

## SECTION 1: Identification of the substance/mixture and of the company

### 1.1. Product identifier

Product form: Soft-Core Endodontic Obturator  
 Trade names: Soft-Core Regular, Soft-Core Classic, One-Step Obturator, 360 Fill Obturator, TF Adaptive Obturator, Thermoobturator, Herofill, Obturador Gutapercha EndoGal

### 1.2. Relevant identified uses of the substance or mixture and uses advised against

For filling of prepared root canals following a prescribed heating process.

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

Company name: CMS Dental A/S, Elmevej 8, 7870 Roslev  
 Telephone number: +45 32573000  
 E-mail: info@cmsdental.dk

## SECTION 2: Hazards identification

### 2.1. Classification of the substance or mixture

#### Classification according to regulation (EC) No. 1272/2008 (CLP)

<b>Classification</b>	<u>Hazard Category</u>	<u>Hazard Statement</u>
Physical hazards	None	None
Health hazards	None	None
Environmental hazards	None	None

### 2.2. Label elements

None required

#### 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

#### Hazardous components

<b>Identification</b>		<u>Content</u>
Name	<b>Zinc oxide</b>	<25%
CAS No.	1314-13-2	
EC list No.	215-222-5	
<b>Classification</b>		<u>Hazard Category</u>
Physical hazards	Data not sufficient for classification	
Health hazards	Data not sufficient for classification	
Environmental hazards	Aquatic Acute 1	H400: Very toxic to aquatic life.  H410: Very toxic to aquatic life with long lasting effects.
<b>Labeling</b>		<u>Hazard pictogram</u>
		<u>Hazard statements</u> H410: Very toxic to aquatic life with long lasting effects.
	GHS09: Environment	<u>Precautionary statements</u> P273: Avoid release to the environment.  P391: Collect spillage.

<b>Identification</b>		<u>Content</u>
Name	<b>Renacit</b>	<1%
CAS No.	135-57-9	
EC list No.	205-201-9	
<b>Classification</b>		<u>Hazard Category</u>
Physical hazards	Data not sufficient for classification	
Health hazards	Skin Sens. 1	H317: May cause an allergic skin reaction.
Environmental hazards	Aquatic Chronic 4	H413: May cause long lasting harmful effects to aquatic life.
<b>Labeling</b>		<u>Hazard pictogram</u>
		<u>Hazard statements</u> H317: May cause an allergic skin reaction.
	GHS07: Exclamation mark	<u>Precautionary statements</u> None  H413: May cause long lasting harmful effects to aquatic life.

## SECTION 4: First aid measures

### 4.1. Description of first aid measures

General information: No special measures required

After inhalation: Not applicable

After skin contact: Wash with soap and water

After eye contact: Rinse with water

After swallowing: Not hazardous

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

No further relevant information available

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

No further relevant information available

## SECTION 5: Firefighting measures

### 5.1. Extinguishing media

Use fire extinguishing methods suitable to surrounding conditions

### 5.2. Special hazards arising from the substance or mixture

Emits a fume of rubber and oil, not a hazard

### 5.3. Advice for firefighters

Protective equipment: No special measures required

## SECTION 6: Accidental release measure

### 6.1. Personal precautions, protective equipment and emergency procedures

Not required

### 6.2. Environmental precautions

No special measures required

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

Remove excess material mechanically.

Rinse with water and soap

## SECTION 7: Handling and storage

### 7.1. Precautions for safe handling

For dental use only

The heated gutta percha may cause local irritation to exposed skin or mucosa

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

Storage: Store between 0-30° C in dry conditions

### 7.3. Specific end use(s)

No further relevant information available

## SECTION 8: Exposure controls/personal protection

### 8.1. Control parameters

None

### 8.2. Exposure controls

Hand protection: use single-use gloves

## SECTION 9: Physical and chemical properties

### 9.1. Information on basic physical and chemical properties

#### Appearance

Form: Solid

Gutta percha/pink

Odour cold: None

Odour warm: Rubber and oil

#### Change in condition

Melting point/Melting range: 45° C for gutta percha

Boiling point/Boiling range:

Flash point: > 250° C

Self-igniting: Product is not self-igniting

Danger of explosion: Product does not present an explosion hazard

Solubility in water: < 1%

## SECTION 10: Stability and reactivity

### 10.1. Reactivity

Gutta percha is thermoplastic; a low viscosity is reached at approx. 100° C

### 10.2. Chemical stability

Stable under normal storage and handling conditions

Thermal decomposition / conditions to be avoided: No decomposition if used according to specifications.

### 10.3. Possibility of hazardous reactions

No dangerous reactions known

### 10.4. Conditions to avoid

No further relevant information available

### 10.5. Incompatible materials

No further relevant information available

### 10.6. Hazardous decomposition products

No hazardous decomposition products known

## 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.

#### **Sensitizing 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**

Recommendation: Smaller quantities can be disposed of with household waste

## SECTION 14: Transport 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**

Regulation (EC) No 1907/2006

Regulation (EU)2015/830

**SECTION 16: Other information****16.1 Other information**

This information is based on our present knowledge. However, this shall not constitute a guarantee for any specific product features and shall not establish a legally valid contractual relationship.

**16.2 Revision history**

Version	Date	Approval	Change description
V05.1	22.06.2017	JK	Previous template
v20	28-05-2020	MS/JK	Safety Data Sheet according to requirements in REACH, Article 31 and Commission Regulation (EU)2015/830