

according to Regulation (EC) No 1907/2006

**bioflex® (base + catalyst)**

Revision date: 20.09.2016

Product code: 895

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

bioflex® (base + catalyst)

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

Earmould material for use in audiology.

**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****2.3. Other hazards**

No information available.

**SECTION 3: Composition/information on ingredients****3.2. Mixtures****Chemical characterization**

Contains polydimethylsiloxane with functional groups. + fillers and pigment  
catalyst: additionally platinum complex compound.

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

Provide fresh air.

**After contact with skin**

Wash with plenty of water. Take off contaminated clothing and wash it before reuse.

**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.

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**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. Vapours can form explosive mixtures with air.

**5.3. Advice for firefighters**

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

**Additional information**

Use water spray jet to protect personnel and to cool endangered containers.

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

Use personal protection equipment.

**6.2. Environmental precautions**

No special environmental measures are necessary. Clean contaminated objects and areas thoroughly observing environmental regulations.

**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 acids, lyes, alcohols, metallic powders and metallic oxides (release of hydrogen is favoured).

**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)**

Silicone material for use in audiology.

For use by trained specialist staff.

**SECTION 8: Exposure controls/personal protection**

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#### 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:	base: several , catalyst: transparent
Odour:	characteristic

##### 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:	>400 °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:	>180 °C
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##### Oxidizing properties

Not oxidizing.

Vapour pressure: (at 20 °C)	<10 hPa
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Density (at 20 °C):	1,1 g/cm³ DIN 5157
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Water solubility:	insoluble
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#### Solubility in other solvents

not determined

Partition coefficient:

not determined

Viscosity / dynamic:  
(at 23 °C)

150000-2100000 mPa·s BROOKFIELD

Vapour density:

not determined

Evaporation rate:

not determined

#### 9.2. Other information

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 :

#### 10.4. Conditions to avoid

Temperatures > 150°C/ 302 °F.

#### 10.5. Incompatible materials

No information available.

#### 10.6. Hazardous decomposition products

In case of thermic decomposition hydrogen is released. 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.

##### Additional information on tests

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

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## 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

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.

#### 14.4. Packing group:

No dangerous good in sense of this transport regulation.

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#### 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

##### EU regulatory information

2004/42/EC (VOC): 0,001 % (0,016 g/l)

##### National regulatory information

Water contaminating class (D): - - not water contaminating

#### 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%

#### 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.)*