

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 (CO₂). 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:

>150 °C

Density (at 23 °C):

1.8 - 2.0 g/cm³Water solubility:
(at 23 °C)

insoluble

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: >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**

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.

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