SybronEndo

Material **S**afety **D**ata **S**heet
in accordance with Community Regulation 2006/1907/EC (R.E.A.C.H.)

Revision Date: 22th February 2008

SECTION 1
Product & Company identification

1.1 Product name
TUBLI SEAL BASE & TUBLI SEAL 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)	75-85	N	50-53	1314-13-2	215-222-5

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.

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

4.3 Treatment for inhalation (breathing): None.

4.4 Treatment for ingestion (swallowing): Consult a physician.

SECTION 5
Fire-fighting Measures

5.1 Suitable extinguishing media: Carbon dioxide, foam, dry chemical.

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: 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: 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: 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:	For ZnO: TWA: 0,6 ppm (2 mg/m^3); TLV: 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:	Local Exhaust Ventilation: Not necessary. Special Ventilation: None. Mechanical (General) Ventilation: None. Other Ventilation: None.
Respiratory Protection:	None required.
Hands Protection:	Use of disposable vinyl gloves is optional.
Eyes Protection:	Safety glasses or goggles optional.
Skin Protection:	Handle in accordance with good personal hygiene and safety practices.
Other Protective Equipments:	Not applicable (use of a lab coat is optional).
Measures listed in this paragraph are to be consider as indications and NOT as 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: Odorless.
9.2 Information related to health, safety and environment	
pH: Not applicable (N/A) Boiling point: Not applicable Flash point: Not applicable Flammability: Not flammable. Lower Explosivity Limit (L.E.L.): N/A Upper Explosivity Limit (U.E.L.): N/A Oxidizing properties: None Vapour pressure: Not applicable	Relative density: Not available Specific gravity: > 1 g/ml Solubility: Insoluble Partition coefficient n-octanol/water: N/A Viscosity: Not applicable Vapor density (air = 1): N/A Evaporation rate (n-butane = 1): Not applicable Melting point: Not applicable
9.3 Other information (according to communitarian directive 94/9/EC):	
Miscibility: N/D. Solubility in Lipids: Not available	Conducibility: N/D Gases Group: 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_{Lo} (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 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

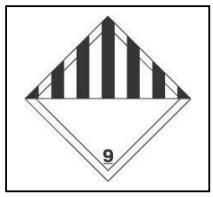
12.6 Other adverse effects: Not available

Aquatic toxicity data for ingredients:

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-F
Stowage/segregation: Category A; Limited Quantity: 5Kg
Proper 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: 9
Proper 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 **C**hemicals **B**ureau (ECB – www.ecb.jrc.it)
European chemical **S**ubstances **I**nformation **S**ystem (ESIS - www.ecb.jrc.it/esis)
A.C.G.I.H. (www.**acgih**.org)
N.I.OS.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.

SybronEndo

Material **S**afety **D**ata **S**heet
in accordance with Community Regulation 2006/1907/EC (R.E.A.C.H.)

Revision Date: 13th February 2008

SECTION 1
Product & Company identification

1.1 Product name
TUBLI SEAL ACCELERATOR & TUBLI SEAL ACCELERATOR 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
Rosin, oligomers (NLP) and Eugenol.

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: Carbon dioxide, foam, dry chemical.

5.2 Forbidden extinguishing media: None.

5.3 Special fire fighting measures: None.

5.4 Unusual fire and explosion hazards: None.

5.5 Special protection equipment: Mask with self breathing apparatus.

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 towels and transfer to 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 in a cool and dry place.

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

7.5 Indication for Combined Storage: Not available.

7.6 Environmental precautions: Not available.

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:	TWA: Not Applicable; TLV: Not Applicable
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: Recommended. Special Ventilation: None. Mechanical (General) Ventilation: None. Other Ventilation: None.
Respiratory Protection:	Avoid breathing of vapours. If concentration exceeds the limits, wear a suitable mask with approved filter for organic vapours.
Hands Protection:	May use gloves (neoprene type) to avoid skin contact.
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.
Measures listed in this paragraph are to be consider as indications and NOT as prescriptions (89/656/EEC)	
8.2.2 Environment exposure control measures Not Applicable.	

SECTION 9 **Physical and Chemical Properties**	
9.1 General information	
Appearance: Amber paste.	Odour: Eugenol odour (oil of cloves).
9.2 Information related to health, safety and environment	
pH: Not applicable (N/A) Boiling point: Not established Flash point: Not applicable Flammability: Not flammable. Lower Explosivity Limit (L.E.L.): N/A Upper Explosivity Limit (U.E.L.): N/A Oxidizing properties: None Vapour pressure: Not determined (N/D)	Relative density: Not available Specific gravity: > 1 g/ml Solubility: Insoluble Partition coefficient n-octanol/water: N/A Viscosity: Not determined Vapor density (air = 1): N/A Evaporation rate (n-butane = 1): Not available Melting point: N/A
9.3 Other information (according to communitarian directive 94/9/EC):	
Miscibility: N/D. Solubility in Lipids: Not available	Conducibility: N/D Gases Group: N/A

SECTION 10
Stability and Reactivity

Stability: Stable.

10.1 Conditions to avoid: Excessive heat.

10.2 Materials to avoid (incompatibility): Not applicable.

10.3 Hazardous decomposition products: Not applicable.

Other precautions:

Hazardous Polymerization Products: Not applicable

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 irritating to the eyes.

Effects and hazards of skin contact: May cause irritation. Repeated contact may cause allergic dermatitis.

Effects and hazards of Inhalation (Breathing): Prolonged exposure may cause drowsiness.

Effects and hazards of Ingestion (Swallowing): May be harmful if swallowed in large quantities.

Effects for prolonged Exposure: Some patients may experience an allergic reaction to the Eugenol contained into the product.

Toxic-kinetic effects: Unknown.

Effects on metabolism: Unknown.

Toxicological data for ingredients:

Eugenol (Acute toxicity):	LD_{50} (oral rat)	1930 mg/Kg
	LD_{50} (intra tracheal rat)	11 mg/Kg
	LD_{50} (oral mouse)	3000 mg/Kg
	LD_{50} (intraperitoneal mouse)	500 mg/Kg
	LD_{50} (intravenous mouse)	72 mg/Kg
	LD_{50} (oral guinea pig)	2130 mg/Kg
	LD_{50} (intra tracheal hamster)	11 mg/Kg

(Irritation data RTECS):	(skin, human)	16 mg/48hrs (moderate)
	(skin rabbit)	100 mg/24hrs (serious)
	(skin pig)	50 mg /48hrs (mild)
	(skin guinea pig)	100 mg/24hrs (moderate)
(Mutagenicity)	Weak citotoxic activity on HeLa cells [RIFM]	
	Mutation in microorganisms (Salmonella typhimurium): 400 mg/plate: mutagenic effects [RTEC, SAX]. Cytogenetic analysis (hamster ovary): 400 mg/plate: mutagenic effects [RTEC].	

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

24 Avoid contact with skin

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

European **C**hemicals **B**ureau (ECB – www.ecb.jrc.it)
European chemical **S**ubstances **I**nformation **S**ystem (ESIS - www.ecb.jrc.it/esis)
A.C.G.I.H. (www.**acgih**.org)
N.I.OS.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)

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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.)

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