according to Regulation (EC) No 1907/2006

PMMA block / Artificial teeth OMP-N + HMP-N / PMMA discs / PMMA veneers / BD Load®

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

1.1. Product identifier

PMMA block / Artificial teeth OMP-N + HMP-N / PMMA discs / PMMA veneers / BD Load®

Further trade names artBloc® Temp artegral® life, artegral®, Polystar® Selection EDITION, integral®, Polystar® Lux HK, Polystar® Selection EDITION 2, DeltaForm®, Polystar Lux® HK M-PM® Disc BDLoad® artVeneer®

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

Use of the substance/mixture

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:	Eetzweg 20	
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 (Giftinformationszer	ntrum-Nord)
number:		

Further Information

none

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

EUH208Contains methyl 2-methylprop-2-enoate; methyl 2-methylpropenoate; methyl methacrylate,
dibenzoyl peroxide; benzoyl peroxide. May produce an allergic reaction.EUH210Safety data sheet available on request.

Additional advice on labelling

There is no requirement for the product to be specially labelled according to EC directives or the corresponding national laws.

2.3. Other hazards

Harmful dust is produced during dry-state pulverisation. Inhalation of dust may cause irritation of the respiratory system.

SECTION 3: Composition/information on ingredients

according to Regulation (EC) No 1907/2006

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3.2. Mixtures

Chemical characterization POLYMETHYL METHACRYLATE

Hazardous components

CAS No	Chemical name			Quantity	
	EC No	Index No	REACH No		
	Classification according to Re	Classification according to Regulation (EC) No. 1272/2008 [CLP]			
80-62-6	methyl 2-methylprop-2-enoate; methyl 2-methylpropenoate; methyl methacrylate				
	201-297-1	607-035-00-6	01-2119452498-28		
	Flam. Liq. 2, Skin Irrit. 2, Skin	Sens. 1, STOT SE 3; H225 H3	15 H317 H335		
94-36-0	dibenzoyl peroxide; benzoyl p	eroxide		0 %	
	202-327-6	617-008-00-0			
	Org. Perox. B, Eye Irrit. 2, Skin Sens. 1; H241 H319 H317				

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

Further Information

May cause sensitisation by skin contact.

SECTION 4: First aid measures

4.1. Description of first aid measures

General information

No special measures are necessary.

After inhalation

Provide fresh air. If breathing is irregular or stopped, administer artificial respiration. Medical treatment necessary. Inhalation of dust may cause irritation of the respiratory system. In case of allergic symptoms, especially in the breathing area, seek medical advice immediately. In all cases of doubt, or when symptoms persist, seek medical advice.

After contact with skin

After contact with skin, wash immediately with polyethylene glycol, followed by plenty of water. Take off immediately all contaminated clothing and wash it before reuse. If skin irritation occurs: Get medical advice/attention. After contact with skin, wash immediately with plenty of water and soap. In case of skin irritation, consult a physician.

After contact with eyes

Rinse immediately carefully and thoroughly with eye-bath or water. 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. No known symptoms to date. Observe risk of aspiration if vomiting occurs. When in doubt or if symptoms are observed, get medical advice.

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

Allergic reactions

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

Treat symptomatically. Apply cortisone spray at early stage.

SECTION 5: Firefighting measures

5.1. Extinguishing media

Suitable extinguishing media

Co-ordinate fire-fighting measures to the fire surroundings. Water mist, Foam, Carbon dioxide (CO2), Extinguishing powder

according to Regulation (EC) No 1907/2006

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Unsuitable extinguishing media

High power water jet

5.2. Special hazards arising from the substance or mixture

Non-flammable. This material is combustible, but will not ignite readily. Exothermal decomposition with formation of: Carbon dioxide (CO2), Carbon monoxide.

5.3. Advice for firefighters

In case of fire: Wear self-contained breathing apparatus. Wear a self-contained breathing apparatus and chemical protective clothing. Co-ordinate fire-fighting measures to the fire surroundings. Collect contaminated fire extinguishing water separately. Do not allow entering drains or surface water. Use caution when applying carbon dioxide in confined spaces. Carbon dioxide can displace oxygen.

Additional information

Collect contaminated fire extinguishing water separately. Do not allow entering drains or surface water. Do not inhale explosion and combustion gases.

SECTION 6: Accidental release measures

6.1. Personal precautions, protective equipment and emergency procedures

Avoid dust formation. Wear breathing apparatus if exposed to vapours/dusts/aerosols. Use personal protection equipment.

6.2. Environmental precautions

Do not allow to enter into surface water or drains. No special environmental measures are necessary. Avoid release to the environment.

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. Wet clean or vacuum up solids. Use approved industrial vacuum cleaner for removal. Do not use a dry brush as dust clouds or static can be created.

6.4. Reference to other sections

Safe handling: see section 7

Personal protection equipment: see section 8

Disposal: see section 13 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. Do not breathe dust. Dust should be exhausted directly at the point of origin. If local exhaust ventilation is not possible or not sufficient, the entire working area should be ventilated by technical means.

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 container tightly closed. 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

Protect against direct sunlight.

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7.3. Specific end use(s)

Specific 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
80-62-6	Methyl methacrylate	50	208		TWA (8 h)	WEL
		100	416		STEL (15 min)	WEL

DNEL/DMEL values

CAS No	Substance			
DNEL type		Exposure route	Effect	Value
80-62-6	methyl 2-methylprop-2-enoate; methyl 2-methylpropenoate	; methyl methacrylate	·	·
Worker DNEL	., long-term	inhalation	local	210 mg/m³
Worker DNEL	., long-term	dermal	systemic	13,67 mg/kg bw/day
94-36-0	dibenzoyl peroxide; benzoyl peroxide			
Consumer DI	NEL, long-term	inhalation	systemic	2,9 mg/m³
Worker DNEL	., long-term	dermal	systemic	6,6 mg/kg bw/day
Consumer DI	IEL, long-term	oral	systemic	1,65 mg/kg bw/day
Worker DNEL	., long-term	inhalation	systemic	11,75 mg/m³
Consumer D	NEL, long-term	dermal	systemic	3,3 mg/kg bw/day

PNEC values

CAS No	Substance	
Environmen	tal compartment	Value
80-62-6	methyl 2-methylprop-2-enoate; methyl 2-methylpropenoate; methyl methacrylate	
Freshwater		< 0,94 mg/l
Marine wate	r	< 0,94 mg/l
Soil		
Air		
94-36-0	dibenzoyl peroxide; benzoyl peroxide	
Freshwater		0,000602 mg/l
Marine wate	r	0,0000602 mg/l
Freshwater	sediment	0,338 mg/kg
Micro-organisms in sewage treatment plants (STP)		0,35 mg/l
Soil		0,0758 mg/kg

Additional advice on limit values

Monitoring and observation processes:

8.2. Exposure controls

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Appropriate engineering controls

If handled uncovered, arrangements with local exhaust ventilation should be used if possible. Hand tool with integrated exhaust. Use an "effective exhaust ventilation system" according to 2001/59/EC (Annex 7A).. Preferably use hand tools or low-speed tools equipped, if necessary, with an appropriate dust-extraction facility. If high-speed tools are used, they should always be equipped with such a facility.

Protective and hygiene measures

Take off contaminated clothing. Wash hands before breaks and after work. When using do not eat or drink. When using do not eat, drink, smoke, sniff. Do not breathe dust. General health and safety measures.

Eye/face protection

Wear eye/face protection. Dust protection eye glasses.

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. Tested protective gloves must be worn. Wear cotton undermitten if possible. Take recovery periods for skin regeneration.

Skin protection

Discustant states

Wear suitable protective clothing. Wear suitable protective clothing.

- - 1: -1

Respiratory protection

In case of inadequate ventilation wear 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. Observe the wear time limits according GefStoffV in combination with the rules for using respiratory protection apparatus (BGR 190).

Environmental exposure controls

No special environmental measures are necessary.

SECTION 9: Physical and chemical properties

9.1. Information on basic physical and chemical properties

Physical state:	solid			
Colour:	whitish - light beige			
Odour:	odourless			
			Test method	
pH-Value:		not applicable		
Changes in the physical state				
Melting point:		not applicable		
Initial boiling point and boiling range:		not applicable		
Sublimation point:		not applicable		
Softening point:		not applicable		
Pour point:		not applicable		
Flash point:		> 250 °C	ASTM D 1929-68	
Sustaining combustion:		Not sustaining combustion		
Flammability				
Solid:		not determined		

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Gas:	not applicable					
Explosive properties The product in the delivered form is n the danger of dust explosion.	ot dust explosion capable; the enrichment of fine dust	t however leads to				
Lower explosion limits:	not determined					
Upper explosion limits:	not determined					
Ignition temperature:	> 400 °C	ASTM D 1929-68				
Auto-ignition temperature Solid: Gas:	not determined not applicable					
Decomposition temperature: Oxidizing properties This material is combustible, but will r	> 250 °C					
Vapour pressure:	not applicable					
Vapour pressure:	not applicable					
Density: Bulk density:	1,189 – 1,198 g/cm³ not applicable					
Water solubility:	insoluble					
Solubility in other solvents not determined						
Partition coefficient:	not applicable					
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.

10.2. Chemical stability

The product is chemically stable under recommended conditions of storage, use and temperature. Decompostion takes place from temperatures above: > $250 \degree$ C

10.3. Possibility of hazardous reactions

No hazardous reaction when handled and stored according to provisions.

10.4. Conditions to avoid

Harmful dust is produced during dry-state pulverisation.

10.5. Incompatible materials

Oxidising agent, strong

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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 (Control parameters)

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.

No information available.

CAS No	Chemical name	Chemical name					
	Exposure route	Dose		Species	Source	Method	
80-62-6	methyl 2-methylprop-2-e	noate; methy	/I 2-methylpro	openoate; methyl methacr	ylate		
	oral	LD50 mg/kg	7900	Rat	J. Ind. Hyg. Toxicol	standard acute metho	
	dermal	LD50 mg/kg	> 5000	Rabbit	REACH Dossier	OECD 402	
	inhalative (4 h) vapour	LC50	29,8 mg/l	Rat	REACH Dossier	standard acute metho	
94-36-0	dibenzoyl peroxide; benz	oyl 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. No information available.

Sensitising effects

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

May cause sensitisation especially in sensitive humans. People who suffer from skin sensitazion problems, asthma, allergies, chronic or recurring respiratory illnesses should not be deployed in any process using this preparation.

Carcinogenic/mutagenic/toxic effects for reproduction

Based on available data, the classification criteria are not met. Based on existing data the substance does not fullfill the criteria of CMR-substances Cat. 1 and 2 according 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. No indications of human germ cell mutagenicity exist. No indications of human reproductive toxicity exist.

STOT-single exposure

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

STOT-repeated exposure

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

Aspiration hazard

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

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Specific effects in experiment on an animal

No information available.

Additional information on tests

The mixture is classified as not hazardous according to regulation (EC) No 1272/2008 [CLP]. none

Practical experience

Observations relevant to classification

No information available.

Other observations

No information available.

Further information

Toxicological data are not available. May cause allergy or asthma symptoms or breathing difficulties if inhaled. Do not breathe dusts or mists.

SECTION 12: Ecological information

12.1. Toxicity

Due to the consistency along with the low water solubility of the product a bioavailability is unlikely.

CAS No	Chemical name								
	Aquatic toxicity	Dose		[h] [d]	Species	Source	Method		
80-62-6	methyl 2-methylprop-2-enoate; methyl 2-methylpropenoate; methyl methacrylate								
	Acute fish toxicity	LC50 mg/l	> 79	96 h	Oncorhynchus mykiss (Rainbow trout)	REACH Dossier	EPA OTS 797.1400		
	Acute algae toxicity	ErC50 mg/l	> 110	72 h	Pseudokirchneriella subcapitata	REACH Dossier	OECD 201		
	Acute crustacea toxicity	EC50	69 mg/l	48 h	Daphnia magna (Big water flea)	REACH Dossier	EPA OTS 797.1300		
	Fish toxicity	NOEC	40 mg/l	96 d	Oncorhynchus mykiss (Rainbow trout)	REACH Dossier	EPA OTS 797.1400		
	Algea toxicity	NOEC	49 mg/l	72 d	Pseudokirchneriella subcapitata	REACH Dossier	OECD 201		
	Crustacea toxicity	NOEC	48 mg/l	48 d	Daphnia magna (Big water flea)	REACH Dossier	EPA OTS 797.1300		
94-36-0	dibenzoyl peroxide; benzoyl peroxide								
	Acute fish toxicity	LC50 mg/l	0,24	96 h	Oryzias latipes (Ricefish)	Nier, Korea 2002c	OECD 203		
	Acute algae toxicity	ErC50 mg/l	0,44	72 h	Selenastrum capricornutum	Nier, Korea 2002f	OECD 201		
	Acute crustacea toxicity	EC50 mg/l	0,07	48 h	Daphnia pulex (water flea)	Nier, Korea 2002g	OECD 202		
	Algea toxicity	NOEC mg/l	0,02	3 d	Pseudokirchneriella subcapitata	REACH Dossier	EU Method C.3		
	Crustacea toxicity	NOEC mg/l	0,001	21 d	Daphnia pulex (water flea)	REACH Dossier	OECD 211		
	Acute bacteria toxicity	0,30 g O2 mg/l)	/g (0,35	0,5 h	activated sludge	REACH Dossier	OECD 209		

12.2. Persistence and degradability

There are no data available on the preparation/mixture itself. According to experiences this product is inert and not degradable.

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CAS No	Chemical name						
	Method	Value	d	Source			
	Evaluation	-					
80-62-6	methyl 2-methylprop-2-enoate; methyl 2-methylpropenoate; methyl methacrylate						
	OECD 301C/ ISO 9408/ EEC 92/69/V, C.4-F	94 %	14	Publication			
	Readily biodegradable (according to OECD criteria).						
	EPA, title 40 Code of Federal Regulations Part 160	> 99 %	2	40 CFR 160			
	Readily biodegradable (according to OECD criteria).	-	-				
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

Water solubility < 1 mg/L at 20°C. The product has not been tested. On the basis of existing data about the elimination/degradation and bioaccumulation potential longer term damage to the environment is unlikely.

Partition coefficient n-octanol/water

CAS No	Chemical name	Log Pow
80-62-6	methyl 2-methylprop-2-enoate; methyl 2-methylpropenoate; methyl methacrylate	1,38
94-36-0	dibenzoyl peroxide; benzoyl peroxide	3,2

BCF

CAS No	Chemical name	BCF	Species	Source
	methyl 2-methylprop-2-enoate; methyl 2-methylpropenoate; methyl methacrylate	2,74	n/n	EpiSuite QSAR tool
94-36-0	dibenzoyl peroxide; benzoyl peroxide	47,4	n/n	EpiSuite QSAR tool

12.4. Mobility in soil

No data available.

12.5. Results of PBT and vPvB assessment

No information available.

12.6. Other adverse effects

No data available.

Further information

Do not allow to enter into surface water or drains. Do not allow to enter into soil/subsoil. none

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. Waste disposal according to EC directives 75/442/EEC and 91/689/EEC in the corresponding versions, covering waste and dangerous waste. Dispose according to legislation. Can be incinerated together with household waste in compliance with applicable technical regulations following consultation with approved waste disposal management companies and authorities in charge.

Waste disposal number of waste from residues/unused products

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

Waste disposal number of used product

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

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Waste disposal number of 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

Contaminated packaging

Non-contaminated packages may be recycled. Handle contaminated packages in the same way as the substance itself. Recycling possible without special treatment. May be disposed of in household waste landfill. Recycle sales packaging via DSD (Duales System Deutschland).

SECTION 14: Transport information

Land transport (ADR/RID)

<u>14.1. UN number:</u>	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)		
<u>14.1. UN number:</u>	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)		
<u>14.1. UN number:</u>	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)		
<u>14.1. UN number:</u>	Not restricted	
14.2. UN proper shipping name:	Not restricted	
14.3. Transport hazard class(es):	Not restricted	
14.4. Packing group:	Not restricted	
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		
No dangerous good in sense of this transport regulation.		
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):	0,9 %
2004/42/EC (VOC):	0,9 %
Additional information	

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none		
National regulatory information		
Employment restrictions:	Observe restrictions to employment for juvenils according work protection guideline' (94/33/EC). Observe employm under the Maternity Protection Directive (92/85/EEC) for nursing mothers. Observe employment restrictions for wo child-bearing age.	ent restrictions expectant or
Water contaminating class (D):	2 - water contaminating	
Skin resorption/Sensitization:	Causes allergic hypersensitivity reactions.	

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): 1,2,3,4,5,6,7,8,9,10,11,12,13,14,15,16.

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%

LD50: Lethal dose, 50%

Relevant H and EUH statements (number and full text)

H225	Highly flammable liquid and vapour.
H241	Heating may cause a fire or explosion.
H315	Causes skin irritation.
H317	May cause an allergic skin reaction.
H319	Causes serious eye irritation.
H335	May cause respiratory irritation.
EUH208	Contains methyl 2-methylprop-2-enoate; methyl 2-methylpropenoate; methyl methacrylate,
	dibenzoyl peroxide; benzoyl peroxide. May produce an allergic reaction.
EUH210	Safety data sheet available on request.

Further Information

The information is based on present level of our knowledge. It does not, however, give assurances of product properties and establishes no contract legal rights. The receiver of our product is singulary responsible for adhering to existing laws and regulations. Key literature references and sources for data: Hazardous ingredients ECHA - REACH Dossier OECD - SIDS EPA - Chemistry Dashboard ICCA - GPS Chemicals Portal TOXNET - ChemIDplus

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