmental Release Categories
 PC: Chemical Products Categories
 PROC: Process Categories
 SU: Sectors of Use
 SVHC: Substance of very high concern

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

Substance name: Bis(α,α -dimethylbenzyl) peroxide

EC number: 201-279-3

CAS number: 80-43-3

- 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

Bis(α,α -dimethylbenzyl) peroxide is covered by index number 617-006-00-X of Regulation (EC) No 1272/2008 in Annex VI, part 3, Table 3 (the list of harmonised classification and labelling of hazardous substances) and it is classified in the hazard class toxic for reproduction category 1B (H360D: "May damage the unborn child").

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 1A or 1B in accordance with Article 57 (c) of REACH.

Registration dossiers submitted for the substance: Yes

PART I

Justification

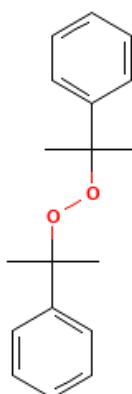
1. Identity of the substance and physical and chemical properties

1.1 Name and other identifiers of the substance

Table 1: Substance identity

EC number:	201-279-3
EC name:	Bis(α,α -dimethylbenzyl) peroxide
CAS number (in the EC inventory):	80-43-3
CAS number:	80-43-3
IUPAC name:	1,1'-(dioxydipropene-2,2-diyl)dibenzene
Index number in Annex VI of the CLP Regulation	617-006-00-X
Molecular formula:	C ₁₈ H ₂₂ O ₂ (C ₆ H ₅ C(CH ₃) ₂) ₂
Molecular weight range:	270.4 g/mol
Synonyms:	Dicumyl peroxide

Structural formula:



1.2 Composition of the substance

Name:Bis(α,α -dimethylbenzyl) peroxide**Description:** Organic**Substance type:** mono-constituent**Table 2: Constituents other than impurities/additives**

Constituents	Typical concentration	Concentration range	Remarks
Bis(α,α -dimethylbenzyl) peroxide EC no: 201-279-3	$\geq 80\%$ w/w		

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 the REACH Regulation.

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 the REACH Regulation.

1.5 Physicochemical properties

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

2. Harmonised classification and labelling

The Risk Assessment Committee (RAC) adopted its opinion on the proposal for harmonised classification and labelling (CLH) of bis(α,α -dimethylbenzyl) peroxide on 8 June 2018 (ECHA, 2018) and the substance is included in the 15th ATP to CLP and listed in Regulation (EC) No 1272/2008 in Annex VI, part 3, Table 3.1 (the list of harmonised classification and labelling of hazardous substances) and classified in the hazard class reproductive toxicity category 1B (hazard statement H360D: "May damage the unborn child").

Bis(α,α -dimethylbenzyl) peroxide is covered by Index number 617-006-00-X in part 3 of Annex VI to the CLP Regulation as follows:

Table 3: Classification according to Annex VI, Table 3 (list of harmonised classification and labelling of hazardous substances) of Regulation (EC) No 1272/2008

Index No	Chemical name	EC No	CAS No	Classification		Labelling			Spec. Conc. Limits, M-factors and ATEs ¹	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)		
617-006-00-X	Bis(α,α -dimethylbenzyl) peroxide	201-279-3	80-43-3	Org. Perox. F Skin Irrit. 2 Eye Irrit. 2 Aquatic Chronic 2 Repr. 1B	H242 H315 H319 H411 H360D	GHS02 GHS08 GHS07 GHS09 Dgr	H242 H315 H319 H411 H360D			

¹ Acute Toxicity Estimate

3. Environmental fate properties

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

4. Human health hazard assessment

Please see section 2 (Harmonised classification and labelling).

5. Environmental hazard assessment

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

6. Conclusions on the SVHC Properties

6.1 CMR assessment

Bis(α,α -dimethylbenzyl) peroxide is covered by index number 617-006-00-X of Regulation (EC) No 1272/2008 in Annex VI, part 3, Table 3 (the list of harmonised classification and labelling of hazardous substances) and it is classified in the hazard class toxic for reproduction category 1B ('May damage the unborn child').

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 1A or 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 the REACH Regulation.

6.3 Assessment under Article 57(f)

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

Part II

7. Registration and C&L notification status

7.1 Registration status

Table 4 Registration status

From the ECHACHEM Chemicals database ³	
Registrations	<input checked="" type="checkbox"/> Full registration(s) (Art. 10)

7.2 CLP notification status

Table 5: CLP notifications

	CLP Notifications ⁴
Number of aggregated notifications	15
Total number of notifiers	1215

8. Total tonnage of the substance

Table 6: Tonnage status

Total tonnage band for the registered substance (excluding the volume registered under Art 17 or Art 18) ⁵	10 000- 100 000 t/pa
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9. Information on uses of the substance

According to information available in ECHA's dissemination website (ECHA, 2023a) and presented in the table below, bis(α,α -dimethylbenzyl) peroxide is manufactured, formulated and then used at industrial sites in the polymer industry and in the non-polymer industry. Articles service life is registered mainly for workers (AC 4: Stone, plaster, cement, glass and ceramic articles; AC 11: Wood articles; AC 13: Plastic articles) but also for consumers for wood articles.

Table 7: Uses

	Use(s)	Registered use <i>(If not, specify the source of the information)</i>	Use likely to be in the scope of Authorisation
Uses as intermediate		No	No
Formulation or repacking	<p>This substance is used in the following products: polymers. Release to the environment of this substance can occur from industrial use: formulation in materials and formulation of mixtures.</p> <p>Formulation and (re)packaging of organic peroxides and mixtures and distribution in the Chemical Distribution sector ERC2: Formulation into mixture ERC3: Formulation into solid matrix PROC: 1, 2, 3, 5, 7, 8a, 8b, 9, 10, 13, 14, 15 PC 32: Polymer preparations and compounds</p>	Yes	Yes
Uses at industrial sites	<p>This substance is used in the following products: polymers.</p> <p>This substance is used for the manufacture of: plastic products, chemicals, and rubber products.</p> <p>Release to the environment of this substance can occur from industrial use: as processing aid, as processing aid and in the production of articles.</p> <p>Industrial use of reactive processing aids ERC6b: Use of reactive processing aid at industrial site (no inclusion into or onto article) PROC: 4 PC: 32 Polymer preparations and compounds SU 12: Manufacture of plastics products, including compounding and conversion</p> <p>Industrial use of organic peroxides as polymerization initiators, crosslinking agents or curing agents ERC6d: Use of reactive process regulators in polymerisation processes at industrial site (inclusion or not into/onto article) PROC: 1, 2, 3, 4, 5, 6, 7, 8a, 8b, 9, 10, 13, 14, 15 SU 11: Manufacture of rubber products SU 12: Manufacture of plastics products, including compounding and conversion</p> <p>Industrial use of organic peroxides in the polymer industry</p>	Yes	No

	<p>ERC 6d: Use of reactive process regulators in polymerisation processes at industrial site (inclusion or not into/onto article) PROC: 1, 2, 3, 4, 5, 8a, 8b, 9, 15 SU: 12: Manufacture of plastics products, including compounding and conversion</p> <p>Uses at industrial sites ERC 6d: Use of reactive process regulators in polymerisation processes at industrial site (inclusion or not into/onto article) PROC: 1, 2, 3, 4, 5, 8a, 8b, 9, 15 SU: 12: Manufacture of plastics products, including compounding and conversion</p> <p>Industrial use of bis(α,α-dimethylbenzyl) peroxide ERC 6d: Use of reactive process regulators in polymerisation processes at industrial site (inclusion or not into/onto article) PROC: 2, 3, 5, 8b, 9 PC 32: Polymer preparations and compounds SU12: Manufacture of plastics products, including compounding and conversion</p> <p>Professional indoor use of organic peroxides ERC5: Use at industrial site leading to inclusion into/onto article PROC: 1, 3, 8b PC 32: Polymer preparations and compounds SU 12: Manufacture of plastics products, including compounding and conversion</p> <p>Industrial use of organic peroxides in non-polymer industries ERC5: Use at industrial site leading to inclusion into/onto article ERC6b: Use of reactive processing aid at industrial site (no inclusion into or onto article) PROC: 1, 2, 3, 4, 5, 7, 8a, 8b, 9, 10, 13, 14, 15 SU 8: Manufacture of bulk, large scale chemicals (including petroleum products) SU 9: Manufacture of fine chemicals SU 10: Formulation [mixing] of preparations and/or re-packaging (excluding alloys) SU 0: Other:</p>		
Uses by professional workers	No data available in the registration	No	No
Consumer uses	No data available in the registration	No	No
Article service life	Other release to the environment of this substance is likely to occur from: outdoor use in long-life materials with low release rate	Yes	Yes

	<p>(e.g. metal, wooden and plastic construction and building materials) and indoor use in long-life materials with low release rate (e.g. flooring, furniture, toys, construction materials, curtains, foot-wear, leather products, paper and cardboard products, electronic equipment).</p> <p>This substance can be found in products with material based on: wood (e.g. floors, furniture, toys), stone, plaster, cement, glass or ceramic (e.g. dishes, pots/pans, food storage containers, construction and isolation material) and plastic (e.g. food packaging and storage, toys, mobile phones).</p> <p>Service life (worker; professional worker) AC4: Stone, plaster, cement, glass and ceramic articles AC11: Wood articles AC13: Plastic articles AC0; 01; 02: Others ERC: 10a Widespread use of articles with low release (outdoor), 11a Widespread use of articles with low release (indoor) PROC21: Low energy manipulation of substances bound in materials and/or articles</p> <p>Service life of articles containing organic peroxide as flame retardant synergist Articles used by consumers: ERC10a: Widespread use of articles with low release (outdoor) ERC11a: Widespread use of articles with low release (indoor) AC 11: Wood articles</p>		
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For explanation of PROCs see Guidance on Information Requirements and Chemical Safety Assessment, Chapter R.12: Use description ([R_12_CARACAL_cross_check_TC \(europa.eu\)](https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX:32017R0607-02-01)).

10. Information on structure of the supply chain

Organic peroxides are mainly used industrially as a processing aid and cross-linker in polymers. Professionally bis(α,α -dimethylbenzyl) peroxide is used as process regulator in vulcanisation or polymeration process. Bis(α,α -dimethylbenzyl) peroxide is also described with service life in articles used by professional workers and consumers as a flame retardant (ECHA, 2023a).

11. Additional information

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

Bis(α,α -dimethylbenzyl) peroxide is a member of the group "organic peroxides" in the published Assessment of Regulatory Needs (ECHA, 2023b). Other organic peroxides listed in the ARN are:

EC 201-128-1; 203-733-6; 213-944-5; 218-664-7; 220-479-1; 222-389-8; 234-042-8; 246-678-3; 410-840-3; 412-140-3. None of these are on the candidate list.

11.2 Alternatives

As described in section 11.1 above, bis(α,α -dimethylbenzyl) peroxide is grouped together with other organic peroxides in the ARN (ECHA, 2023b). However, it is possible that some group members listed in the ARN can act as alternatives. In addition, it is possible that other structurally similar substances, found in the ECHA registration database, could function as alternative substances.

11.3 Existing EU legislation

Bis(α,α -dimethylbenzyl) peroxide is included in the 15th ATP to CLP and listed in Regulation (EC) No 1272/2008, see section 2. The substance is listed in Regulation 1223/2009/EC on Cosmetic Products Regulation, Annex II on Prohibited Substances. It is also listed in Seveso Annex I (substances for which industrial accident prevention and reporting requirements have been established). We are not aware of any other EU legislation for this substance.

For references to REACH and CLP, see EU (2006; 2007; 2008 and 2009).

11.4 Previous assessments by other authorities/ongoing regulatory activities

ECHA: The Assessment of Regulatory needs on Organic hydroperoxides and aliphatic/cumyl peroxides that was published in July 2023 (ECHA, 2023b)

Substance evaluation of bis(α,α -dimethylbenzyl) peroxide, concluded 2023 (ECHA 2023c).

REFERENCES

References for Part I

ECHA (2018): RAC opinion proposing harmonised classification and labelling at EU level of bis(α,α -dimethylbenzyl) peroxide EC Number: 201-279-3 CAS Number: 80-43-3 CLH-O-0000001412-86-217/F, published on ECHA's website <https://www.echa.europa.eu/documents/10162/5cc6d220-7525-1c76-4c59-d7b8b8b5d90d>.

References for Part II

ECHA (2023a): Information on registered substances, published on ECHA's website [Bis\(\$\alpha,\alpha\$ -dimethylbenzyl\) peroxide](#) (accessed on 21 September 2023).

ECHA (2023b): Assessment of regulatory needs. Group name: [Organic hydroperoxides and aliphatic/cumyl peroxides](#)

ECHA (2023c): [Substance evaluation of bis\(\$\alpha,\alpha\$ -dimethylbenzyl\) peroxide](#)

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 91/155/EEC, 93/67/EEC, 93/105/EC and 2000/21/EC. Official Journal of the European Union, L396: 1-849.

EU (2007). Corrigendum to 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 91/155/EEC, 93/67/EEC, 93/105/EC and 2000/21/EC. Official Journal of the European Union, L136: 3-280.

EU (2008). Regulation (EC) No 1272/2008 of the European Parliament and of the Council of 16 December 2008 on classification, labelling and packing of substances and mixtures, amending and repealing Directives 67/548/EEC and 1999/45/EC, and amending Regulation (EC) No 1907/2006. Official Journal of the European Union, L353: 1-1355.

EU (2009). Regulation (EC) No 552/2009 of 22 June 2009 amending Regulation (EC) No 1907/2006 as regards of the European Parliament and of the Council on the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH) as regards Annex XVII. Official Journal of the European Union, L164: 7-31.