

SybronEndo

Material Safety Data Sheet

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

Revision Date: 27th February 2008

SECTION 1

Product & Company identification

1.1 Product name

SEALAPEX CATALYST & SEALAPEX CATALYST EXPRESS

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)

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	None	None	None	None	None

3.2 Other non-hazardous ingredients

The product contains traces of Methyl Salicylate (See also Sections 11 and 16)
and 1-3% of Titanium Dioxide (TiO₂).

SECTION 4**First aid measures**

4.1 Treatment for eye contact: Flush eye with water for at least 15 minutes. If irritation persists, consult a physician.

4.2 Treatment for skin contact: Wash with soap and water.

4.3 Treatment for inhalation (breathing): Inhalation of the material, due to its physical form and the modality of use, should be an unlikely event.

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: None particular.

6.3 Reclaiming Methods: Absorb spill with paper towels and transfer into suitable containers.

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

7.1 Handling Precautions: Use protective clothes listed in Section VIII. Wash after handling.

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

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: Not available.

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. Do not invert caps on tubes as this will cause hardening of material in the tubes.

SECTION 8	
Exposure controls/personal protection	
8.1 Exposure Limits:	<u>TWA/TLV</u> (TiO ₂): 3,1ppm (10mg/m ³)
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> : Not needed. <u>Special Ventilation</u> : None. <u>Mechanical (General) Ventilation</u> : None. <u>Other Ventilation</u> : None.
Respiratory Protection:	None.
Hands Protection:	It's sufficient to use disposable vinyl 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>	
8.2.2 Environment exposure control measures Not Applicable.	

SECTION 9	
Physical and Chemical Properties	
9.1 General information	
<u>Appearance</u> : Off-white paste.	<u>Odour</u> : Typical odour.
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 established	<u>Specific gravity</u> : > 1 g/ml
<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 determined
<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 available
<u>Vapour pressure</u> : Not determined (N/D)	<u>Melting point</u> : N/A
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.

10.1 Conditions to avoid: Unknown.

10.2 Materials to avoid (incompatibility): Unknown.

10.3 Hazardous decomposition products: Unknown.

Other precautions:

Hazardous Polymerization Products: Unknown

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):

The product contains Methyl Salicylate, which has shown evidence of teratogenicity in animals. See also Section 16.

Effects and hazards of eye contact: May be irritant.

Effects and hazards of skin contact: May dry skin.

Effects and hazards of Inhalation (Breathing): None.

Effects and hazards of Ingestion (Swallowing): May cause irritation to the oral-pharyngeal and digestive tracts.

Effects for prolonged Exposure: None.

Toxic-kinetic effects: Unknown.

Effects on metabolism: Unknown.

Toxicological data for ingredients:

Titanium Dioxide	LD ₅₀ (oral rat)	> 20000 mg/Kg
	LD ₅₀ (skin rabbit)	> 10000 mg/Kg
	LC ₅₀ (inhalation rat/4hrs)	> 6,8 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:

Titanium Dioxide	LC ₀ (Leuciscus Idus)	> 1000 mg/l (48 hours)
	EC ₀ (Daphnia magna, crustacea)	> 3 mg/l (30days)
	EC ₀ (Pseudomonas fluorescens)	> 10000 mg/l (24 hours)

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)

Evidence of methyl Salicylate teratogenicity in animals:

-Dangerous Properties of Industrial Materials, Ed. Sax & Lewis, 7th Ed.

-Dushyant Gulati et al., Environmental Health Perspectives Supplements Volume 105, Number S1, February 1997.

-George P. Daston et al., Functional Teratogens of the Rat Kidney, Toxicological Sciences, Volume 11, Number 1 - Pp. 381-400, 1988.

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.

SybronEndo

Material Safety Data Sheet

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

Revision Date: 27th February 2008

SECTION 1

Product & Company identification

1.1 Product name

SEALAPEX BASE & SEALAPEX BASE EXPRESS

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)	5	N	50/53	1314-13-2	215-222-5

3.2 Other non-hazardous ingredients

Rosin, oligomers (NLP)

SECTION 4**First aid measures**

4.1 Treatment for eye contact: Flush immediately with water for at least 15 minutes. If irritation persists, consult a physician.

4.2 Treatment for skin contact: Wash with soap and water.

4.3 Treatment for inhalation (breathing): Inhalation of the material, due to its physical form and the modality of use, should be an unlikely event.

4.4 Treatment for ingestion (swallowing): If large quantities are ingested, administer large quantities of water or milk if available. Do not induce vomiting. Do not administer anything to unconscious persons. 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: None particular.

6.3 Reclaiming Methods: Absorb the product with paper and transfer in suitable containers.

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

7.1 Handling Precautions: Use protective clothes listed in Section VIII. Wash after handling.

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

7.3 Storage Conditions: Store at ambient temperature. High moisture level may cause material hardening.

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

7.5 Indication for Combined Storage: Avoid contact with strong 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. Do not invert caps on tubes as this will cause hardening of material in the tubes.

SECTION 8**Exposure controls/personal protection**

8.1 Exposure Limits:	Zinc Oxide: <u>TWA</u> : 0,6 ppm (2 mg/m ³); <u>TLV</u> : 3 ppm (10 mg/m ³)
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> : Not needed, due to its physical form. <u>Special Ventilation</u> : None. <u>Mechanical (General) Ventilation</u> : None. <u>Other Ventilation</u> : None.
Respiratory Protection:	None.
Hands Protection:	Impervious optional 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>	
8.2.2 Environment exposure control measures Not Applicable.	

SECTION 9**Physical and Chemical Properties**

9.1 General information	
<u>Appearance</u> : White paste.	<u>Odour</u> : Odourless.
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 established	<u>Specific gravity</u> : N/A
<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 determined
<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 available
<u>Vapour pressure</u> : Not determined (N/D)	<u>Melting point</u> : N/A
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.

10.1 Conditions to avoid: Unknown. High moisture level may cause material hardening.

10.2 Materials to avoid (incompatibility): Strong acids.

10.3 Hazardous decomposition products: Unknown.

Other precautions:

Hazardous Polymerization Products: Unknown

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 be irritant.

Effects and hazards of skin contact: May dry skin.

Effects and hazards of Inhalation (Breathing): None.

Effects and hazards of Ingestion (Swallowing): May cause irritation to the oral-pharyngeal and digestive tracts.

Effects for prolonged Exposure: None.

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**

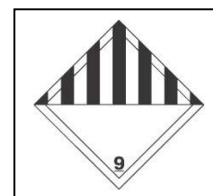
Refer to data regarding Zinc Oxide.

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

51/53 Toxic to aquatic organisms, may cause long term adverse effects in the aquatic environment.
(Refers to the finished product: Sealapex Base)

50/53 Very toxic to aquatic organisms, may cause long term adverse effects in the aquatic environment
(Refers to the ingredient: Zinc Oxide)

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.