

## Safety Data Sheet

according to Regulation (EC) No. 1907/2006

### Molloplast® B

Revision date: 28.11.2022

Product code: 10216

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

### 1.1. Product identifier

Molloplast® B

UFI: U39W-V03M-100Y-KEVA

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

#### Use of the substance/mixture

Relining material for use in dentistry.

### 1.3. Details of the supplier of the safety data sheet

Company name:	DETAX GmbH	
Street:	Carl-Zeiss-Straße 4	
Place:	D-76275 Ettlingen	
Telephone:	+49 7243/510-0	Telefax: +49 7243/510-100
e-mail:	post@detax.com	
Internet:	www.detax.com	
Responsible Department:	This number is only obtainable during office hours (Monday - Thursday 8.00 a.m. - 5.00 p.m., Friday 8.00 a.m. - 4.00 p.m.)	

1.4. Emergency telephone number: +1-800-424-9300 (CHEMTREC worldwide)

## SECTION 2: Hazards identification

### 2.1. Classification of the substance or mixture

#### Regulation (EC) No. 1907/2006

Skin Sens. 1; H317  
Aquatic Chronic 3; H412

Full text of hazard statements: see SECTION 16.

### 2.2. Label elements

#### Regulation (EC) No. 1907/2006

##### Hazard components for labelling

dibenzoyl peroxide; benzoyl peroxide

Signal word: Warning

##### Pictograms:



##### Hazard statements

H317 May cause an allergic skin reaction.  
H412 Harmful to aquatic life with long lasting effects.

##### Precautionary statements

P261 Avoid breathing dust/fume/gas/mist/vapours/spray.  
P273 Avoid release to the environment.  
P280 Wear protective gloves/protective clothing/eye protection/face protection/hearing protection.  
P302+P352 IF ON SKIN: Wash with plenty of water.  
P333+P313 If skin irritation or rash occurs: Get medical advice/attention.  
P362+P364 Take off contaminated clothing and wash it before reuse.  
P501 Dispose of contents/ container in accordance with local and national regulations.

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#### 2.3. Other hazards

No information available.

### SECTION 3: Composition/information on ingredients

#### 3.2. Mixtures

##### Chemical characterization

Contains: polydimethylsiloxane + inert filler and pigment + part of organic peroxide

##### Hazardous components

CAS No	Chemical name			Quantity
	EC No	Index No	REACH No	
	Classification (Regulation (EC) No. 1907/2006)			
94-36-0	dibenzoyl peroxide; benzoyl peroxide			1 - < 2 %
	202-327-6	617-008-00-0	01-2119511472-50	
	Org. Perox. B, Eye Irrit. 2, Skin Sens. 1, Aquatic Acute 1, Aquatic Chronic 1; H241 H319 H317 H400 H410			
75-09-2	dichloromethane, (see methylene chloride)			< 0,3 %
	200-838-9	602-004-00-3		
	Carc. 2, Skin Irrit. 2, Eye Irrit. 2, STOT SE 3; H351 H315 H319 H336			

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	
94-36-0	202-327-6	dibenzoyl peroxide; benzoyl peroxide	1 - < 2 %
		inhalation: LC50 = 24,3 mg/l (dusts or mists); oral: LD50 = >5000 mg/kg M acute; H400: M=10 M chron.; H410: M=10	
75-09-2	200-838-9	dichloromethane, (see methylene chloride)	< 0,3 %
		inhalation: LC50 = 52 mg/l (vapours); dermal: LD50 = >2000 mg/kg; oral: LD50 = >2000 mg/kg	

### SECTION 4: First aid measures

#### 4.1. Description of first aid measures

##### After inhalation

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

##### After contact with skin

After contact with skin, wash immediately with plenty of water and soap. Take off immediately all contaminated clothing and wash it before reuse. Medical treatment necessary.

##### 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 1 glass of water.  
Do not induce vomiting. If you feel unwell, 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

Treat symptomatically.

### SECTION 5: Firefighting measures

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#### **5.1. Extinguishing media**

##### **Suitable extinguishing media**

Co-ordinate fire-fighting measures to the fire surroundings.

#### **5.2. Special hazards arising from the substance or mixture**

Non-flammable.

#### **5.3. Advice for firefighters**

Wear a self-contained breathing apparatus and chemical protective clothing. Full protection suit.

#### **Additional information**

Suppress gases/vapours/mists with water spray jet. 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**

##### **General advice**

Provide adequate ventilation. Do not breathe gas/fumes/vapour/spray. Avoid contact with skin, eyes and clothes. Use personal protection equipment.

#### **6.2. Environmental precautions**

Do not allow to enter into surface water or drains.

#### **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.

##### **Other information**

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**

No special measures are necessary.

##### **Advice on protection against fire and explosion**

No special fire protection measures are necessary.

##### **Advice on general occupational hygiene**

Remove contaminated, saturated clothing immediately. Draw up and observe skin protection programme. Wash hands and face before breaks and after work and take a shower if necessary. When using do not eat, drink, smoke, sniff. Remove contaminated, saturated clothing immediately. Draw up and observe skin protection programme. Wash hands and face before breaks and after work and take a shower if necessary. When using do not eat or drink.

#### **7.2. Conditions for safe storage, including any incompatibilities**

##### **Requirements for storage rooms and vessels**

Keep container tightly closed.

##### **Hints on joint storage**

Do not store with spontaneous flammable materials. Do not store with combustible materials.

##### **Further information on storage conditions**

Keep only in the original container in a cool, dry and well-ventilated place, away from foodstuffs.

#### **7.3. Specific end use(s)**

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Silicone material for denture relinings.  
For use by trained specialist staff.

## SECTION 8: Exposure controls/personal protection

### 8.1. Control parameters

#### Exposure limits (EH40)

CAS No	Substance	ppm	mg/m <sup>3</sup>	fibres/ml	Category	Origin
94-36-0	Dibenzoyl peroxide	-	5		TWA (8 h)	WEL
75-09-2	Dichloromethane	100	353		TWA (8 h)	WEL
		200	706		STEL (15 min)	WEL

#### Biological Monitoring Guidance Values (EH40)

CAS No	Substance	Parameter	Value	Test material	Sampling time
75-09-2	Dichloromethane	carbon monoxide	30 ppm	end-tidal breath	Post shift

### 8.2. Exposure controls

#### Individual protection measures, such as personal protective equipment

##### 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.

Suitable are gloves of the following material: NBR (Nitrile rubber)

##### Skin protection

Use of protective clothing.

##### Respiratory protection

In case of inadequate ventilation wear respiratory protection.

## SECTION 9: Physical and chemical properties

### 9.1. Information on basic physical and chemical properties

Physical state: Paste  
 Colour: gingiva coloured  
 Odour: odourless

#### Test method

Melting point/freezing point: not determined  
 Boiling point or initial boiling point and boiling range: not determined  
 Flammability  
     Solid/liquid: not determined  
     Gas: not applicable  
 Lower explosion limits: not determined  
 Upper explosion limits: not determined  
 Flash point: >100 °C DIN 51755  
 Auto-ignition temperature: >200 °C DIN 51794  
 Decomposition temperature: >250 °C

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pH-Value: not determined

Water solubility: The study does not need to be conducted because the substance is known to be insoluble in water.

Solubility in other solvents  
not determined

Partition coefficient n-octanol/water: not determined

Vapour pressure:  
(at 20 °C) <1 hPa

Density (at 20 °C): 1,1 g/cm<sup>3</sup> DIN 51757

Relative vapour density: not determined

### 9.2. Other information

#### Information with regard to physical hazard classes

Explosive properties

The product is not: Explosive.

Oxidizing properties

The product is not: oxidising.

#### Other safety characteristics

Evaporation rate: not determined

Solid content: not determined

## 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 stable under storage at normal ambient temperatures.

### 10.3. Possibility of hazardous reactions

Reacts with : combustible materials.

### 10.4. Conditions to avoid

The material may autopolymerise at a temperature exceeding 60°C/ 140°F. Therefore keep containers tightly closed in a refrigerator at 2°C-12°C/ 36°F-54°F.

### 10.5. Incompatible materials

No information available.

### 10.6. Hazardous decomposition products

At a temperature of approx. 150°C/ 302°F a small amount of formaldehyde can be released by oxidative degradation.

## SECTION 11: Toxicological information

### 11.1. Information on hazard classes as defined in Regulation (EC) No. 1907/2006

#### Acute toxicity

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

For the product itself no toxicological data are available. In products with a comparable composition, a LD50 (orally, species rat) of > 5000 mg/kg has been found.

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CAS No	Chemical name				
	Exposure route	Dose	Species	Source	Method
94-36-0	dibenzoyl peroxide; benzoyl peroxide				
	oral	LD50 >5000 mg/kg	Rat		
	inhalation (4 h) dust/mist	LC50 24,3 mg/l	Rat	OECD 403	
75-09-2	dichloromethane, (see methylene chloride)				
	oral	LD50 >2000 mg/kg	Rat	ECHA	
	dermal	LD50 >2000 mg/kg	Rat	ECHA	
	inhalation (4 h) vapour	LC50 52 mg/l	Rat	TOXNET	

#### Irritation and corrosivity

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

#### Sensitising effects

May cause an allergic skin reaction. (dibenzoyl peroxide; benzoyl peroxide)

#### Carcinogenic/mutagenic/toxic effects for reproduction

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

#### STOT-single exposure

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

#### STOT-repeated exposure

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

#### Aspiration hazard

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

#### Further information

The mixture is classified as hazardous according to regulation (EC) No 1272/2008 [CLP].

### SECTION 12: Ecological information

#### 12.1. Toxicity

Harmful to aquatic life with long lasting effects.

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CAS No	Chemical name					
	Aquatic toxicity	Dose	[h]   [d]	Species	Source	Method
94-36-0	dibenzoyl peroxide; benzoyl peroxide					
	Acute fish toxicity	LC50 mg/l	0,06	96 h	Oncorhynchus mykiss (Rainbow trout)	OECD 203
	Acute algae toxicity	ErC50 mg/l	0,07	72 h	Pseudokirchneriella subcapitata	OECD 201
	Acute crustacea toxicity	EC50 mg/l	0,11	48 h	Daphnia magna (Big water flea)	OECD 202
	Acute bacteria toxicity	(EC50	35 mg/l)	0,5 h		OECD 209
75-09-2	dichloromethane, (see methylene chloride)					
	Acute fish toxicity	LC50	193 mg/l	96 h	Pimephales promelas (fathead minnow)	ECOTOX
	Acute algae toxicity	ErC50 mg/l	>660	96 h	Pseudokirchneriella subcapitata	IUCLID
	Acute crustacea toxicity	EC50 mg/l	1682	48 h	Daphnia magna (Big water flea)	IUCLID
	Acute bacteria toxicity	(EC50	2,88		Photobacterium phosphoreum	IUCLID

#### 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		
	Biodegradable.				
75-09-2	dichloromethane, (see methylene chloride)				
	OECD 301C/ ISO 9408/ EEC 92/69/V, C.4-F	5-26%	28		
	Not readily biodegradable (according to OECD criteria)				

#### 12.3. Bioaccumulative potential

The product has not been tested.

#### 12.4. Mobility in soil

The product has not been tested.

#### 12.5. Results of PBT and vPvB assessment

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

#### 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

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

##### Disposal recommendations

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

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according to applicable legislation.

#### 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)

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

#### Inland waterways transport (ADN)

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

#### Marine transport (IMDG)

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

#### Air transport (ICAO-TI/IATA-DGR)

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

#### 14.6. Special precautions for user

No dangerous good in sense of this transport regulation.

#### 14.7. Maritime transport in bulk according to IMO instruments

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

Restrictions on use (REACH, annex XVII):

Entry 59, Entry 75

Information according to 2012/18/EU (SEVESO III): Not subject to 2012/18/EU (SEVESO III)

##### Additional information

To follow: 850/2004/EC, 79/117/EEC, 689/2008/EC

##### National regulatory information

Employment restrictions: Observe restrictions to employment for juveniles according to the 'juvenile work protection guideline' (94/33/EC).

Water hazard class (D): 1 - slightly 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



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#### 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%

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

SVHC: Substance of Very High Concern

For abbreviations and acronyms, see table at <http://abbrev.esdscom.eu>

#### Classification for mixtures and used evaluation method according to Regulation (EC) No. 1907/2006

Classification	Classification procedure
Skin Sens. 1; H317	Calculation method
Aquatic Chronic 3; H412	Calculation method

#### Relevant H and EUH statements (number and full text)

H241	Heating may cause a fire or explosion.
H315	Causes skin irritation.
H317	May cause an allergic skin reaction.
H319	Causes serious eye irritation.
H336	May cause drowsiness or dizziness.
H351	Suspected of causing cancer.
H400	Very toxic to aquatic life.
H410	Very toxic to aquatic life with long lasting effects.
H412	Harmful to aquatic life with long lasting effects.

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#### 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.

#### Identified uses

No	Short title	LCS	SU	PC	PROC	ERC	AC	TF	Specification
1	Gewerblich	-	-	-	-	-	-	-	2

LCS: Life cycle stages

PC: Product categories

ERC: Environmental release categories

TF: Technical functions

SU: Sectors of use

PROC: Process categories

AC: Article categories

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