

## **SAFETY DATA SHEETS**

**This SDS packet was issued with item:**

073782570

**The safety data sheets (SDS) in this packet apply to one or more components included in the items listed below. Items listed below may require one or more SDS. Please refer to invoice for specific item number(s).**

073782554 073782562 073782620

# Safety Data Sheet „Non Dangerous Substances“

In accordance with the Dangerous Substances Act of 1<sup>st</sup> November 1993 (91/155/EWG) EU Safety Data Sheets are provided for dangerous substances and preparations. The product mentioned herein is a non dangerous substance. The provision of the data is not based on the guidelines 91/155/EWG and is solely for informative purposes.

Date of issue: 28.09.2007

Supersedes version of: 06.09.2005

## 1. Product and Company Information

1.1	Common name:	Root canal filling material
	Commercial name:	<b>GuttaFlow<sup>®</sup></b>
1.2	Manufacturer:	Coltène/Whaledent GmbH + Co. KG Raiffeisenstr. 30 D-89129 Langenau / Germany Telefon: ++49-7345-805-0 Telefax: ++49-7345-805-201

## 2. Composition and Information on Ingredients

2.1	Components:	Polydimethylpolymethylhydrogensiloxane Silicone oil Paraffin oil Zirconium dioxide Platin catalyst Guttapercha Zinc oxide Barium sulfate Nano silver
	Chemical description:	None
2.2	Hazardous constituents:	None

## 3. Possible Hazards

3.1	Hazards identification:	Not applicable
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## 4. First Aid Measures

4.1	General instructions:	
4.2	Inhalation:	
4.3	Skin contact:	Rinse with plenty of H <sub>2</sub> O and soap
4.4	Eye contact:	Rinse with plenty of H <sub>2</sub> O and consult a doctor
4.5	Ingestion:	Seek medical advice immediately
4.6	Instructions to the Doctor:	

## 5. Fire and Explosion Data

5.1	Recommended fire fighting media:	CO <sub>2</sub> , H <sub>2</sub> O
5.2	Proscribed fire fighting media:	None
5.3	Dangerous products of combustion:	None
5.4	Special protective gear:	None
5.5	Additional instructions:	None

## Safety Data Sheet „Non Dangerous Substances“

### 6. Accidental Release Measures

6.1	Personal safety measures:	None
6.2	Environmental safety measures:	No negative ecological effects known
6.3	Clean-up procedure:	Wipe out with absorbent material
6.4	Additional instructions:	None

### 7. Storage and Handling

7.1	Handling:	For professional dental use only
7.2	Storage:	Avoid direct sunlight. Store in a cool place, store away from food.

### 8. Exposure Controls / Personal Protection

8.1	Engineering controls:	None
8.2	Components with specific tolerances:	Contains no relevant quantities of components with limits of values to be supervised at the workplace.
8.3	Personal protection:	Normal hygienic measures

### 9. Physical and Chemical Properties

9.1	Form:	Paste
	Color:	Dark Pink /Orange
	Odour:	Odorless
9.2	Volatility:	Not applicable for prescribed use
9.3	Melting point:	Not applicable
9.4	Auto-ignition temperature:	Not applicable
9.5	Danger of explosion:	Not applicable
9.6	Flash point:	Not applicable
9.7	Density at 20 °C:	1,80 g/m <sup>3</sup>
9.8	Solubility in water at 20 °C:	Slightly soluble in toluene or petrol ether
9.9	pH:	Neutral
9.10	Viscosity:	Ca. 30 Pas
9.11	Critical temperature:	Not applicable
9.12	Thermal decomposition:	Not applicable
9.13	Additional information:	None

### 10. Stability and Reactivity Data

10.1	Conditions to avoid:	Little formation of hydrogen by contact with acids, bases, alcohols, powdered metals and metal oxides.
10.2	Substances to avoid:	
10.3	Dangerous decomposition products:	
10.4	Additional information:	None

## Safety Data Sheet „Non Dangerous Substances“

### 11. Toxicological Information

11.1	Acute toxicity:	No toxic characteristics known for the whole product
11.2	Chronic toxicity:	None

### 12. Ecological Information

12.1	Information for elimination:	
12.2	Behaviour in environmental compartments:	
12.3	Ecotoxicity:	None
12.4	Additional ecological Information:	Causes no damage as far as known

### 13. Disposal Considerations

13.1	Product:	Use proper landfill disposal or incineration in accordance with local, state and federal regulations.
13.2	Packing:	Consult regional or local authorities.

### 14. Transport Information

	Dangerous goods:	No dangerous goods according to regulations. Store away from food, acids and bases.
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### 15. Regulations

15.1	Marking:	No classification necessary
15.2	National regulations:	None

### 16. Other Information

		None
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This information is based on our present state knowledge and cannot be considered as warranted quality features in legal sense. Legal regulations have to be considered on personal responsibility.

according to Regulation (EC) No 1907/2006

**GuttaFlow 2**

Revision date: 21.04.2016

Print date: 21.04.2016

Page 1 of 4

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

GuttaFlow 2

**Further trade names**

GuttaFlow 2 FAST

**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**

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

Preparation/mixture without hazards for human health or environment

**2.2. Label elements****Additional advice on labelling**

According to EC directives or the corresponding national regulations the product does not have to be labelled.

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

Polymer preparations and compounds

**SECTION 4: First aid measures****4.1. Description of first aid measures****After contact with skin**

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.

**4.3. Indication of any immediate medical attention and special treatment needed**

No information available.

according to Regulation (EC) No 1907/2006

**GuttaFlow 2**

Revision date: 21.04.2016

Print date: 21.04.2016

Page 2 of 4

**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****6.2. 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 the 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**

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
Odour:	odourless

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

Initial boiling point and boiling range:	>150 °C
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Density (at 23 °C):	1.8 g/cm <sup>3</sup>
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according to Regulation (EC) No 1907/2006

**GuttaFlow 2**

Revision date: 21.04.2016

Print date: 21.04.2016

Page 3 of 4

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**

UV-radiation/sunlight.

**10.5. Incompatible materials**

Acid, alkali, Alcohols

**10.6. Hazardous decomposition products**

Hydrogen.

**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.

**Irritation and corrosivity**

Based on available data, the classification criteria are not met.  
Irritant effect on the skin: (Rabbit)  
Not an irritant.

**Sensitising effects**

Based on available data, the classification criteria are not met.  
Guinea-pig.  
no danger of sensitization.

**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**

No special environmental measures are necessary.

**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.

according to Regulation (EC) No 1907/2006

**GuttaFlow 2**

Revision date: 21.04.2016

Print date: 21.04.2016

Page 4 of 4

**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****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.)*