

Safety Data Sheet

according to UK REACH Regulation

artBloc Temp / M-PM Disc / BD Load

Revision date: 25.01.2024 Product code: -KZhne Page 1 of 12

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

1.1. Product identifier

artBloc Temp / M-PM Disc / BD Load

Further trade names

artBloc® Temp

M-PM® Disc / PMMA Disc

BDLoad®, BDLoad® ECO, BDLoad® HI, BDLoad® TS, BDLoad® XP

Product group: Intermediates

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

Use of the substance/mixture

Material for the manufacture of dental medical devices.

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)

<u>1.4. Emergency telephone</u> +49-(0)551-19240 (Giftinformationszentrum-Nord)

number:

SECTION 2: Hazards identification

2.2. Label elements

GB CLP Regulation

Special labelling of certain mixtures

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

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.

SECTION 3: Composition/information on ingredients

3.2. Mixtures

Chemical characterization

POLYMETHYL METHACRYLATE



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Relevant ingredients

CAS No	Chemical name			Quantity	
	EC No	Index No	REACH No		
	Classification (GB CLP Regu	ılation)	•		
80-62-6	methyl methacrylate	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 H315 H317 H335				
94-36-0	dibenzoyl peroxide; benzoyl	dibenzoyl peroxide; benzoyl peroxide			
	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.

Specific Conc. Limits, M-factors and ATE

CAS No	EC No	Chemical name	Quantity	
	Specific Conc. Limits, M-factors and ATE			
80-62-6	201-297-1	methyl methacrylate	0.1 - < 1 %	
	inhalation: LC50 = 29,8 mg/l (vapours); dermal: LD50 = > 5000 mg/kg; oral: LD50 = 7872 mg/kg			
94-36-0	202-327-6	dibenzoyl peroxide; benzoyl peroxide	0.1 - < 1 %	
	inhalation: LC50 = > 24300 mg/l (dusts or mists); oral: LD50 = > 2000 mg/kg			

Further Information

May cause sensitization 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.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

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.

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 1 glass of 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

No information available.

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

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

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),



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Extinguishing powder

Unsuitable extinguishing media

Full 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

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

SECTION 6: Accidental release measures

6.1. Personal precautions, protective equipment and emergency procedures

General advice

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

For 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 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.

Advice on general occupational hygiene

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.

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

none

Hints on joint storage

none

7.3. Specific end use(s)



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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
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 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 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 DNE	EL, long-term	dermal	systemic	3,3 mg/kg bw/day

PNEC values

CAS No	Substance	
Environmental	compartment	Value
80-62-6	methyl methacrylate	
Freshwater		< 0,94 mg/l
Marine water		< 0,94 mg/l
Soil	Soil	
Air		
94-36-0	dibenzoyl peroxide; benzoyl peroxide	
Freshwater		0,000602 mg/l
Marine water	Marine water	
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





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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.

Individual protection measures, such as personal protective equipment

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

Use of protective clothing. Wear suitable protective clothing.

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: beige
Odour: odourless

Test method

Print date: 16.10.2024

Flammability: not determined

not applicable

Flash point: $> 250 \, ^{\circ}\text{C}$ ASTM D 1929-68 Auto-ignition temperature: $> 400 \, ^{\circ}\text{C}$ ASTM D 1929-68

Decomposition temperature: > 250 °C

Solubility in other solvents

No data available

Density: 1,2 g/cm³

9.2. Other information

Information with regard to physical hazard classes

Explosive properties

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

Self-ignition temperature

Gas: not applicable

Oxidizing properties

none

Other safety characteristics

Evaporation rate: not applicable
Solvent separation test: not applicable



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Solid content: 100 %
Softening point: ca. 125 °C VST

not applicable:

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)

SECTION 11: Toxicological information

11.1. Information on hazard classes as defined in GB CLP Regulation

Acute toxicity

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

No information available.

ATEmix calculated

ATE (oral) > 2000 mg/kg; ATE (dermal) > 2000 mg/kg; ATE (inhalation vapour) > 20 mg/l; ATE (inhalation dust/mist) > 5 mg/l

CAS No	Chemical name	Chemical name				
	Exposure route	Dose		Species	Source	Method
80-62-6	methyl methacrylate					
	oral	LD50 mg/kg	7872	Rat	RTECS	
	dermal	LD50 mg/kg	> 5000	Rabbit	REACH Dossier	OECD 402
	inhalation (4 h) vapour	LC50	29,8 mg/l	Rat	REACH Dossier	standard acute metho
94-36-0	dibenzoyl peroxide; benz	zoyl peroxid	е			
	oral	LD50 mg/kg	> 2000	Mouse	Nier, Korea 2001	OECD 401
	inhalation dust/mist	LC50 mg/l	> 24300	Rat		

Irritation and corrosivity

Skin corrosion/irritation: Based on available data, the classification criteria are not met.

Serious eye damage/eye irritation: Based on available data, the classification criteria are not met.

No information available.

Sensitising effects



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

Contains methyl methacrylate; methyl 2-methylprop-2-enoate; methyl 2-methylpropenoate, dibenzoyl peroxide; benzoyl peroxide. May produce an allergic reaction.

Similar to related material, not skin sensitizing. Contains: dibenzoyl peroxide, methyl methacrylate. There is no danger as long as the substances are immobilized within the polymer matrix. Only through the Destruction of the polymer matrix, e.g. by suitable solvents, can cause the sensitizing components be mobilized again. In people who have already been sensitized, the remobilized components can lead to allergic reactions.

Carcinogenic/mutagenic/toxic effects for reproduction

Germ cell mutagenicity: Based on available data, the classification criteria are not met.

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

Reproductive toxicity: 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.

Specific effects in experiment on an animal

No information available.

Additional information on tests

none

Practical experience

No information available.

11.2. Information on other hazards

Other information

No information available.

Further information

The mixture is classified as not hazardous according to regulation (EC) No 1272/2008 [CLP]. 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.



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CAS No	Chemical name						
	Aquatic toxicity	Dose		[h] [d]	Species	Source	Method
80-62-6	methyl methacrylate						
	Acute fish toxicity	LC50	191 mg/l	96 h	Lepomis macrochirus (Bluegill)	Merck	
	Acute algae toxicity	ErC50 mg/l	> 110	72 h	Pseudokirchneriella subcapitata	REACH Dossier	OECD 201
	Acute crustacea toxicity	EC50	69 mg/l		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	I .	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		Daphnia pulex (water flea)	Nier, Korea 2002g	OECD 202
	Algae 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	EC50 mg/l (0,30	0,35 g O2/g)	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 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

The product has not been tested.

Partition coefficient n-octanol/water

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

BCF

CAS No	Chemical name	BCF	Species	Source
80-62-6	methyl methacrylate	2,97 - 3,5	Pisces	SDB HIT-ICE, B
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



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

The product has not been tested.

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.

12.7. Other adverse effects

No information available.

Further information

Avoid release to the environment. none

SECTION 13: Disposal considerations

13.1. Waste treatment methods

Disposal recommendations

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.

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

Contaminated packaging

Wash with plenty of water. Completely emptied packages can be recycled. 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

I and	transpor	t /AD	ID/RID/

14.1. UN number or ID 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 or ID 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 or ID 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.

Air transport (ICAO-TI/IATA-DGR)

No dangerous good in sense of this transport regulation.
No dangerous good in sense of this transport regulation.
No dangerous good in sense of this transport regulation.
No dangerous good in sense of this transport regulation.

14.5. Environmental hazards

ENVIRONMENTALLY HAZARDOUS: No





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14.6. Special precautions for user

Not restricted

14.7. Maritime transport in bulk according to IMO instruments

Not restricted

SECTION 15: Regulatory information

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

EU regulatory information

Information according to Directive

2012/18/EU (SEVESO III):

Not subject to 2012/18/EU (SEVESO III)

Additional information

none

National regulatory information

Water hazard class (D): -- non-hazardous to water

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): 7,11,16.



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Abbreviations and acronyms

Org. Perox

Flam. Liq: Flammable liquids Skin Irrit: Skin irritation Eye Irrit: Eye irritation Skin Sens: Skin sensitisation

STOT SE: Specific target organ toxicity - single exposure

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%

CLP: Classification, labelling and Packaging

REACH: Registration, Evaluation and Authorization of Chemicals

GHS: Globally Harmonised System of Classification, Labelling and Packaging of Chemicals

UN: United Nations

DNEL: Derived No Effect Level
DMEL: Derived Minimal Effect Level
PNEC: Predicted No Effect Concentration

ATE: Acute toxicity estimate LL50: Lethal loading, 50% EL50: Effect loading, 50%

EC50: Effective Concentration 50%

ErC50: Effective Concentration 50%, growth rate NOEC: No Observed Effect Concentration

BCF: Bio-concentration factor

PBT: persistent, bioaccumulative, toxic vPvB: very persistent, very bioaccumulative

RID: Regulations concerning the international carriage of dangerous goods by rail

ADN: European Agreement concerning the International Carriage of Dangerous Goods by Inland Waterways (Accord européen relatif au transport international des marchandises dangereuses par voies de navigation intérieures)

EmS: Emergency Schedules MFAG: Medical First Aid Guide

ICAO: International Civil Aviation Organization

MARPOL: International Convention for the Prevention of Marine Pollution from Ships

IBC: Intermediate Bulk Container VOC: Volatile Organic Compounds SVHC: Substance of Very High Concern

For abbreviations and acronyms, see: ECHA Guidance on information requirements and chemical safety assessment, chapter R.20 (Table of terms and abbreviations).

Key literature references and sources for data

(EU) 2020/878

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.



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

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

EUH210 Safety data sheet available on request.

Further Information

The information is based on the present level of our knowledge. It does not, however, give assurance of product properties and establishes no contract legal rights. The receiver of our product is singularly responsible for adhering to existing laws and regulations.

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