

Date of Print:

Date of last Alteration: 15.03.2016 - Version 1.0 : English

Product Name, Art.-No.: **Kohlersil Mandibular** Art.No.: 8011**1. Identification of the substance / mixture and of the company / undertaking**

- 1.1 Product identifier Kohlersil Mandibular
- 1.2 Relevant identified uses of the substance or mixture and uses advised against
- Use or preparation Dental product
- 1.3 Details of the supplier of the safety data sheet
- Company name: Kohdent Roland Kohler Medizintechnik GmbH & Co. KG  
 Street: Bodenseeallee 14-16  
 Place: D-78333 Stockach  
 Telephone: +49 7771 / 649 99-0  
 Telefax: +49 7771 / 649 99-50  
 e-mail: [info@kohler-medizintechnik.de](mailto:info@kohler-medizintechnik.de)  
 Internet: [www.kohler-medizintechnik.de](http://www.kohler-medizintechnik.de)
- 1.4 Emergency telephone number +49 7771 / 649 99-0  
 This number is obtainable during office hours  
 (Mo.- Do. 7.00 a.m. – 5.30 p.m., Fr. 7.00 a.m. – 12.30 p.m.)
- +49 228 19240 (24 hour)  
 Poison information centre, D-53113 Bonn

**2. Hazards identification**

- 2.1 Classification of the substance or mixture
- Classification according to Regulation (EC) 1272/2008 void
- Information concerning particular hazards for human and environment The product does not have to be labeled due to the calculation procedure of the „General classification guideline for preparations of the EU“ in the latest valid version.
- 2.2 Label elements -
- Labeling according to Regulation (EC) 1272/2008 -
- Labeling according to EU guidelines Medical devices as defined in Directive 93/42/EEC and which are invasive or used in direct physical contact with the human body; are exempted from the provisions of Regulation (EC) No. 1272/2008 (CLP/GHS) usually if they are in the finished state and intended for the final user.
- 2.3 Other hazards
- Results of PBT and vPvB assessment **PBT:** not applicable  
**vPvB:** not applicable

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Product Name, Art.-No.: **Kohlersil Mandibular** Art.No.: 8011**3. Composition / information on ingredients**3.1 Substances3.2 Mixtures**Chemical characterization**

Description: Mixture of polydimethyl polymethyl vinyl siloxane, polydimethyl polymethyl hydrogen siloxane and silica

Hazardous components: none

**4. First aid measures**4.1 Description of first aid measures

General information: no special measures required

after skin contact: wash with plenty of water and soap

after eye contact: rinse with plenty of water and consult a doctor

after swallowing: if symptoms persist consult a doctor

4.2 Most important symptoms and effects, both acute and delayed -4.3 Indication of any immediate medical attention and special treatment needed -**5. Firefighting measures**5.1 Extinguishing media CO<sub>2</sub>, water5.2 Special hazards arising from the substance or mixture -5.3 Advice for firefighters

Protective equipment no special measures required

**6. Accidental release measures**6.1 Personal precautions, protective equipment and emergency procedures not required6.2 Environmental precautions no special measures required

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6.3 Methods and material for containment and cleaning up pick up mechanically

6.4 Reference to other sections none

## 7. Handling and storage

### 7.1 Precautions for safe handling

Information for safe handling: For dental use only. No special measures required.

Recommendation for fire and explosion protection: No special measures required

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

Requirements at storerooms and containers: No special measures required

Requirements for storage with other products: not required

Further information on storage conditions: none

7.3 Specific end use(s) -

## 8. Exposure controls / personal protection

### 8.1 Control parameters

Components with limits of values to be supervised at the workplace: The product does not contain any relevant quantities of materials with critical values that have to be monitored at the workplace.

Additional information: The lists valid during the making were used as basis.

### 8.2 Exposure controls

Personal protective equipment: -

General measures of protection and hygiene: normal hygienic measures

Respiratory protection: not required

Protection of hands: not required

Eye protection: not absolute required

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## 9. Physical and chemical properties

### 9.1 Information on basic physical and chemical properties

#### Appearance:

Form: Paste  
 Color: A-Comp.: white, B-Comp.: blue-green  
 Odor: odorless

	Value	Unit	Method
<b>Information on change in the physical state</b>			
Melting point/melting range:	n.a.		°C
Boiling point/boiling range:	n.a.		°C
Flash point:	n.a.		°C
Autoignition temperature:	n.a.		
Danger of explosion:	none		
Density:	1,31 (20°C)	g/cm3	
Vapor pressure:	n.a.	mbar	
Viscosity	Paste		
pH:	neutral		
Solubility in / miscibility with:	Partially soluble in toluene, petrol ether		
Water:	insoluble		
Content of solvents:	none		
Organic solvents:	-		
Water:	-		
Content of solids:	n.a.		

### 9.2 Other information

-

## 10. Stability and reactivity

- |      |   |   |
|------|---|---|
| 10.1 | <u>Reactivity</u>                         | -   |
| 10.2 | <u>Chemical stability</u>                 | -   |
| 10.3 | <u>Possibility of hazardous reactions</u> | -   |
| 10.4 | <u>Conditions to avoid</u>                | No decomposition if used according to specification |
| 10.5 | <u>Incompatible materials</u>             | -   |
| 10.6 | <u>Hazardous decomposition products</u>   | None under normal conditions of storage and use     |

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Product Name, Art.-No.: **Kohlersil Mandibular** Art.No.: 8011**11. Toxicological information****11.1** Information on toxicological effects

Acute toxicity: -

Primary irritation: -

skin no irritating effect  
eye no irritating effect

Additional toxicological information : When used and handled according to specifications, the product does not have any harmful effects to our experience and the information provided to us.

**12. Ecological information****12.1** Toxicity

General information avoid transfer into environment

Classification of water endangerment: WGK 1 (German regulation) slightly hazardous for water

**12.2** Persistence and degradability -**12.3** Bioaccumulative potential -**12.4** Mobility in soil -**12.5** Results of PBT- and vPvB-assessment -**12.6** Other adverse effects -**13. Disposal considerations****13.1** Waste treatment methods**Product**

Recommendation: Small quantities can be disposed of with household waste.

Use proper landfill disposal or incineration in accordance with local, state and federal regulations.

**Uncleaned packaging**

Recommendation: Disposal must be made according to official regulations.

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Product Name, Art.-No.: **Kohlersil Mandibular** Art.No.: 8011**14. Transport information**

Land transport (ADR/RID)		
14.1	UN number:	-
14.2	UN proper shipping name:	-
14.3	Transport hazard class(es):	-
14.4	Packing group:	-
Maritime transport (IMDG)		
14.1	UN number:	-
14.2	UN proper shipping name:	-
14.3	Transport hazard class(es):	-
14.4	Packing group:	-
Air transport (ICAO-TI/IATA-DGR)		
14.1	UN number:	-
14.2	UN proper shipping name:	-
14.3	Transport hazard class(es):	-
14.4	Packing group:	-
14.5	Environmental hazards	-
14.6	Special precautions for user	-
14.7	Transport in bulk according to Annex II of MARPOL 73/78 and the IBC-Code	-

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

Classification according to EC-guidelines: The product is a medical device according to EC-directive 93/42 EEC.

**15.2** Chemical safety assessment

A Chemical Safety Assessment has not been carried out.

**16. Other information****Changes compared with the previous version:** Adaptation according to 1907/2006/EG, Article 31

The above information is based on our present day knowledge and relates solely to the safety requirements of the product. The data do not signify any warranty with regards to products properties. However users of the product should satisfy themselves that the information given is sufficient and correct for their specific circumstances of use.

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