

# SybronEndo

## Material Safety Data Sheet

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

Revision Date: 02<sup>nd</sup> May 2009

### SECTION 1

#### Product & Company identification

1.1 Product name

**REAL SEAL PRIMER**

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](mailto:safety@kerrhawe.com)

### SECTION 2

#### Hazard identification

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

Irritating; Sensitizing.

2.2 Other hazard

None.

### 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.
HydroxyEthylMethAcrylate (HEMA)	60-75	Xi	36/38-43	868-77-9	212-782-2
2-ethyl-2-[[[(1-oxoallyl)oxy]methyl]-1,3-propanediyl diacrylate	1-10	Xi	36/38-43	15625-89-5	239-701-3

3.2 Other non-hazardous ingredients

Initiators and inhibitors of polymerization.

**SECTION 4****First aid measures**

- 4.1 Treatment for eye contact: Flush with water for 15-30 minutes with copius amounts of water, including under eyelids. Consult an ophthalmologist if discomforts persist.
- 4.2 Treatment for skin contact: Remove with copius amounts of water. Consult a physician if irritation occurs.
- 4.3 Treatment for inhalation (breathing): Move to fresh air and seek physician assistance.
- 4.4 Treatment for ingestion (swallowing): Consult a physician immediately. Rinse oral cavity with water and exude or expectorate. Induce vomiting. Seek fresh air.

**SECTION 5****Fire-fighting Measures**

- 5.1 Suitable extinguishing media: Carbon dioxide, dry chemical powder and appropriate chemical foam.
- 5.2 Forbidden extinguishing media: Unknown.
- 5.3 Special fire fighting measures: None. Wear self-contained breathing apparatus and full protective gear. Use water spray to cool containers.
- 5.4 Unusual fire and explosion hazards: Unknown.
- 5.5 Special protection equipment: Sealed overall against liquids and gases.

**SECTION 6****Accidental Release Measures**

- 6.1 Personal Precautions: Adopt same precautions of section 8.
- 6.2 Environmental Precautions: Keep spilled material out of sewers.
- 6.3 Reclaiming Methods: Collect as much as possible in a clean container for (preferably) reuse or disposal. Absorb the remainder with inert material.

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

7.1 Handling Precautions: Wear protective goggles and gloves listed in section 8.

7.2 Precautions in case of Fire and Explosion: None particular.

7.3 Storage Conditions: Store in a cool and dry place.

7.4 Suggested container(s): The original containers provided by manufacturer.

7.5 Indication for Combined Storage: Avoid the contact with oxidizing agents, acids, alkalies, salts, metals, amines and peroxide catalysts.

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. Apply the product wetting a brush tip and using an intraoral rubber dam.

**SECTION 8****Exposure controls/personal protection**

8.1 Exposure Limits: TWA/TLV : None

8.2 Exposure control measures8.2.1 Precautionary Measures:

(according to communitarian directives 89/686/EEC & article 4 of 98/24/EC)

Ventilation:	<u>Local Exhaust Ventilation:</u> Good general ventilation recommended. <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.
Other Protective Equipments:	Lab coat or other protective clothing.

*Measures listed in this paragraph are to be considered as indications and NOT prescriptions (89/656/EEC)*

8.2.2 Environment exposure control measures

Not Applicable.

**SECTION 9****Physical and Chemical Properties**9.1 General information

Appearance: Slight yellow liquid.

Odour: Ester-like odour.

<i>9.2 Information related to health, safety and environment</i>	
<u>pH</u> : ~ 1,5	<u>Relative density</u> : Not available
<u>Boiling point</u> : Not applicable (N/A)	<u>Specific gravity</u> : ~ 1,0 g/ml
<u>Flash point</u> : Not applicable	<u>Solubility</u> : 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)
<i>9.3 Other information (according to communitarian directive 94/9/EC):</i>	
<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): Strong bases, finely powdered metals.

10.3 Hazardous decomposition products: Smoke, Carbon monoxide.

Other precautions:

Hazardous Polymerization Products: Unknown.

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

Stabilizers: The product is stabilized with non-hazardous polymerization inhibitors.

**SECTION 11****Toxicological Information**

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

None.

Effects and hazards of eye contact: May cause severe irritation.

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): Ingestion of large amounts may cause severe damages to mucous membranes and may be harmful.

Effects for prolonged Exposure: May be sensitizing by skin contact.

Toxic-kinetic effects: Unknown.

Effects on metabolism: Unknown.

Toxicological data for ingredients:

<b>HEMA</b>	LD <sub>50</sub> (oral rat)	> 5000 mg/Kg
	LD <sub>50</sub> (skin rabbit)	> 3000 mg/Kg
	LC <sub>50</sub> (inhalation rat/3 weeks)	> 0,5 mg/Kg

**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:

<b>HEMA</b> Easily biodegradable: 84% (OCSE 301D, closed bottle test, 28 days)	LC <sub>50</sub> (Fish, Oryzias Latipes)	> 100 mg/l (OCSE 203, 96h)
	LC <sub>50</sub> (Fish, Oryzias Latipes)	> 100 mg/l (OCSE 204, 14 days)
	NOEC (Daphnia magna)	24,1 mg/l (OCSE 202/2, 21 days)
	EC <sub>50</sub> (Daphnia magna)	380 mg/l (OCSE 202/1, 48h)
	EC <sub>50</sub> (Selenastrum Copricornutum)	345 mg/l (OCSE 201, 72h)
	EC <sub>50</sub> (Pseudomonas fluorescens)	> 3000 mg/l (DEV LB, 16h)

**SECTION 13****Disposal considerations**

Unpolymerized (uncured) material may be hazardous waste. Dispose of in accordance with 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

- 36/38 Irritating to eyes and skin.  
43 May cause sensitisation by skin.

16.1.1 Safety phrases of all ingredients

- 2 Keep out of the reach of children.  
26 In case of contact with eyes, rinse immediately with plenty of water and seek medical advice.  
28 After contact with skin, wash immediately with plenty of water.

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

European Chemicals Bureau (ECB – [www.ecb.jrc.it](http://www.ecb.jrc.it))  
 European chemical Substances Information System (ESIS - [www.ecb.jrc.it/esis](http://www.ecb.jrc.it/esis))  
 A.C.G.I.H. ([www.acgih.org](http://www.acgih.org))  
 N.I.O.S.H. ([www.cdc.gov/niosh/](http://www.cdc.gov/niosh/))  
 O.S.H.A. ([www.osha.gov/](http://www.osha.gov/))  
 U.E. ([www.europa.eu/index\\_it.htm](http://www.europa.eu/index_it.htm))  
 I.A.R.C. ([www.iarc.fr/](http://www.iarc.fr/))  
 N.T.P. ([www.ntp.niehs.nih.gov](http://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.**