according to Regulation (EC) No 1907/2006

artBloc Temp® / artificial Teeth OMP-N® + HMP-N® / PMMA-Discs / artVeneer® / BD Load®

Revision date: 30.04.2019 Product code: D101-2 Page 1 of 11

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

1.1. Product identifier

artBloc Temp® / artificial Teeth OMP-N® + HMP-N® / PMMA-Discs / artVeneer® / BD Load®

Further trade names

artBloc® Temp

artegral® life, artegral®, artegral® HD, Polystar HK, Polystar® Selection EDITION, Polystar® Selection

EDITION HD, integral®, Polystar® Lux HK,

Polystar® Selection EDITION 2, DeltaForm®, DeltaForm® HD,

M-PM® Disc

BDLoad®, BDLoad® ECO, BDLoad® HI

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 (Giftinformationszentrum-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

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.

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.

Safety Data Sheet

according to Regulation (EC) No 1907/2006

artBloc Temp® / artificial Teeth OMP-N® + HMP-N® / PMMA-Discs / artVeneer® / BD Load®

Revision date: 30.04.2019 Product code: D101-2 Page 2 of 11

SECTION 3: Composition/information on ingredients

3.2. Mixtures

Chemical characterization

POLYMETHYL METHACRYLATE

Hazardous components

CAS No	Chemical name			Quantity	
	EC No	Index No	REACH No		
	Classification according to Reg	ulation (EC) No. 1272/2008 [C	LP]		
	РММА			> 98 %	
		-	•		
80-62-6	methyl 2-methylprop-2-enoate; methyl 2-methylpropenoate; methyl methacrylate				
	201-297-1	607-035-00-6			
	Flam. Liq. 2, STOT SE 3, Skin	rrit. 2, Skin Sens. 1; H225 H3	35 H315 H317		
94-36-0	dibenzoyl peroxide; benzoyl pe	roxide		< 1 %	
	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

Inhalation of dust may cause irritation of the respiratory system. In case of allergic symptoms, especially in the breathing area, seek medical advice immediately. Provide fresh air. In all cases of doubt, or when symptoms persist, seek medical advice.

After contact with skin

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. In case of eye irritation consult an ophthalmologist.

After ingestion

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

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

SECTION 5: Firefighting measures

5.1. Extinguishing media

Safety Data Sheet

according to Regulation (EC) No 1907/2006

artBloc Temp® / artificial Teeth OMP-N® + HMP-N® / PMMA-Discs / artVeneer® / BD Load®

Revision date: 30.04.2019 Product code: D101-2 Page 3 of 11

Suitable extinguishing media

Water mist, Foam, Carbon dioxide (CO2), Extinguishing powder

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. Exothermal decomposition with formation of: Carbon dioxide (CO2), Carbon monoxide.

5.3. Advice for firefighters

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

Do not inhale explosion and combustion gases. 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. Wear breathing apparatus if exposed to vapours/dusts/aerosols. Use personal protection equipment.

6.2. Environmental precautions

No special environmental measures are necessary. Avoid release to the environment.

6.3. Methods and material for containment and cleaning up

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. 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. 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 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.

7.3. Specific end use(s)

Specific use(s): Observe instructions for use.

according to Regulation (EC) No 1907/2006

artBloc Temp® / artificial Teeth OMP-N® + HMP-N® / PMMA-Discs / artVeneer® / BD Load®

Revision date: 30.04.2019 Product code: D101-2 Page 4 of 11

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

DNEL/DMEL values

CAS No	Substance						
DNEL type		Exposure route	Effect	Value			
94-36-0	-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			

PNEC values

CAS No	Substance		
Environmenta	Environmental compartment Value		
94-36-0	dibenzoyl peroxide; benzoyl peroxide		
Freshwater		0,000602 mg/l	
Marine water		0,0000602 mg/l	
Freshwater se	diment	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



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

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

according to Regulation (EC) No 1907/2006

artBloc Temp® / artificial Teeth OMP-N® + HMP-N® / PMMA-Discs / artVeneer® / BD Load®

Revision date: 30.04.2019 Product code: D101-2 Page 5 of 11

Eye/face protection

Dust protection eye glasses. Wear eye/face protection.

Hand protection

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

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. 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:

Initial boiling point and boiling range:

Sublimation point:

Softening point:

The call 125 °C VST Pour point:

The call 125 °C VST not applicable on the call 125 °C V

not applicable:

Flash point: > 250 °C ASTM D 1929-68

Sustaining combustion: Not sustaining combustion

Flammability

Solid: not determined
Gas: not applicable

Explosive properties

The product in the delivered form is not dust explosion capable; the enrichment of fine dust however leads to the danger of dust explosion.

Lower explosion limits: not determined Upper explosion limits: not determined

Ignition temperature: > 400 °C ASTM D 1929-68

Auto-ignition temperature

Solid: not determined Gas: not applicable

Decomposition temperature: > 250 °C

Oxidizing properties

none

Vapour pressure: not applicable
Vapour pressure: not applicable

according to Regulation (EC) No 1907/2006

artBloc Temp® / artificial Teeth OMP-N® + HMP-N® / PMMA-Discs / artVeneer® / BD Load®

Revision date: 30.04.2019 Product code: D101-2 Page 6 of 11

Density: 1,189 – 1,198 g/cm³
Bulk density: not applicable
Water solubility: insoluble

Solubility in other solvents

No data available

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 °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

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.

Safety Data Sheet

according to Regulation (EC) No 1907/2006

artBloc Temp® / artificial Teeth OMP-N® + HMP-N® / PMMA-Discs / artVeneer® / BD Load®

Revision date: 30.04.2019 Product code: D101-2 Page 7 of 11

CAS No	Chemical name	Chemical name						
	Exposure route	Dose		Species	Source	Method		
80-62-6	methyl 2-methylprop-2-e	noate; meth	nyl 2-methylpr	openoate; methyl methacr	ylate			
	oral	LD50 mg/kg	> 5000	Rat	OECD 401			
	dermal	LD50 mg/kg	> 5000	Rabbit				
	inhalative (4 h) vapour	LC50	29,8 mg/l	Rat				
94-36-0	dibenzoyl peroxide; benz	zoyl peroxid	le					
	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. 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.

Specific effects in experiment on an animal

No information available.

Additional information on tests

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

according to Regulation (EC) No 1907/2006

artBloc Temp® / artificial Teeth OMP-N® + HMP-N® / PMMA-Discs / artVeneer® / BD Load®

Revision date: 30.04.2019 Product code: D101-2 Page 8 of 11

12.1. Toxicity

Due to the consistency along with the low water solubility of the product a bioavailability is unlikely. 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
80-62-6	methyl 2-methylprop-2-er	oate; methy	l 2-methylpro	penoate	; methyl methacrylate		
	Acute fish toxicity	LC50 mg/l	> 79	96 h	Oncorhynchus mykiss (Rainbow trout)	OECD 203	
	Acute algae toxicity	ErC50 mg/l	> 110	72 h	Selenastrum capricornutum	OECD 201	
	Acute crustacea toxicity	EC50	69 mg/l	48 h	Daphnia magna (Big water flea)	OECD 202	
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.

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	SDB Evonik	
	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
94-36-0	dibenzoyl peroxide; benzoyl peroxide	47,4	n/n	EpiSuite QSAR tool

according to Regulation (EC) No 1907/2006

artBloc Temp® / artificial Teeth OMP-N® + HMP-N® / PMMA-Discs / artVeneer® / BD Load®

Revision date: 30.04.2019 Product code: D101-2 Page 9 of 11

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

none

SECTION 13: Disposal considerations

13.1. Waste treatment methods

Advice on disposal

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

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)

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

Safety Data Sheet

according to Regulation (EC) No 1907/2006

artBloc Temp® / artificial Teeth OMP-N® + HMP-N® / PMMA-Discs / artVeneer® / BD Load®

Revision date: 30.04.2019 Product code: D101-2 Page 10 of 11

Air transport (ICAO-TI/IATA-DGR)

14.1. UN number:Not restricted14.2. UN proper shipping name:Not restricted14.3. Transport hazard class(es):Not restricted14.4. Packing group:Not restricted

14.5. Environmental hazards

ENVIRONMENTALLY HAZARDOUS: no

14.6. Special precautions for user

Not restricted

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

Not restricted

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): 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).

Water contaminating class (D): 1 - slightly 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.

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.

according to Regulation (EC) No 1907/2006

artBloc Temp® / artificial Teeth OMP-N® + HMP-N® / PMMA-Discs / artVeneer® / BD Load®

Revision date: 30.04.2019 Product code: D101-2 Page 11 of 11

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 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.)