according to Regulation (EC) No 1907/2006

Promolux Polymer / Promolux HI Polymer

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SECTION 1: Identification of the substance/mixture and of the company/undertaking

1.1. Product identifier

Promolux Polymer / Promolux HI Polymer

Further trade names

Promolux Polymer div. / Promolux Polymer HI div.

1.2. Relevant identified uses of the substance or mixture and uses advised against

Use of the substance/mixture

Polymer preparations and compounds: transparent / pink

The product is intended for professional use.

Uses advised against

Do not use for private purposes (household).

1.3. Details of the supplier of the safety data sheet

Company name: Merz Dental GmbH

Street: Kieferweg 1

Place: D-24321 Lütjenburg (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: Qualitätssicherung (Quality Assurance)

1.4. Emergency telephone +49-(0)551-19240 (Giftinformationszentrum-Nord)

number:

SECTION 2: Hazards identification

2.2. Label elements

Regulation (EC) No. 1272/2008

Special labelling of certain mixtures

EUH208 Contains methyl 2-methylprop-2-enoate; methyl 2-methylpropenoate; methyl methacrylate

+ dibenzoyl peroxide; benzoyl peroxide. May produce an allergic reaction.

Additional advice on labelling

No label required according to 1999/45/EC, annex V B, No. 9.

2.3. Other hazards

No information available.

SECTION 3: Composition/information on ingredients

3.2. Mixtures

Chemical characterization

POLYMETHYL METHACRYLATE

according to Regulation (EC) No 1907/2006

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Hazardous components

CAS No	Chemical name	Chemical name			
	EC No	Index No	REACH No		
	Classification accordi	Classification according to Regulation (EC) No. 1272/2008 [CLP]			
94-36-0	dibenzoyl peroxide; be	dibenzoyl peroxide; benzoyl peroxide			
	202-327-6	617-008-00-0			
	Org. Perox. B, Eye Irr	Org. Perox. B, Eye Irrit. 2, Skin Sens. 1; H241 H319 H317			

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

Further Information

none

SECTION 4: First aid measures

4.1. Description of first aid measures

General information

Change contaminated clothing.

After inhalation

Provide fresh air. In all cases of doubt, or when symptoms persist, seek medical advice.

After contact with skin

Wash with plenty of water. Take off contaminated clothing and wash it before reuse.

After contact with eyes

Rinse immediately carefully and thoroughly with eye-bath or water. In case of eye irritation consult an ophthalmologist.

After ingestion

Rinse mouth immediately and drink plenty of water. In all cases of doubt, or when symptoms persist, seek medical advice.

4.2. Most important symptoms and effects, both acute and delayed

No information available.

4.3. Indication of any immediate medical attention and special treatment needed

When in doubt or if symptoms are observed, get medical advice.

SECTION 5: Firefighting measures

5.1. Extinguishing media

Suitable extinguishing media

Extinguishing powder, Carbon dioxide (CO2), Water spray jet, Foam.

Unsuitable extinguishing media

High power water jet

5.2. Special hazards arising from the substance or mixture

This material is combustible, but will not ignite readily. In case of fire may be liberated: Carbon dioxide (CO2), Carbon monoxide

5.3. Advice for firefighters

In case of fire: Wear self-contained breathing apparatus.

Additional information

Collect contaminated fire extinguishing water separately. Do not allow entering drains or surface water.

SECTION 6: Accidental release measures

6.1. Personal precautions, protective equipment and emergency procedures

Avoid dust formation. Do not breathe dust. Wear breathing apparatus if exposed to vapours/dusts/aerosols.

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Wear personal protection equipment. Special danger of slipping by leaking/spilling product.

6.2. Environmental precautions

Clean contaminated articles and floor according to the environmental legislation. Do not allow to enter into surface water or drains.

6.3. Methods and material for containment and cleaning up

Take up mechanically. Treat the recovered material as prescribed in the section on waste disposal.

6.4. Reference to other sections

Safe handling: see section 7

Personal protection equipment: see section 8

Disposal: see section 13

SECTION 7: Handling and storage

7.1. Precautions for safe handling

Advice on safe handling

Measures to prevent aerosol and dust generation.

Advice on protection against fire and explosion

No special fire protection measures are necessary.

Further information on handling

Dust should be exhausted directly at the point of origin.

7.2. Conditions for safe storage, including any incompatibilities

Requirements for storage rooms and vessels

Keep the packing dry and well sealed to prevent contamination and absorbtion of humidity.

Advice on storage compatibility

To follow: Storage class

Further information on storage conditions

Keep cool. Protect from sunlight. storage temperature: < 40 °C

7.3. Specific end use(s)

Observe instructions for use.

SECTION 8: Exposure controls/personal protection

8.1. Control parameters

Exposure limits (EH40)

CAS No	Substance	ppm	mg/m³	fibres/ml	Category	Origin
94-36-0	Dibenzoyl peroxide	-	5		TWA (8 h)	WEL
		-	-		STEL (15 min)	WEL

DNEL/DMEL values

CAS No	Substance				
DNEL type		Exposure route	Effect	Value	
94-36-0	dibenzoyl peroxide; benzoyl peroxide				
Consumer DNEL, long-term		inhalation	systemic	2,9 mg/m³	
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/m³	
Consumer DNEL, long-term		dermal	systemic	3,3 mg/kg bw/day	

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PNEC values

CAS No	Substance		
Environmental	compartment	Value	
94-36-0 dibenzoyl peroxide; benzoyl peroxide			
Freshwater 0,000602 mg/l		0,000602 mg/l	
Marine water 0,000060		0,0000602 mg/l	
Freshwater sediment 0,338 m		0,338 mg/kg	
Micro-organisms in sewage treatment plants (STP)		0,35 mg/l	
Soil 0,0758		0,0758 mg/kg	

Additional advice on limit values

Monitoring and observation processes: "NIOSH Manual of Analytical Methods", National Institute for Occupational Safety and Health

8.2. Exposure controls

Appropriate engineering controls

Provide adequate ventilation as well as local exhaustion at critical locations. Use an "other exhaust ventilation system" according to 2001/59/EC (Annex 7A).. If local exhaust ventilation is not possible or not sufficient, the entire working area should be ventilated by technical means.

Protective and hygiene measures

Take off contaminated clothing. Wash hands before breaks and after work. When using do not eat or drink.

Eye/face protection

Wear eye/face protection.

Hand protection

When handling with chemical substances, protective gloves must be worn with the CE-label including the four control digits. The quality of the protective gloves resistant to chemicals must be chosen as a function of the specific working place concentration and quantity of hazardous substances. For special purposes, it is recommended to check the resistance to chemicals of the protective gloves mentioned above together with the supplier of these gloves. Recommendation: Suitable material: PE (polyethylene).

Skin protection

Wear suitable protective clothing.

Respiratory protection

If technical exhaust or ventilation measures are not possible or insufficient, respiratory protection must be worn. Respiratory protection necessary at: exceeding exposure limit values. Use only respiratory protection equipment with CE-symbol including four digit test number. The filter class must be suitable for the maximum contaminant concentration (gas/vapour/aerosol/particulates) that may arise when handling the product. If the concentration is exceeded, self-contained breathing apparatus must be used. Half-face mask or quarter facepiece: maximum use concentration for substances with exposure limits: P1 filter: up to a max. of 4 times the exposure limit. P2 filter: up to a max. of 10 times the exposure limit. P3 filter: up to a max. of 30 times the expo.

Quarter-face mask (DIN EN 140) / Half-face mask (DIN EN 140). Observe the wear time limits according GefStoffV in combination with the rules for using respiratory protection apparatus (BGR 190).

Environmental exposure controls

Do not allow uncontrolled discharge of product into the environment.

SECTION 9: Physical and chemical properties

9.1. Information on basic physical and chemical properties

Physical state: Powder Colour: pink Odour: odourless

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Test method

pH-Value: not applicable

Changes in the physical state

Melting point:

Initial boiling point and boiling range:

Sublimation point:

Softening point:

Pour point:

not determined
not applicable
not applicable
ca. 110 °C
not applicable

Flash point: > 250 °C ASTM D 1929

Flammability

Solid: not determined
Gas: not applicable

Explosive properties

Danger of dust explosion.

Lower explosion limits:

Upper explosion limits:

Ignition temperature:

not determined
not determined
not determined
Not determined
not determined
Not determined

Auto-ignition temperature

Solid: not determined
Gas: not applicable

Decomposition temperature: not determined

Oxidizing properties

This material is combustible, but will not ignite readily. Not oxidizing.

Vapour pressure:

Density (at 20 °C):

Bulk density (at 20 °C):

Water solubility:

not applicable

1,16 g/cm³

700-750 kg/m³

insoluble

Solubility in other solvents

not determined

Partition coefficient: not determined Viscosity / dynamic: not applicable Viscosity / kinematic: not applicable Flow time: not applicable Vapour density: not applicable Evaporation rate: not applicable Solvent separation test: not applicable Solvent content: not applicable

9.2. Other information

Solid content: 100 %

none

SECTION 10: Stability and reactivity

10.1. Reactivity

No hazardous reaction when handled and stored according to provisions.

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10.2. Chemical stability

The product is stable under storage at normal ambient temperatures.

Decomposition temperature (°C): > 250

10.3. Possibility of hazardous reactions

No known hazardous reactions.

10.4. Conditions to avoid

Decompostion takes place from temperatures above: 250 °C

10.5. Incompatible materials

Oxidising agent

10.6. Hazardous decomposition products

Thermal decomposition can lead to the escape of irritating gases and vapours. Hazardous decomposition products: SECTION 8: Exposure controls/personal protection

Further information

none

SECTION 11: Toxicological information

11.1. Information on toxicological effects

Toxicocinetics, metabolism and distribution

No information available.

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 : mg/kg	> 2000	Mouse	Nier, Korea 2001	OECD 401
	inhalative aerosol	LC50 : mg/l	> 24300	Rat		

Irritation and corrosivity

Based on available data, the classification criteria are not met. slightly irritant but not relevant for classification. Irritating to eyes.

Sensitising effects

Based on available data, the classification criteria are not met. In case of skin contact: sensitising

Carcinogenic/mutagenic/toxic effects for reproduction

Based on available data, the classification criteria are not met. No information available.

STOT-single exposure

Based on available data, the classification criteria are not met. There are no data available on the preparation/mixture itself.

STOT-repeated exposure

Based on available data, the classification criteria are not met. There are no data available on the preparation/mixture itself.

Aspiration hazard

Based on available data, the classification criteria are not met. There are no data available on the preparation/mixture itself.

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Specific effects in experiment on an animal

There are no data available on the preparation/mixture itself.

Additional information on tests

none

Practical experience

Observations relevant to classification

No information available.

Other observations

No information available.

Further information

The ingredients in this preparation do not meet the criteria for classification as CMR category 1 or 2 according to 67/548/EEC. The ingredients in this mixture do not meet the criteria for classification as CMR category 1 A or 1B according to CLP. Toxicological data are not available. People who suffer from skin sensitazion problems, asthma, allergies, chronic or recurring respiratory illnesses should not be deployed in any process using this preparation. May cause allergy or asthma symptoms or breathing difficulties if inhaled.

SECTION 12: Ecological information

12.1. Toxicity

According to the criteria of the European classification and labelling system, the substance/the product has not to be labelled as "dangerous for the environment".

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	7 48 h	Daphnia pulex (water flea)	Nier, Korea 2002g	OECD 202			
	Algea toxicity	NOEC 0,02 mg/l	2 3 0	Pseudokirchneriella subcapitata	REACH Dossier	EU Method C.3			
	Crustacea toxicity	NOEC 0,00 mg/l)1 21 0	Daphnia pulex (water flea)	REACH Dossier	OECD 211			
	Acute bacteria toxicity	0,30 g O2/g (0,3 mg/l)	5 0,5 h	activated sludge	REACH Dossier	OECD 209			

12.2. Persistence and degradability

The product has not been tested.

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

The product has not been tested.

Partition coefficient n-octanol/water

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

according to Regulation (EC) No 1907/2006

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BCF

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

12.4. Mobility in soil

The product has not been tested.

12.5. Results of PBT and vPvB assessment

The product has not been tested.

12.6. Other adverse effects

Very toxic to aquatic organisms.

Further information

Do not allow to enter into surface water or drains. Do not allow to enter into soil/subsoil.

SECTION 13: Disposal considerations

13.1. Waste treatment methods

Advice on disposal

Do not allow to enter into surface water or drains. Do not allow to enter into soil/subsoil. Dispose of waste according to applicable legislation. Non-contaminated packages may be recycled.

Waste disposal number of waste from residues/unused products

180107 WASTES FROM HUMAN OR ANIMAL HEALTH CARE AND/OR RELATED RESEARCH (EXCEPT

KITCHEN AND RESTAURANT WASTES NOT ARISING FROM IMMEDIATE HEALTH CARE); wastes from natal care, diagnosis, treatment or prevention of disease in humans; chemicals other

than those mentioned in 18 01 06

Waste disposal number of used product

180107 WASTES FROM HUMAN OR ANIMAL HEALTH CARE AND/OR RELATED RESEARCH (EXCEPT

KITCHEN AND RESTAURANT WASTES NOT ARISING FROM IMMEDIATE HEALTH CARE); wastes from natal care, diagnosis, treatment or prevention of disease in humans; chemicals other

than those mentioned in 18 01 06

Contaminated packaging

Non-contaminated packages may be recycled. Handle contaminated packages in the same way as the substance itself.

SECTION 14: Transport information

Land transport (ADR/RID)

14.1. UN number:	No dangerous good in sense of this transport regulation.
14.2. UN proper shipping name:	No dangerous good in sense of this transport regulation.
14.3. Transport hazard class(es):	No dangerous good in sense of this transport regulation.
14.4. Packing group:	No dangerous good in sense of this transport regulation.

Inland waterways transport (ADN)

14.1. UN number:	No dangerous good in sense of this transport regulation.
14.2. UN proper shipping name:	No dangerous good in sense of this transport regulation.
14.3. Transport hazard class(es):	No dangerous good in sense of this transport regulation.
14.4. Packing group:	No dangerous good in sense of this transport regulation.

Marine transport (IMDG)

14.1. UN number:	No dangerous good in sense of this transport regulation.
14.2. UN proper shipping name:	No dangerous good in sense of this transport regulation.
14.3. Transport hazard class(es):	No dangerous good in sense of this transport regulation.
14.4. Packing group:	No dangerous good in sense of this transport regulation.

according to Regulation (EC) No 1907/2006

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Air transport (ICAO-TI/IATA-DGR)

14.1. UN number:No dangerous good in sense of this transport regulation.14.2. UN proper shipping name:No dangerous good in sense of this transport regulation.14.3. Transport hazard class(es):No dangerous good in sense of this transport regulation.14.4. Packing group:No dangerous good in sense of this transport regulation.

14.5. Environmental hazards

ENVIRONMENTALLY HAZARDOUS: no

14.6. Special precautions for user

No information available.

14.7. Transport in bulk according to Annex II of Marpol and the IBC Code

not applicable

Other applicable information

none

SECTION 15: Regulatory information

15.1. Safety, health and environmental regulations/legislation specific for the substance or mixture

EU regulatory information

2010/75/EU (VOC): not applicable 2004/42/EC (VOC): not applicable

Additional information

none

National regulatory information

Employment restrictions: Observe restrictions to employment for juvenils according to the 'juvenile

work protection guideline' (94/33/EC). Observe employment restrictions under the Maternity Protection Directive (92/85/EEC) for expectant or nursing mothers. Observe employment restrictions for women of

child-bearing age.

Water contaminating class (D): 1 - slightly water contaminating

Biocide registry number: not applicable

Additional information

none

15.2. Chemical safety assessment

Chemical safety assessments for substances in this mixture were not carried out.

SECTION 16: Other information

Changes

This data sheet contains changes from the previous version in section(s): 1,3,7,11.

Abbreviations and acronyms

ADR: Accord européen sur le transport des marchandises dangereuses par Route

(European Agreement concerning the International Carriage of Dangerous Goods by Road)

IMDG: International Maritime Code for Dangerous Goods

IATA: International Air Transport Association

GHS: Globally Harmonized System of Classification and Labelling of Chemicals

EINECS: European Inventory of Existing Commercial Chemical Substances

ELINCS: European List of Notified Chemical Substances

CAS: Chemical Abstracts Service LC50: Lethal concentration, 50%

according to Regulation (EC) No 1907/2006

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LD50: Lethal dose, 50%

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 eve irritation.

EUH208 Contains methyl 2-methylprop-2-enoate; methyl 2-methylpropenoate; methyl methacrylate

+ dibenzoyl peroxide; benzoyl peroxide. May produce an allergic reaction.

Further Information

The above information describes exclusively the safety requirements of the product and is based on our present-day knowledge. The information is intended to give you advice about the safe handling of the product named in this safety data sheet, for storage, processing, transport and disposal. The information cannot be transferred to other products. In the case of mixing the product with other products or in the case of processing, the information on this safety data sheet is not necessarily valid for the new made-up material.

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