

SybronEndo

Material Safety Data Sheet

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

Revision Date: 19th May 2009

SECTION 1

Product & Company identification

1.1 Product name

REAL SEAL POINTS/PELLETS

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)

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

Barium Sulphate, **BaSO₄**.

SECTION 4**First aid measures**

- 4.1 Treatment for eye contact: Rinse with plenty of water and consult an ophthalmologist.
- 4.2 Treatment for skin contact: Wash with plenty of water and soap.
- 4.3 Treatment for inhalation (breathing): Not applicable due to physical status of product.
- 4.4 Treatment for ingestion (swallowing): Seek medical attention.

SECTION 5**Fire-fighting Measures**

- 5.1 Suitable extinguishing media: CO₂, water.
- 5.2 Forbidden extinguishing media: Unknown.
- 5.3 Special fire fighting measures: None particular.
- 5.4 Unusual fire and explosion hazards: Unknown.
- 5.5 Special protection equipment: None particular.

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: Wipe up with absorbent material.

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

- 7.1 Handling Precautions: None particular. Keep away from food stuffs.
- 7.2 Precautions in case of Fire and Explosion: None particular.
- 7.3 Storage Conditions: Store in a dry place.
- 7.4 Suggested container(s): The original containers provided by manufacturer.
- 7.5 Indication for Combined Storage: Avoid contact with acids, bases, alcohols and strong oxidizing agents.
- 7.6 Environmental precautions: None.
- 7.7 Other Precautions: Use according to directions and good personal hygiene and safety practices.

SECTION 8	
Exposure controls/personal protection	
<i>8.1 Exposure Limits:</i>	<u>TWA/TLV (BaSO₄)</u> : 10 mg/m ³ (Italy), 0,5 mg/m ³ (Denmark), 4 mg/m ³ (U.K.)
<i>8.2 Exposure control measures</i>	
<i>8.2.1 Precautionary Measures:</i> (according to communitarian directives 89/686/EEC & article 4 of 98/24/EC)	
Ventilation:	<u>Local Exhaust Ventilation</u> : Adequate. <u>Special Ventilation</u> : None required. <u>Mechanical (General) Ventilation</u> : General. <u>Other Ventilation</u> : None required.
Respiratory Protection:	None particular.
Hands Protection:	Impervious rubber gloves.
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>	
<i>8.2.2 Environment exposure control measures</i> Not Applicable.	

SECTION 9	
Physical and Chemical Properties	
<i>9.1 General information</i>	
<u>Appearance</u> : Light pink solid cones (various sizes).	<u>Odour</u> : Odourless.
<i>9.2 Information related to health, safety and environment</i>	
<u>pH</u> : Not applicable (N/A)	<u>Relative density</u> : Not available
<u>Boiling point</u> : Not applicable	<u>Specific gravity</u> : 2,0 g/ml @ 20°C
<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> : 70-80°C
<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: Excessive heat and humidity.

10.2 Materials to avoid (incompatibility): Acids, bases, alcohols and strong oxidizing agents.

10.3 Hazardous decomposition products: Hydrocarbons, Sulphur Oxides.

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 if not removed promptly.

Effects and hazards of skin contact: No effect adverse.

Effects and hazards of Inhalation (Breathing): Due to physical form, inhalation of this product is an unlikely event.

Effects and hazards of Ingestion (Swallowing): Not applicable.

Effects for prolonged Exposure: Not applicable.

Toxic-kinetic effects: Unknown.

Effects on metabolism: Unknown.

Toxicological data for ingredients:

None.

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

CAUTION: PRODUCT FOR PROFESSIONAL USE

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