

SybronEndo

Material Safety Data Sheet

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	
<i>8.1 Exposure Limits:</i>	<u>TWA</u> : Not Applicable; <u>TLV</u> : Not Applicable
<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:	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.
<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> : Amber paste.	<u>Odour</u> : Eugenol odour (oil of cloves).
<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 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
<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: 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 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

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