

SybronEndo

Material Safety Data Sheet

in accordance with Community Regulation 2006/1907/EC (R.E.A.Ch.)

Revision Date: 02nd May 2009

SECTION 1

Product & Company identification

1.1 Product name

REAL SEAL Root Canal Sealant (CATALYST)

1.2 Uses/Application:

Thermoplastic dental root canal filling material.

1.3 Company (Name, address and info phone number)

ORMCO B.V./SybronEndo

Basicweg, 20

NL 3821 BR AMERSFOORT (NETHERLAND)

00-800-3032-3032

1.4 Emergency phone (according to communitarian directive 99/45/EC, article 17)

+39.081.8508.325 (08.00-17.00, European time, GMT+1)

E-mail address: safety@kerrhawe.com

SECTION 2

Hazard identification

2.1 Hazard classification (according to communitarian directives 67/548/EEC & 99/45/EC)

Harmful; Irritating.

2.2 Other hazard

Risk of serious damage to eyes; Harmful to aquatic organisms.

SECTION 3

Composition/Information on Ingredients

(according to communitarian directives 67/548/EEC, 99/45/EC & 2001/58/EC)

3.1 Hazardous ingredients

HAZARDOUS INGREDIENTS	%	HAZARD SYMBOLS	RISK PHRASES	CAS N.	EINECS N.
Cumene HydroPerOxide (CHPO)	0,1 - 4	O; T; Xn; C; N	7-23-21/22-48/20/22-34-51-53	80-15-9	201-254-7

3.2 Other non-hazardous ingredients

None.

SECTION 4**First aid measures**

- 4.1 Treatment for eye contact: Flush with water for 15 minutes including under eyelids.
- 4.2 Treatment for skin contact: Wash thoroughly with soap and water.
- 4.3 Treatment for inhalation (breathing): Remove to fresh air-get medical attention if discomfort persists.
- 4.4 Treatment for ingestion (swallowing): Rinse mouth out with water—do not introduce vomiting. Seek medical attention.

SECTION 5**Fire-fighting Measures**

- 5.1 Suitable extinguishing media: CO₂, water, dry chemical.
- 5.2 Forbidden extinguishing media: Unknown.
- 5.3 Special fire fighting measures: None. Wear self-contained breathing apparatus.
- 5.4 Unusual fire and explosion hazards: Heat can cause polymerization with rapid release of energy.
- 5.5 Special protection equipment: Sealed overall against liquids and gases.

SECTION 6**Accidental Release Measures**

- 6.1 Personal Precautions: Adopt the same precautions of section 8.
- 6.2 Environmental Precautions: Keep spilled material out of sewers.
- 6.3 Reclaiming Methods: Absorb spills with inert material and collect in a proper container for disposal.

SECTION 7**Handling and Storage** (according to article 5 of communitarian directive 98/24/EC)

- 7.1 Handling Precautions: Keep away from sources of ignition. Adopt precautions listed in section 8.
- 7.2 Precautions in case of Fire and Explosion: None particular.
- 7.3 Storage Conditions: Refrigeration required (2-12°C). Store in a cool, dry place away from heat, light and ignition sources. Over expire date, spontaneous polymerization may occur.
- 7.4 Suggested container(s): The original containers provided by manufacturer.
- 7.5 Indication for Combined Storage: Avoid the contact with reducing and oxidizing agents, peroxides and amines.
- 7.6 Environmental precautions: Avoid contamination of sewers with product.
- 7.7 Other Precautions: Use according to directions and good personal hygiene and safety practices.

SECTION 8	
Exposure controls/personal protection	
8.1 Exposure Limits:	<u>TWA/TLV</u> : None
<u>8.2 Exposure control measures</u>	
8.2.1 Precautionary Measures: (according to communitarian directives 89/686/EEC & article 4 of 98/24/EC)	
Ventilation:	<u>Local Exhaust Ventilation</u> : Good general ventilation should be sufficient to control airborne levels of vapours released by uncured material. <u>Special Ventilation</u> : None required. <u>Mechanical (General) Ventilation</u> : Good general ventilation recommended. <u>Other Ventilation</u> : None required.
Respiratory Protection:	Avoid prolonged or excessive breathing of vapours of uncured material.
Hands Protection:	Impervious rubber gloves recommended when contacting uncured material.
Eyes Protection:	Safety glasses.
Skin Protection:	Handle in accordance with good personal hygiene and safety practices. These practices include avoiding unnecessary exposure to uncured material.
Other Protective Equipments:	It would be better use a lab coat.
<i>Measures listed in this paragraph are to be considered as indications and NOT prescriptions (89/656/EEC)</i>	
8.2.2 Environment exposure control measures Not Applicable.	

SECTION 9	
Physical and Chemical Properties	
<u>9.1 General information</u>	
<u>Appearance</u> : White paste.	<u>Odour</u> : Ester-like odour.
<u>9.2 Information related to health, safety and environment</u>	
<u>pH</u> : Not applicable (N/A)	<u>Relative density</u> : Not available
<u>Boiling point</u> : Not applicable	<u>Specific gravity</u> : 1,8 g/ml
<u>Flash point</u> : Not applicable	<u>Solubility</u> : Slightly soluble in water
<u>Flammability</u> : Not applicable.	<u>Partition coefficient n-octanol/water</u> : N/A
<u>Lower Explosivity Limit (L.E.L.)</u> : N/A	<u>Viscosity</u> : Not applicable
<u>Upper Explosivity Limit (U.E.L.)</u> : N/A	<u>Vapor density (air = 1)</u> : N/A
<u>Oxidizing properties</u> : None	<u>Evaporation rate (n-butane = 1)</u> : Not applicable
<u>Vapour pressure</u> : Not applicable	<u>Melting point</u> : Not determined (N/D)
<u>9.3 Other information (according to communitarian directive 94/9/EC)</u> :	
<u>Miscibility</u> : N/D.	<u>Conducibility</u> : N/D
<u>Solubility in Lipids</u> : Not available	<u>Gases Group</u> : N/A

SECTION 10

Stability and Reactivity

Stability: Stable if stored as directed.

10.1 Conditions to avoid: Heat, light, aging and contamination.

10.2 Materials to avoid (incompatibility): Reducing and oxidizing agents, peroxides and amines.

10.3 Hazardous decomposition products: Oxides of Carbon.

Other precautions:

Hazardous Polymerization Products: Not determined

Safety significance in case of change in physical appearance: None known

Stabilizers: Not applicable

SECTION 11

Toxicological Information

CMR effects (Carcinogenicity, Mutagenicity and toxicity for reproduction):

None.

Effects and hazards of eye contact: May cause irritation and damage if not removed promptly.

Effects and hazards of skin contact: Prolonged or repeated exposure to uncured material may cause irritation or skin rash especially in sensitive individuals.

Effects and hazards of Inhalation (Breathing): Prolonged or excessive inhalation may cause respiratory tract irritation.

Effects and hazards of Ingestion (Swallowing): Uncured material may be harmful or fatal if swallowed.

Effects for prolonged Exposure: Not applicable.

Toxic-kinetic effects: Unknown.

Effects on metabolism: Unknown.

Toxicological data for ingredients:

CHPO	LD ₅₀ (oral rat)	382 mg/Kg
	LD ₅₀ (skin rat)	500 mg/Kg
	LC ₅₀ (inhalation mouse/4 hours)	200 ppm

SECTION 12**Ecological Information**

This product has not known ecological hazardous effects.

12.1 Eco-toxicity: Not available

12.2 Mobility: Not available

12.3 Persistence and degradability: Not available

12.4 Bioaccumulative potential: Not available

12.5 Results of PBT (Persistent Bio-Toxicity) assessment: Not available

12.6 Other adverse effects: Not available

Aquatic toxicity data for ingredients:

None.

SECTION 13**Disposal considerations**

Dispose of in accordance of local regulations.

SECTION 14**Transport information**

14.1 Sea transportation (IMDG)

The product is not regulated.

14.2 Air transportation (ICAO/IATA)

The product is not regulated.

14.3 Transportation by Road/Railway (RID/ADR)

The product is not regulated.

SECTION 15 (Classification according to communitarian directives 67/548/EEC & 99/45/EC)

Regulatory information

Hazard labelling not required.

This product is an exempted medical device (directive 1999/45/EC, article 1, paragraph 5g).

SECTION 16**Other information**16.1 Risk phrases of all ingredients

- 7 May cause fire.
 21/22 Harmful in contact with the skin and if swallowed.
 23 Toxic by inhalation.
 34 Causes burns.
 48/20/22 Harmful: danger of serious damage to health by prolonged exposure through inhalation and if swallowed.
 51/53 Toxic to aquatic organisms, may cause long term adverse effects in the aquatic environment.

16.1.1 Safety phrases of all ingredients

- 1/2 Keep locked up and out of the reach of children.
 3/7 Keep container tightly closed in a cool place.
 36/37/39 Wear suitable protective clothing, gloves and eye/face protection.
 45 In case of accident or if you feel unwell, seek medical advice immediately (show the label where possible).

16.2 Sources of key data used to compile the Safety Data Sheet:

European Chemicals Bureau (ECB – www.ecb.jrc.it)

European chemical Substances Information System (ESIS - www.ecb.jrc.it/esis)

A.C.G.I.H. (www.acgih.org)

N.I.O.S.H. (www.cdc.gov/niosh/)

O.S.H.A. (www.osha.gov/)

U.E. (www.europa.eu/index_it.htm)

I.A.R.C. (www.iarc.fr/)

N.T.P. (www.ntp.niehs.nih.gov)

European Community Directives:

67/548/EEC:	Classification, packaging and labelling of dangerous substances.
99/45/EC:	Directive concerning the approximation of the laws, regulations and administrative provisions of the Member States relating to the classification, packaging and labelling of dangerous preparations.
2001/58/EC:	Second amendment of directive 91/155/EEC for the definition of a detailed arrangement of specific information relating to dangerous preparations (art. 14 of 99/45/EC) and substances (art. 27 of 67/548/EEC).
89/656/EEC:	Directive on the minimum health and safety requirements for the use by workers of personal protective equipment at the workplace (third individual directive within the meaning of Article 16 (1) of Directive 89/391/EEC).
89/686/EEC:	Approximation of the laws of the Member States relating to personal protective equipment.
94/9/EC:	Approximation of the laws of the Member States concerning equipment and protective systems intended for use in potentially explosive atmospheres
98/24/EC:	Protection of the health and safety of workers from the risks related to chemical agents at work.

Document modification history: First version in compliance of Community Regulation 2006/1907/EC
(R.E.A.Ch.)

CAUTION: PRODUCT FOR PROFESSIONAL USE

The information on this Safety Sheet is based on presently available data and to our best knowledge for the correct handling of the product under normal conditions. Any use of this product in any way not indicated on this Sheet or the use of this product together with any other process/procedure will be exclusively under the user's responsibility. This document does not constitute explicit or implicit warranty of product quality or fitness for a particular purpose.