

MATERIAL SAFETY DATA SHEET

Page 1 of 1
July 27, 2004

1. Chemical Product and Contact Information

Product Name: Real Seal Thinning Resin

Date of Issue: 09/12/03
Revision Date: 01/21/04
Distributor Identification: Omco Corporation
1717 West Collins Avenue
Orange, CA 92667
1-800-854-1741

Emergency Information Chemtrec: 800-424-9300
Chemtrec International: 202-483-7616

2. Composition/Information on Ingredients

Chemical characteristics: EBPADMA resins with ph oto initiator, amines, stabilizer and Red #40.
Description:
Hazardous components: None known.
CAS No: 109-57-9
Name: thiosinamine
% R-classification: unknown

3. Hazard Identification

Risk Identification: None known.
Special risks for human beings and environment: None known.
Classification: Not hazardous. Those people known to be allergic to methacrylate resins should avoid the use of this product.

4. First Aid Measures

General information: Unknown.
After skin contact: Wash with plenty of soap and water.
After eye contact: Rinse with plenty of water, and contact an ophthalmologist.
After swallowing: Seek medical advice immediately.

5. Fire Fighting Measures

Extinguishing media: CO₂, water, dry chemical.
Protective equipment: Unknown.

6. Accidental Release Measures

Personal precautions: Wear protective equipment. Avoid direct contact.
Environmental precautions: Unknown.
Methods for cleaning up: Absorb with inert material. Collect in closed containers and dispose of as recommended.
Additional information: Incineration according to Federal, state, and local regulations.

7. Handling and Storage

Handling: Always handle with care.
Handling procedures: Unknown.
Recommendation for fire and explosion protection: Unknown.
Storage: Store away from direct light. Store the dual cure activator at 4°C.
Requirements at storerooms and containers: Store in a cool, dry place at or below room temperature.
Additional storage conditions: Not applicable.
Storage classification: Unknown.
VBF classification: Unknown.

8. Exposure Controls/Personal Protection

Additional information for technical plans:
Components with limits of values to be supervised at the workplace:
CAS No. Name % Air Value Unit
The product contains no relevant quantities of components with limits of values to be supervised at the workplace.
Additional information: Protective gloves and goggles are recommended.
Personal protective equipment: Follow normal hygienic measures.
General measure of protection and hygiene:
Respiration: Not necessary.
Hands: Protective gloves.
Eyes: OSHA approved goggles.

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9. Physical and Chemical Properties

Appearance: Form: Liquid.
Color: reddish.
Odor: Esterlike.

Information on change in the physical state

Melting point/melting range:

Not applicable.

Boiling point/boiling range:

4.80°F.

Flash point:

Not applicable.

Autoignition temperature:

Not applicable.

Danger of explosion:

Not likely.

Density:

1.1

Vapor pressure:

70°F.

Viscosity:

Not applicable.

pH:

Not applicable.

Solubility in/miscibility with:

Water:

Slightly.

Content of solvents:

None.

Organic solvents:

None.

Content of solids:

< 5%.

10. Stability and Reactivity

Incompatibility with other substances: Strong oxidizing and reducing agents, heat, direct sun-light.

Hazardous decomposition products: Unknown.

11. Toxicological Information

Carcinogenicity:

None of the components of this material are listed by IARC, NTP, OSHA, or AICGH as carcinogens.

TLV:

Oral rat 5.2 ml/kg.

Primary Routes of entry:

Inhalation, skin, and eyes.

12. Ecological Information

Unknown.

13. Disposal Considerations

Disposal consideration:

Dispose of in accordance with Federal, State, and local regulations.

14. Transport Information

Not classified as dangerous goods.

15. Regulatory information

Unknown.

16. Other Information

Revision Summary:

The following revision was made on July 27, 2004: the Note in Section 16 was added.

Notes: This MSDS was prepared in accordance with the requirements of the OSHA Hazard Communication Standard (29 CFR 1910.1200) and is to be used only for this product. The information contained in this MSDS is, to the best of our knowledge, believed to be accurate.

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 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

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-(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 ophtamologist 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:

HEMA	LD ₅₀ (oral rat)	> 5000 mg/Kg
	LD ₅₀ (skin rabbit)	> 3000 mg/Kg
	LC ₅₀ (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:

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

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.

SybronEndo

Material Safety Data Sheet

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

Revision Date: 28th February 2012

SECTION 1

Product & Company identification

1.1 Product name

REAL SEAL Root Canal Sealant (BASE)

1.2 Uses/Application:

Dental root canal sealer and 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)

None.

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.
None	N/A	N/A	N/A	N/A	N/A

3.2 Other non-hazardous ingredients

Calcium hydroxide, **Ca(OH)₂** and Barium Sulphate, **BaSO₄**.

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.

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:	TWA/TLV (mg/m ³): Ca(OH)₂: 5 BaSO₄: 10 (Italy), 0,5 (Denmark), 4 (U.K.)
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8.2 Exposure control measures**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.

*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**

<u>Appearance</u> : Pink paste.	<u>Odour</u> : Ester-like odour.
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9.2 Information related to health, safety and environment

<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)

9.3 Other information (according to communitarian directive 94/9/EC):

<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:

Ca(OH) ₂	LD ₅₀ (oral rat)	7340 mg/Kg
	LD ₅₀ (oral mouse)	7300 mg/Kg
(Irritation data RTECS)	LC ₅₀ (rabbit eyes)	10 mg

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

None.

16.1.1 Safety phrases of all ingredients

None.

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:02nd May 2009 First version in compliance of Community Regulation 2006/1907/EC (R.E.A.Ch.)28th February 2012 Second revision: Uses/applications description, in paragraph 1.2, have been corrected.

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.

SybronEndo

Material Safety Data Sheet

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

Revision Date: 28th February 2012

SECTION 1

Product & Company identification

1.1 Product name

REAL SEAL Root Canal Sealant (CATALYST)

1.2 Uses/Application:

Dental root canal sealer and 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:**

TWA/TLV: None

8.2 Exposure control measures**8.2.1 Precautionary Measures:***(according to communitarian directives 89/686/EEC & article 4 of 98/24/EC)***Ventilation:**Local Exhaust Ventilation: Good general ventilation should be sufficient to control airborne levels of vapours released by uncured material.Special Ventilation: None required.Mechanical (General) Ventilation: Good general ventilation recommended.Other Ventilation: 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.

*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: White paste.Odour: Ester-like odour.**9.2 Information related to health, safety and environment**pH: Not applicable (N/A)Relative density: Not availableBoiling point: Not applicableSpecific gravity: 1,8 g/mlFlash point: Not applicableSolubility: Slightly soluble in waterFlammability: Not applicable.Partition coefficient n-octanol/water: N/ALower Explosivity Limit (L.E.L.): N/AViscosity: Not applicableUpper Explosivity Limit (U.E.L.): N/AVapor density (air = 1): N/AOxidizing properties: NoneEvaporation rate (n-butane = 1): Not applicableVapour pressure: Not applicableMelting point: Not determined (N/D)**9.3 Other information (according to communitarian directive 94/9/EC):**Miscibility: N/D.Conducibility: N/DSolubility in Lipids: Not availableGases Group: 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:

02 nd May 2009	First version in compliance of Community Regulation 2006/1907/EC (R.E.A.Ch.)
28 th February 2012	Second revision: Uses/applications description, in paragraph 1.2, have been corrected.

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.

SybronEndo

Material Safety Data Sheet

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

Revision Date: 28th February 2012

SECTION 1

Product & Company identification

1.1 Product name

REAL SEAL Root Canal Sealant Self-Etch (CATALYST)

1.2 Uses/Application:

Dental root canal sealer and 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)

Sensitizing.

2.2 Other hazard

Mildly irritating.

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)	10-15	Xi	36/38-43	868-77-9	212-782-2
Benzoyl PerOxide (BPO)	< 1	E; O; Xi	3-7-36-43	94-36-0	202-327-6

3.2 Other non-hazardous ingredients

None.

SECTION 4**First aid measures**

- 4.1 Treatment for eye contact: Flush with water for at least 15 minutes including under eyelids.
- 4.2 Treatment for skin contact: Wash thoroughly with soap and water. If irritation persists, consult a physician.
- 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.

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:****TWA/TLV:** (BPO): 5 mg/m³;**8.2 Exposure control measures****8.2.1 Precautionary Measures:***(according to communitarian directives 89/686/EEC & article 4 of 98/24/EC)***Ventilation:****Local Exhaust Ventilation:** Good general ventilation should be sufficient to control airborne levels of vapours released by uncured material.**Special Ventilation:** None required.**Mechanical (General) Ventilation:** Good general ventilation recommended.**Other Ventilation:** 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.

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

Toxic-kinetic effects: Unknown.

Effects on metabolism: Unknown.

Toxicological data for ingredients:

HEMA	LD ₅₀ (oral rat)	> 5000 mg/Kg
	LD ₅₀ (skin rabbit)	> 3000 mg/Kg
	LC ₅₀ (inhalation rat/3 weeks)	> 0,5 mg/Kg
BPO	LD ₅₀ (oral rat)	> 5000 mg/Kg
	LC ₅₀ (inhalation rat/4hrs)	> 24,3 mg/l

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:

HEMA	LC ₅₀ (Fish, Oryzias Latipes)	> 100 mg/l (OCSE 203, 96h)
Easily biodegradable: 84% (OCSE 301D, closed bottle test, 28 days)	LC ₅₀ (Fish, Oryzias Latipes)	> 100 mg/l (OCSE 204, 14 days)
	NOEC (Daphnia magna)	24,1 mg/l (OCSE 202/2, 21 days)
	EC ₅₀ (Daphnia magna)	380 mg/l (OCSE 202/1, 48h)
	EC ₅₀ (Selenastrum Copricornutum)	345 mg/l (OCSE 201, 72h)
	EC ₅₀ (Pseudomonas fluorescens)	> 3000 mg/l (DEV LB, 16h)
BPO	LC ₅₀ (Fishes, acute toxicity)	2,0 mg/l (96 hours)
	EC ₅₀ (Daphnia)	2,91 mg/l (48 hours)
	EC ₅₀ (Bacteria, breathing inhibition of active muds)	35 mg/l

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

- 3 Extreme risk of explosion by shock, friction, fire or other sources of ignition
- 7 May cause fire.
- 36/38 Irritating to eyes and skin.
- 43 May cause sensitisation by skin.

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.
- 14 Keep away from reducing agents (i.e. amines), acids, alkali and chemicals containing heavy metal.
- 36/37/39 Wear suitable protective clothing, gloves and eye/face protection.

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:

14 th May 2009	First version in compliance of Community Regulation 2006/1907/EC (R.E.A.Ch.)
28 th February 2012	Second revision: Uses/applications description, in paragraph 1.2, have been corrected.

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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.