

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

SMEAR CLEAR

1.2 Uses/Application:

Endodontic irrigating solution.

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.
Polyethylene glycol octyl phenyl ether	< 1	Xi; N	36-37-38-51/53	92046-34-9	Polymer

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): 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: Unknown.
- 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 the same precautions of section 8.
- 6.2 Environmental Precautions: Keep spilled material out of sewers.
- 6.3 Reclaiming Methods: 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 section 8.
- 7.2 Precautions in case of Fire and Explosion: None 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: Unknown.
- 7.6 Environmental precautions: Avoid contamination of sewers with product.
- 7.7 Other Precautions: Use according to directions and good personal hygiene and safety practices.

SECTION 8 Exposure controls/personal protection	
<i>8.1 Exposure Limits:</i>	None
<i>8.2 Exposure control measures</i>	
<i>8.2.1 Precautionary Measures:</i> <i>(according to communitarian directives 89/686/EEC & article 4 of 98/24/EC)</i>	
Ventilation:	<u>Local Exhaust Ventilation</u> : Not needed. <u>Special Ventilation</u> : None required. <u>Mechanical (General) Ventilation</u> : Should be sufficient. <u>Other Ventilation</u> : None required.
Respiratory Protection:	Not needed
Hands Protection:	Impervious gloves.
Eyes Protection:	Safety glasses.
Skin Protection:	Handle in accordance with good personal hygiene and safety practices.
Other Protective Equipments:	It would be better to use a lab coat.
<i>Measures listed in this paragraph are to be considered as indications and NOT 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> : Clear liquid.	<u>Odour</u> : Odourless.
<i>9.2 Information related to health, safety and environment</i>	
<u>pH</u> : Not determined	<u>Relative density</u> : Not applicable
<u>Boiling point</u> : Not determined	<u>Specific gravity</u> : Not determined
<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> : Similar to water
<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 applicable
<u>Vapour pressure</u> : Not applicable	<u>Melting point</u> : Not applicable
<i>9.3 Other information (according to communitarian directive 94/9/EC):</i>	
<u>Miscibility</u> : N/D.	<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.

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 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: Unknown.

Toxic-kinetic effects: Unknown.

Effects on metabolism: Unknown.

Toxicological data for ingredients:

None.

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

- 36/37/38 Irritating to eyes, respiratory system and skin.
 51/53 Toxic to aquatic organisms, may cause long term adverse effects in the aquatic environment.

16.1.1 Safety phrases of all ingredients

- 2 Keep out of the reach of children.
 24/25 Avoid contact with skin and eyes.
 57 Use appropriate container to avoid environmental contamination

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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