

according to Regulation (EC) No 1907/2006

**GuttaFlow bioseal**

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

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

for dental use only

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

Company name:	Coltène/Whaledent GmbH & Co. KG
Street:	Raiffeisenstraße 30
Place:	D-89129 Langenau
Telephone:	+49 (7345) 805 0
Telefax:	+49 (7345) 805 201
e-mail:	info.de@coltene.com
Internet:	www.coltene.com

**Further Information**

Only supplied to dentists and dental laboratories or upon their instructions

**SECTION 2: Hazards identification****2.1. Classification of the substance or mixture****Classification according to Regulation (EC) No. 1272/2008 [CLP]**

Hazard categories:

Hazardous to the aquatic environment: Aquatic Chronic 2

Hazard Statements:

Toxic to aquatic life with long lasting effects.

**2.2. Label elements**

Pictograms: GHS09

**Hazard statements**

H411 Toxic to aquatic life with long lasting effects.

**Precautionary statements**

P273 Avoid release to the environment.

P391 Collect spillage.

**Additional advice on labelling**

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.

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

Polymer preparations and compounds

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**Hazardous components**

EC No	Chemical name	Quantity
CAS No	Classification according to Directive 67/548/EEC	
Index No	Classification according to Regulation (EC) No. 1272/2008 [CLP]	
REACH No		
215-222-5	zinc oxide	1 - < 5 %
1314-13-2	N - Dangerous for the environment R50-53	
030-013-00-7	Aquatic Acute 1, Aquatic Chronic 1; H400 H410	

Full text of R, H and EUH phrases: see section 16.

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

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.

**After ingestion**

Call a doctor if you feel unwell.

**4.2. Most important symptoms and effects, both acute and delayed**

No information available.

**SECTION 5: Firefighting measures****5.1. Extinguishing media****Suitable extinguishing media**Water. Foam. Extinguishing powder. Carbon dioxide (CO<sub>2</sub>). Sand.**Additional information**

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

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

Avoid contact with skin and eyes.

**6.2. Environmental precautions**

Do not allow to enter into surface water or drains.

**6.3. Methods and material for containment and cleaning up**

Wipe up with absorbent material (eg. cloth, fleece). Clear contaminated areas thoroughly.

**SECTION 7: Handling and storage****7.1. Precautions for safe handling****Advice on safe handling**

Keep out of reach of children. The product is intended for professional use.

Observe instructions for use.

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

Conditions to avoid: UV-radiation/sunlight.

**Further information on storage conditions**

Keep the packing dry and well sealed to prevent contamination and absorption of humidity.

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Recommended storage temperature: 18 - 24 °C

**SECTION 8: Exposure controls/personal protection****8.1. Control parameters****8.2. Exposure controls****Protective and hygiene measures**

When using do not eat, drink or smoke.

**Eye/face protection**

Framed glasses.

**Hand protection**

Single-use gloves.

Unsuitable material: NR (Natural rubber (Caoutchouc), Natural latex).

**SECTION 9: Physical and chemical properties****9.1. Information on basic physical and chemical properties**

Physical state: Paste  
 Colour: grey - pink

**Test method****Changes in the physical state**

Initial boiling point and boiling range: &gt;150 °C

Density (at 23 °C): 1.8 - 2.0 g/cm<sup>3</sup>Water solubility: insoluble  
(at 23 °C)**Solubility in other solvents**

ketone.

**SECTION 10: Stability and reactivity****10.2. Chemical stability**

The mixture is chemically stable under recommended conditions of storage, use and temperature.

**10.4. Conditions to avoid**Moisture-sensitive.  
UV-radiation/sunlight.**SECTION 11: Toxicological information****11.1. Information on toxicological effects****Acute toxicity**

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

LD50: &gt;2000 mg/kg (Rat)

The statement is derived from products of similar composition.

CAS No	Chemical name				
	Exposure route	Method	Dose	Species	Source
1314-13-2	zinc oxide				
	oral	LD50	> 5000 mg/kg	Rat	IUCLID

**Irritation and corrosivity**

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Based on available data, the classification criteria are not met.  
Irritant effect on the skin: (Rabbit)  
Not an irritant.  
The statement is derived from products of similar composition.

**Sensitising effects**

Based on available data, the classification criteria are not met.  
Guinea-pig.  
no danger of sensitization.  
The statement is derived from products of similar composition.

**STOT-single exposure**

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

**Severe effects after repeated or prolonged exposure**

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.

**Aspiration hazard**

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

**SECTION 12: Ecological information****Further information**

Do not allow to enter into surface water or drains.

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

Can be burnt together with household waste in compliance with official regulations in contact with approved waste disposal companies and with authorities in charge.

**SECTION 14: Transport information****Land transport (ADR/RID)**

**14.1. UN number:** UN ----

**Marine transport (IMDG)**

**14.1. UN number:** UN ----

**Air transport (ICAO)**

**14.1. UN number:** UN ----

**Other applicable information**

Not a hazardous material with respect to these transportation regulations.

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

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**SECTION 16: Other information**

according to Regulation (EC) No 1907/2006

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**Relevant R phrases (number and full text)**

- 50 Very toxic to aquatic organisms.
- 53 May cause long-term adverse effects in the aquatic environment.

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

- H400 Very toxic to aquatic life.
- H410 Very toxic to aquatic life with long lasting effects.
- H411 Toxic to aquatic life with long lasting effects.

**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.

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