

according to Regulation (EC) No 1907/2006

**Gingivamoll® epithesis material**

Revision date: 12.08.2016

Product code: 10191

Page 1 of 6

**SECTION 1: Identification of the substance/mixture and of the company/undertaking****1.1. Product identifier**

Gingivamoll® epithesis material

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

Epithesis material for use in dentistry.

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

Company name:	DETAX GmbH & Co. KG	
Street:	Carl-Zeiss-Strasse	
Place:	D-76275 Ettlingen	
Telephone:	+49 7243/510-0	Telefax: +49 7243/510-100
e-mail:	post@detax.de	
Internet:	www.detax.de	
Responsible Department:	Emergency number:	

+49 7243/510-0

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:**

+49 7243/510-0

This number is only obtainable during office hours (Monday - Thursday 8.00 a.m. - 5.00 p.m., Friday 8.00 - 4.00 p.m.)

**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 "dibenzoyl peroxide; benzoyl peroxide". May produce an allergic reaction.
EUH210	Safety data sheet available on request.

**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

**SECTION 4: First aid measures****4.1. Description of first aid measures****After inhalation**

Provide fresh air. If breathing is irregular or stopped, administer artificial respiration. Medical treatment necessary.

**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.

according to Regulation (EC) No 1907/2006

**Gingivamoll® epithesis material**

Revision date: 12.08.2016

Product code: 10191

Page 2 of 6

**After contact with eyes**

Rinse immediately carefully and thoroughly with eye-bath or water.

**After ingestion**

Rinse mouth immediately and drink plenty 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****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**

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

**Additional information**

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

**SECTION 6: Accidental release measures****6.1. Personal precautions, protective equipment and emergency procedures**

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**

Absorb with liquid-binding material (e.g. sand, diatomaceous earth, acid- or universal binding agents). 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.

**7.2. Conditions for safe storage, including any incompatibilities****Requirements for storage rooms and vessels**

Keep container tightly closed.

**Advice on storage compatibility**

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

**Further information on storage conditions**

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

according to Regulation (EC) No 1907/2006

### Gingivamoll® epithesis material

Revision date: 12.08.2016

Product code: 10191

Page 3 of 6

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

Silicone material for the fabrication of gingival epithesis.

### SECTION 8: Exposure controls/personal protection

#### 8.1. Control parameters

#### 8.2. Exposure controls

##### Protective and hygiene measures

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

##### Eye/face protection

Wear eye/face protection.

##### Hand protection

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

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

##### Skin protection

Wear suitable 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:	pink, lighth pink , opaque
Odour:	odourless

#### Test method

pH-Value:	not determined
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##### Changes in the physical state

Melting point:	not determined
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Initial boiling point and boiling range:	not determined
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Flash point:	>100 °C	DIN 51755
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##### Flammability

Solid:	not applicable
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Gas:	not applicable
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Lower explosion limits:	not determined
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Upper explosion limits:	not determined
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Ignition temperature:	>200 °C	DIN 51794
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##### Auto-ignition temperature

Solid:	not applicable
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Gas:	not applicable
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Decomposition temperature:	>250 °C
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##### Oxidizing properties

Not oxidizing.

according to Regulation (EC) No 1907/2006

**Gingivamoll® epithesis material**

Revision date: 12.08.2016

Product code: 10191

Page 4 of 6

Vapour pressure: (at 20 °C)	<1 hPa
Density (at 20 °C):	1,1 g/cm <sup>3</sup> DIN 51757
Water solubility:	insoluble
<b>Solubility in other solvents</b> not determined	
Partition coefficient:	not determined
Vapour density:	not determined
Evaporation rate:	not determined

**9.2. Other information**

Solid content:	not determined
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**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 toxicological effects****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.

**Irritation and corrosivity**

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

**Sensitising effects**

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

**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.

according to Regulation (EC) No 1907/2006

**Gingivamoll® epithesis material**

Revision date: 12.08.2016

Product code: 10191

Page 5 of 6

**Additional information on tests**

This mixture is classified as not hazardous according to regulation (EC) 1272/2008 [CLP].

**SECTION 12: Ecological information****12.1. Toxicity**

The product is not: Ecotoxic.

**12.2. Persistence and degradability**

The product has not been tested.

**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**

Not identified as PBT/ vPvB substances

**12.6. Other adverse effects**

No information available.

**Further information**

Avoid release to the environment.

**SECTION 13: Disposal considerations****13.1. Waste treatment methods****Advice on disposal**

Do not allow to enter into surface water or drains. Dispose of waste according to applicable legislation.

**Contaminated packaging**

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

**SECTION 14: Transport information****Land transport (ADR/RID)****14.1. UN number:**

No dangerous good in sense of this transport regulation.

**14.2. UN proper shipping name:**

No dangerous good in sense of this transport regulation.

**14.3. Transport hazard class(es):**

No dangerous good in sense of this transport regulation.

**14.4. Packing group:**

No dangerous good in sense of this transport regulation.

**Inland waterways transport (ADN)****14.1. UN number:**

No dangerous good in sense of this transport regulation.

**14.2. UN proper shipping name:**

No dangerous good in sense of this transport regulation.

**14.3. Transport hazard class(es):**

No dangerous good in sense of this transport regulation.

**14.4. Packing group:**

No dangerous good in sense of this transport regulation.

**Marine transport (IMDG)****14.1. UN number:**

No dangerous good in sense of this transport regulation.

**14.2. UN proper shipping name:**

No dangerous good in sense of this transport regulation.

**14.3. Transport hazard class(es):**

No dangerous good in sense of this transport regulation.

**14.4. Packing group:**

No dangerous good in sense of this transport regulation.

**Air transport (ICAO-TI/IATA-DGR)****14.1. UN number:**

No dangerous good in sense of this transport regulation.

**14.2. UN proper shipping name:**

No dangerous good in sense of this transport regulation.

**14.3. Transport hazard class(es):**

No dangerous good in sense of this transport regulation.

according to Regulation (EC) No 1907/2006

### Gingivamoll® epithesis material

Revision date: 12.08.2016

Product code: 10191

Page 6 of 6

#### 14.4. Packing group:

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

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

##### National regulatory information

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

#### 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)

EUH208 Contains "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.

#### Identified uses

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

SU main: Main user groups

SU: Sectors of use

PC: Product categories

PROC: Process categories

ERC: Environmental release 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.)*