

SybronEndo

Material Safety Data Sheet

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

Revision Date: 08th February 2008

SECTION 1

Product & Company identification

1.1 Product name

PULP CANAL SEALER E.W.T. POWDER

1.2 Uses/Application:

Dental root canal sealer.

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)

Dangerous for environment.

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.
Zinc Oxide (ZnO)	40-50	N	50-53	1314-13-2	215-222-5

3.2 Other non-hazardous ingredients

Rosin (oligomers) and Silver powder, metallic.

SECTION 4**First aid measures**

- 4.1 Treatment for eye contact: Flush with water for at least 15 minutes.
- 4.2 Treatment for skin contact: Wash with soap and water.
- 4.3 Treatment for inhalation (breathing): Remove to fresh air.
- 4.4 Treatment for ingestion (swallowing): Consult a physician.

SECTION 5**Fire-fighting Measures**

- 5.1 Suitable extinguishing media: Not applicable.
- 5.2 Forbidden extinguishing media: Not applicable.
- 5.3 Special fire fighting measures: Not applicable.
- 5.4 Unusual fire and explosion hazards: Not applicable.
- 5.5 Special protection equipment: Not applicable.

SECTION 6**Accidental Release Measures**

- 6.1 Personal Precautions: Adopt precautions listed in following sections (VII and VIII).
- 6.2 Environmental Precautions: Do not allow product reaching rivers or sewers and avoid soil contamination. Avoid dust formation which could be spread by wind.
- 6.3 Reclaiming Methods: Sweep up/ vacuum clean spilled product.

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

- 7.1 Handling Precautions: Adopt precautions listed in following sections (VII and VIII).
- 7.2 Precautions in case of Fire and Explosion: Not applicable.
- 7.3 Storage Conditions: Store at ambient temperature.
- 7.4 Suggested container(s): The original containers provided by manufacturer.
- 7.5 Indication for Combined Storage: Avoid contact with acids .
- 7.6 Environmental precautions: Store in a dry place far from sewers and water.
- 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>	1) ZnO <u>TWA</u> : 0,6 ppm (2 mg/m ³); <u>TLV</u> : 3 ppm (10 mg/m ³) 2) Silver <u>TWA</u> : 0,02 ppm/ (0,1 mg/m ³)
<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> : Recommended. <u>Special Ventilation</u> : None. <u>Mechanical (General) Ventilation</u> : None. <u>Other Ventilation</u> : None.
Respiratory Protection:	If dust exceeds exposure limits, use approved respirator.
Hands Protection:	May be used protective gloves.
Eyes Protection:	Safety glasses or goggles optional.
Skin Protection:	Handle in accordance with good personal hygiene and safety practices.
Other Protective Equipments:	It would be better use a lab coat.
<i>Measures listed in this paragraph are to be consider as indications and NOT as 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> : Beige powder.	<u>Odour</u> : Odorless.
<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> : Not established
<u>Flash point</u> : Not applicable	<u>Solubility</u> : Insoluble
<u>Flammability</u> : Not flammable.	<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> : 960°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.

10.1 Conditions to avoid: Avoid contact with strong acids.

10.2 Materials to avoid (incompatibility): Strong acids (Nitric acid).

10.3 Hazardous decomposition products: Nitrous oxide.

Other precautions:

Hazardous Polymerization Products: Will not occur

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

Stabilizers Product is not required to be stabilized.

SECTION 11**Toxicological Information**

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

None.

Effects and hazards of eye contact: May cause irritation.

Effects and hazards of skin contact: May cause irritation. Over a prolonged period of time, the entry of fine particles may produce a local pigmentation.

Effects and hazards of Inhalation (Breathing): May cause irritation to the nasal passages.

Effects and hazards of Ingestion (Swallowing): May cause gastric pain.

Effects for prolonged Exposure: Not determined.

Toxic-kinetic effects: Unknown.

Effects on metabolism: Unknown.

Toxicological data for ingredients:

ZnO		
(Acute toxicity):	LD ₅₀ (oral mouse)	7950 mg/Kg
	LD ₅₀ (skin rat)	> 2000 mg/Kg
	LD _{L0} (oral human)	500 mg/Kg
	LC ₅₀ (inhalation rat/4hrs)	> 5700 mg/m ³ (4 hrs)

SECTION 12**Ecological Information**

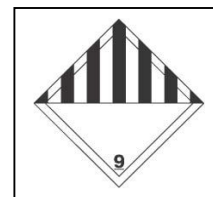
Refer to data regarding Zinc Oxide.

12.1 Eco-toxicity: Not available12.2 Mobility: Not available12.3 Persistence and degradability: Not available12.4 Bioaccumulative potential: Not available12.5 Results of PBT (Persistent Bio-Toxicity) assessment: Not available12.6 Other adverse effects: Not availableAquatic toxicity data for ingredients:

ZnO (Acute toxicity):	EC ₅₀ (Daphnia magna)	> 1000 mg/l (48 hrs)
	LC ₅₀ (Oncorhynchus mykiss)	1,1 mg/l (96 hrs)
	LC ₅₀ (Lepomis macrochirus)	> 320 mg/l (96 hrs)
	LC ₅₀ (Pimephales promelas)	2246 mg/l (96 hrs)
	EC ₅₀ (Selenastrum capricornutum)	0,17 mg/l (72 hr; Lisec 1997)

SECTION 13**Disposal considerations**

Dispose of in accordance of local regulations.

SECTION 14**Transport information**14.1 Sea transportation (IMDG)UN number: 3077 Class: 9 Packing group: III EMS-No: F-A, S-FStowage/segregation: Category A; Limited Quantity: 5KgProper shipping name: Environmentally hazardous substance, solid, n.o.s.14.2 Air transportation (ICAO/IATA)UN number: 3077; Class: 9; Packing group: III; Label: 9 (Miscellaneous dangerous substances)Limited Quantity: 30Kg G; Proper shipping name: Environmentally hazardous substance, solid, n.o.s.14.3 Transportation by Road/Railway (RID/ADR)UN number: 3077; Class: 9; Packing group: III (12°C); Hazard identification n°: 90 Label: 9Proper shipping name: Environmentally hazardous substance, solid, n.o.s.Limited Quantity: LQ27 (6Kg/30Kg for combined, 6Kg/20Kg for bandaged trays).

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

50/53 Very toxic to aquatic organisms, may cause long term adverse effects in the aquatic environment.

16.1.1 Safety phrases of all ingredients

60 This material and its container must be disposed of as hazardous waste

61 Avoid release to the environment. Refer to special instructions / safety data sheets

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.C.H.)

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.