SybronEndo

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

Revision Date: 02nd January 2009

SECTION 1
Product & Company identification

1.1 Product name
GUTTA PERCHA

1.2 Uses/Application:
Dental root canal filling.

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)	60-70	N	50-53	1314-13-2	215-222-5

3.2 Other non-hazardous ingredients
Trans-Poly-isoprene (dry natural rubber).

SECTION 4
First aid measures

4.1 Treatment for eye contact: Due to its form, contact with eyes may pose only mechanical hazards.

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

4.3 Treatment for inhalation (breathing): This product is considered safe when used according to directions.

4.4 Treatment for ingestion (swallowing): Ingestion of small amounts of this material under normal conditions would not cause serious harmful effects.

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: None.

5.4 Unusual fire and explosion hazards: None.

5.5 Special protection equipment: None required.

SECTION 6
Accidental Release Measures

6.1 Personal Precautions: Adopt precautions listed in sections 8.

6.2 Environmental Precautions: Product contains zinc oxide, which is considered dangerous for environment. Product should not be allowed to release zinc oxide in the environment.

6.3 Reclaiming Methods: Sweep or wipe up with paper towels and dispose of in a suitable container.

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

7.1 Handling Precautions: Adopt precautions listed in sections 8.

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.

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 considered as indications and NOT prescriptions (89/656/EEC)	
8.2.2 Environment exposure control measures Not Applicable.	

SECTION 9 **Physical and Chemical Properties**	
9.1 General information	
Appearance: Pink colored waxy solid.	Odour: Odourless.
9.2 Information related to health, safety and environment	
pH: Not applicable (N/A)	Relative density: Not available
Boiling point: Not applicable	Specific gravity: Not determined
Flash point: Not applicable	Solubility: Insoluble
Flammability: Not flammable.	Partition coefficient n-octanol/water: N/A
Lower Explosivity Limit (L.E.L.): N/A	Viscosity: Not applicable
Upper Explosivity Limit (U.E.L.): N/A	Vapor density (air = 1): N/A
Oxidizing properties: None	Evaporation rate (n-butane = 1): Not applicable
Vapour pressure: Not applicable	Melting point: 100°C (Softens at about 60°C)
9.3 Other information (according to communitarian directive 94/9/EC):	
Miscibility: N/A	Conducibility: N/A
Solubility in Lipids: Not available	Gases Group: 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: 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 mechanical irritation.

Effects and hazards of skin contact: May cause irritation.

Effects and hazards of Inhalation (Breathing): Not likely to occur when used according to directions.

Effects and hazards of Ingestion (Swallowing): Ingestion of small amounts of this material under normal circumstances would not cause serious harmful effects.

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)
Maximum quantities: No limit (Passenger Aircraft); No limit (Cargo Aircraft only)
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); Kemler 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 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.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.Ch.)

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.