

SybronEndo

Material Safety Data Sheet

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

Revision Date: 17th April 2009

SECTION 1

Product & Company identification

1.1 Product name

SLICK GEL ES

1.2 Uses/Application:

Root canal file lubricating gel.

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	N/A	N/A	N/A	N/A	N/A

3.2 Other non-hazardous ingredients

Propylene Glycol, polyethylene Glycol, Calcium Hydroxide, Sodium Calcium Edetate.

SECTION 4**First aid measures**

- 4.1 Treatment for eye contact: Flush with running water for 15 minutes.
- 4.2 Treatment for skin contact: Wash with soap and water.
- 4.3 Treatment for inhalation (breathing): Product inhalation is an unlikely event.
- 4.4 Treatment for ingestion (swallowing): Give two glasses of water and contact a physician.

SECTION 5**Fire-fighting Measures**

- 5.1 Suitable extinguishing media: Water fog, Carbon dioxide or dry chemicals.
- 5.2 Forbidden extinguishing media: Not applicable.
- 5.3 Special fire fighting measures: Not applicable.
- 5.4 Unusual fire and explosion hazards: None.
- 5.5 Special protection equipment: Wear protective self-breathing apparatus.

SECTION 6**Accidental Release Measures**

- 6.1 Personal Precautions: Follow recommended precautions listed in other sections.
- 6.2 Environmental Precautions: Do not flush to sewers.
- 6.3 Reclaiming Methods: Collect material, wash with water and transfer into a disposal container.

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

- 7.1 Handling Precautions: Wash hands with soap and water after use.
- 7.2 Precautions in case of Fire and Explosion: None.
- 7.3 Storage Conditions: Store in a cool and dry place.
- 7.4 Suggested container(s): Original sealed containers provided by manufacturer.
- 7.5 Indication for Combined Storage: Avoid contact with alkalies, metals (high carbon steels), ammonia, combustible material, salts, sulfates, phenols.
- 7.6 Environmental precautions: None particular. Avoid spillage/release of the product into the environment.
- 7.7 Other Precautions: Avoid contact with eyes and skin. Use according to directions.

SECTION 8**Exposure controls/personal protection**

<i>8.1 Exposure Limits:</i>	Polyethylen Glycol: <u>TWA/TLV:</u> 3 mg/m ³ (respirable); 10 mg/m ³ (total); <u>PEL/STEL:</u> 5 mg/m ³ (respirable); 15 mg/m ³ (total); Propylene Glycol: <u>TWA/TLV:</u> 10 mg/m ³ (8 hours); Calcium Hydroxide: <u>TWA/TLV:</u> 5 mg/m ³
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*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> None required. <u>Special Ventilation:</u> None. <u>Mechanical (General) Ventilation:</u> None. <u>Other Ventilation:</u> None.
Respiratory Protection:	None under normal anticipated conditions.
Hands Protection:	Use of gloves is recommended.
Eyes Protection:	Safety goggles.
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 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*

<u>Appearance:</u> Off-white gel	<u>Odour:</u> Slight.
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9.2 Information related to health, safety and environment

<u>pH:</u> Not established (N/E)	<u>Relative density:</u> Not available
<u>Boiling point:</u> > 200°C	<u>Specific gravity:</u> 1 – 1,2 g/ml @ 25°C
<u>Flash point:</u> Not applicable (N/A)	<u>Solubility:</u> Soluble (in water)
<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> N/E
<u>Upper Explosivity Limit (U.E.L.):</u> N/A	<u>Vapour density (air = 1):</u> > 10
<u>Oxidizing properties:</u> None	<u>Evaporation rate (n-butane = 1):</u> N/E
<u>Vapour pressure:</u> N/A	<u>Melting point:</u> N/E

9.3 Other information (according to communitarian directive 94/9/EC):

<u>Miscibility:</u> Miscible with water.	<u>Conducibility:</u> Similar to water
<u>Solubility in Lipids:</u> Not available	<u>Gases Group:</u> N/A

SECTION 10**Stability and Reactivity**

Stability: Stable solution

10.1 Conditions to avoid: Excessive heat.

10.2 Materials to avoid (incompatibility): Alkalies, metals (high carbon steels), ammonia, combustible materials, salts, sulfates, phenols.

10.3 Hazardous decomposition products: When burning, may generate Nitrous oxides, Carbon oxide and monoxide, ammonia.

Other precautions:

Hazardous Polymerization Products: Will not occur

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

Stabilizers: This 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 mild irritation.

Effects and hazards of Inhalation (Breathing): Product inhalation is an unlikely event.

Effects and hazards of Ingestion (Swallowing): May cause irritation of the throat and respiratory tract.

Effects for prolonged Exposure: Unknown.

Toxic-kinetic effects: Unknown.

Effects on metabolism: Unknown.

Toxicological data for ingredients:

Polyethylene Glycol	LD ₅₀ (oral rat):	> 4000 mg/Kg
Propylene Glycol	LD ₅₀ (oral rat):	20 g/Kg
	LD ₅₀ (oral mouse):	22 g/Kg
	LD ₅₀ (skin rabbit):	10000 mg/Kg
Sodium Calcium Edetate	LD ₅₀ (inhalation rat, 7 hours):	> 1,13 mg/l
	LD ₅₀ (ingestion rat, 10% solution):	> 2000 mg/Kg

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: Log Pow (Sodium Calcium Edetate) = -10,42 (as calculated by EPIWIN/WOWWIN models)

12.5 Results of PBT (Persistent Bio-Toxicity) assessment: Not available

12.6 Other adverse effects: Not available

Aquatic toxicity data for ingredients:

Sodium Calcium Edetate	LC ₅₀ (Bluegill, 96 hours):	2340 mg/l
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SECTION 13**Disposal considerations**

Dispose of in accordance with 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**

The product is not considered hazardous.

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)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

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