

**Safety Data Sheet**

according to Regulation (EC) No 1907/2006

Promolux High Impact Polymer

Revision date: 19.01.2023

Product code: D251_HI_rosa

Page 1 of 5

SECTION 1: Identification of the substance/mixture and of the company/undertaking**1.1. Product identifier**

Promolux High Impact Polymer

Further trade names

Promolux® High Impact rosa

Promolux® High Impact L1

Promolux® High Impact C34

1.2. Relevant identified uses of the substance or mixture and uses advised against**1.3. Details of the supplier of the safety data sheet**

Company name: Merz Dental GmbH
Street: Kieferweg 1
Place: D-24321 Luetjenburg (GERMANY)
Telephone: +49-(0)4381-403-0 Telefax: +49-(0)4381-403-100
e-mail: info@merz-dental.de
Contact person: Dipl. Chem Dr. Thomas Panther Telephone: +49-(0)4381-403-448
e-mail: Thomas.Panther@merz-dental.de
Internet: www.merz-dental.de
Responsible Department: Qualitaetssicherung (Quality Assurance)

1.4. Emergency telephone number: +49-(0)551-19240 (Giftinformationszentrum-Nord)**SECTION 2: Hazards identification****2.1. Classification of the substance or mixture****Regulation (EC) No 1272/2008**

This mixture is not classified as hazardous in accordance with Regulation (EC) No 1272/2008.

2.2. Label elements**Regulation (EC) No 1272/2008****Special labelling of certain mixtures**

EUH208 Contains dibenzoyl peroxide; benzoyl peroxide. May produce an allergic reaction.

SECTION 3: Composition/information on ingredients**3.2. Mixtures****Hazardous components**

CAS No	Chemical name			Quantity
	EC No	Index No	REACH No	
	Classification (Regulation (EC) No 1272/2008)			
94-36-0	dibenzoyl peroxide; benzoyl peroxide			< 0,3 %
	202-327-6	617-008-00-0		
	Org. Perox. B, Eye Irrit. 2, Skin Sens. 1; H241 H319 H317			
556-67-2	octamethylcyclotetrasiloxane; [D4]			< 0,005 %
	209-136-7	014-018-00-1		
	Repr. 2, Aquatic Chronic 1; H361f H410			

Full text of H and EUH statements: see section 16.

Safety Data Sheet

according to Regulation (EC) No 1907/2006

Promolux High Impact Polymer

Revision date: 19.01.2023

Product code: D251_HI_rosa

Page 2 of 5

Specific Conc. Limits, M-factors and ATE

CAS No	EC No	Chemical name	Quantity
		Specific Conc. Limits, M-factors and ATE	
94-36-0	202-327-6	dibenzoyl peroxide; benzoyl peroxide	< 0,3 % %
		inhalation: LC50 = > 24300 mg/l (dusts or mists); oral: LD50 = > 2000 mg/kg	
556-67-2	209-136-7	octamethylcyclotetrasiloxane; [D4]	< 0,005 % %
		Aquatic Chronic 1; H410: M=10	

SECTION 4: First aid measures

4.1. Description of first aid measures

SECTION 5: Firefighting measures

5.1. Extinguishing media

SECTION 6: Accidental release measures

SECTION 7: Handling and storage

7.1. Precautions for safe handling

7.2. Conditions for safe storage, including any incompatibilities

SECTION 8: Exposure controls/personal protection

8.1. Control parameters

Occupational exposure limits

CAS No	Substance	ppm	mg/m ³	fib/cm ³	Category	Origin
94-36-0	Benzoyl peroxid (Dibenzoyl peroxide)	-	5		TWA (8 h)	

DNEL/DMEL values

CAS No	Substance	Exposure route	Effect	Value
94-36-0	dibenzoyl peroxide; benzoyl peroxide			
	Consumer DNEL, long-term	inhalation	systemic	2,9 mg/m ³
	Worker DNEL, long-term	dermal	systemic	6,6 mg/kg bw/day
	Consumer DNEL, long-term	oral	systemic	1,65 mg/kg bw/day
	Worker DNEL, long-term	inhalation	systemic	11,75 mg/m ³
	Consumer DNEL, long-term	dermal	systemic	3,3 mg/kg bw/day

Safety Data Sheet

according to Regulation (EC) No 1907/2006

Promolux High Impact Polymer

Revision date: 19.01.2023

Product code: D251_HI_rosa

Page 3 of 5

PNEC values

CAS No	Substance	
Environmental compartment		Value
94-36-0	dibenzoyl peroxide; benzoyl peroxide	
Freshwater		0,000602 mg/l
Marine water		0,000602 mg/l
Freshwater sediment		0,338 mg/kg
Micro-organisms in sewage treatment plants (STP)		0,35 mg/l
Soil		0,0758 mg/kg

8.2. Exposure controls

SECTION 9: Physical and chemical properties

9.1. Information on basic physical and chemical properties

Physical state: Powder
Colour:

SECTION 10: Stability and reactivity

SECTION 11: Toxicological information

11.1. Information on hazard classes as defined in Regulation (EC) No 1272/2008

Acute toxicity

Based on available data, the classification criteria are not met.

CAS No	Chemical name				
	Exposure route	Dose	Species	Source	Method
94-36-0	dibenzoyl peroxide; benzoyl peroxide				
	oral	LD50 > 2000 mg/kg	Mouse	Nier, Korea 2001	OECD 401
	inhalation dust/mist	LC50 > 24300 mg/l	Rat		

Irritation and corrosivity

Based on available data, the classification criteria are not met.

Sensitising effects

Based on available data, the classification criteria are not met.

Analogous to related material not skin sensitising. Contains: Dibenzoyl peroxide, methyl methacrylate. There is no hazard as long as the substances are immobilised within the polymer matrix. Only when the polymer matrix is destroyed, e.g. by suitable solvents, can the sensitising components be mobilised again. In people who are already sensitised, the remobilised components can lead to allergic reactions.

Carcinogenic/mutagenic/toxic effects for reproduction

Based on available data, the classification criteria are not met.

STOT-single exposure

Based on available data, the classification criteria are not met.

STOT-repeated exposure

Based on available data, the classification criteria are not met.

Aspiration hazard

Based on available data, the classification criteria are not met.

Safety Data Sheet

according to Regulation (EC) No 1907/2006

Promolux High Impact Polymer

Revision date: 19.01.2023

Product code: D251_HI_rosa

Page 4 of 5

SECTION 12: Ecological information

12.1. Toxicity

CAS No	Chemical name					
	Aquatic toxicity	Dose	[h] [d]	Species	Source	Method
94-36-0	dibenzoyl peroxide; benzoyl peroxide					
	Acute fish toxicity	LC50 0,24 mg/l	96 h	Oryzias latipes (Ricefish)	Nier, Korea 2002c	OECD 203
	Acute algae toxicity	ErC50 0,44 mg/l	72 h	Selenastrum capricornutum	Nier, Korea 2002f	OECD 201
	Acute crustacea toxicity	EC50 0,07 mg/l	48 h	Daphnia pulex (water flea)	Nier, Korea 2002g	OECD 202
	Algae toxicity	NOEC 0,02 mg/l	3 d	Pseudokirchneriella subcapitata	REACH Dossier	EU Method C.3
	Crustacea toxicity	NOEC 0,001 mg/l	21 d	Daphnia pulex (water flea)	REACH Dossier	OECD 211
	Acute bacteria toxicity	0,30 g O2/g (EC50 0,35 mg/l)	0,5 h	activated sludge	REACH Dossier	OECD 209

12.2. Persistence and degradability

CAS No	Chemical name			
	Method	Value	d	Source
	Evaluation			
94-36-0	dibenzoyl peroxide; benzoyl peroxide			
	OECD 301D/ EEC 92/69/V, C.4-E	71 %	28	REACH Dossier
	Readily biodegradable (according to OECD criteria).			

12.3. Bioaccumulative potential

Partition coefficient n-octanol/water

CAS No	Chemical name	Log Pow
94-36-0	dibenzoyl peroxide; benzoyl peroxide	3,2

BCF

CAS No	Chemical name	BCF	Species	Source
94-36-0	dibenzoyl peroxide; benzoyl peroxide	47,4	n/n	EpiSuite QSAR tool

12.5. Results of PBT and vPvB assessment

The substances in the mixture do not meet the PBT/vPvB criteria according to REACH, annex XIII.

12.6. Endocrine disrupting properties

This product does not contain a substance that has endocrine disrupting properties with respect to non-target organisms as no components meets the criteria.

SECTION 13: Disposal considerations

13.1. Waste treatment methods

List of Wastes Code - residues/unused products

070213 WASTES FROM ORGANIC CHEMICAL PROCESSES; wastes from the MFSU of plastics, synthetic rubber and man-made fibres; waste plastic

List of Wastes Code - used product

070213 WASTES FROM ORGANIC CHEMICAL PROCESSES; wastes from the MFSU of plastics, synthetic rubber and man-made fibres; waste plastic

**Safety Data Sheet**

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Page 5 of 5

List of Wastes Code - contaminated packaging

150102 WASTE PACKAGING; ABSORBENTS, WIPING CLOTHS, FILTER MATERIALS AND PROTECTIVE CLOTHING NOT OTHERWISE SPECIFIED; packaging (including separately collected municipal packaging waste); plastic packaging

SECTION 14: Transport information**Land transport (ADR/RID)**

14.1. UN number or ID number:	Not restricted
14.2. UN proper shipping name:	Not restricted
14.3. Transport hazard class(es):	Not restricted
14.4. Packing group:	Not restricted

Inland waterways transport (ADN)

14.1. UN number or ID number:	Not restricted
14.2. UN proper shipping name:	Not restricted
14.3. Transport hazard class(es):	Not restricted
14.4. Packing group:	Not restricted

Marine transport (IMDG)

14.1. UN number or ID number:	Not restricted
14.2. UN proper shipping name:	Not restricted
14.3. Transport hazard class(es):	Not restricted
14.4. Packing group:	Not restricted

Air transport (ICAO-TI/IATA-DGR)

14.1. UN number or ID number:	Not restricted
14.2. UN proper shipping name:	Not restricted
14.3. Transport hazard class(es):	Not restricted
14.4. Packing group:	Not restricted

SECTION 15: Regulatory information**15.1. Safety, health and environmental regulations/legislation specific for the substance or mixture****EU regulatory information**

Restrictions on use (REACH, annex XVII):

Entry 70, Entry 75

National regulatory information**SECTION 16: Other information****Changes**

This data sheet contains changes from the previous version in section(s): 1,8,11.

Relevant H and EUH statements (number and full text)

H241	Heating may cause a fire or explosion.
H317	May cause an allergic skin reaction.
H319	Causes serious eye irritation.
H361f	Suspected of damaging fertility.
H410	Very toxic to aquatic life with long lasting effects.

(The data for the hazardous ingredients were taken respectively from the last version of the sub-contractor's safety data sheet.)