

SybronEndo

Material Safety Data Sheet

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

Revision Date: 28th September 2009

SECTION 1

Product & Company identification

1.1 Product name

OBTURA II CLEANING SOLUTION

1.2 Uses/Application:

Post treatment endo cleaning solution in endodontic practice.

1.3 Company (Name, address and info phone number)

ORMCO B.V./SybronEndo

Basicweg, 20

NL 3821 BR AMERSFOORT (THE NETHERLANDS)

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)

Harmful; Sensitizing; Dangerous for environment.

2.2 Other hazard

Irritating; Flammable.

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.
Naphtha (petroleum), heavy alkylate (*)	30-45	Xn	65	64741-65-7	265-067-2
(R)-p-mentha-1,8-diene	45-70	Xi; N	10-38-43-50/53	5989-27-5	227-813-5

(*) This substance is not considered toxic according to Directive 67/548/EEC, note P.

3.2 Other non-hazardous ingredients

None.

SECTION 4**First aid measures**

- 4.1 Treatment for eye contact: Flush with plenty of water also under eyelids for at least 15 minutes.
- 4.2 Treatment for skin contact: Wash with soap and water. Apply medicated skin cream.
- 4.3 Treatment for inhalation (breathing): Move to fresh air and contact a physician. Administer oxygen if breathing is difficult.
- 4.4 Treatment for ingestion (swallowing): Do not induce vomiting. If vomiting occurs spontaneously, keep head below hips to prevent aspiration of liquid into lungs. Get medical attention.

SECTION 5**Fire-fighting Measures**

- 5.1 Suitable extinguishing media: Carbon dioxide, alcohol foam, dries chemical.
- 5.2 Forbidden extinguishing media: Direct stream of water.
- 5.3 Special fire fighting measures: Self-contained breathing apparatus should be provided to fire fighters. Water fog may be used to cool closed containers.
- 5.4 Unusual fire and explosion hazards: Never use welding or cutting torch on or near product.
- 5.5 Special protection equipment: Sealed overall for liquid and gases; self contained breathing apparatus.

SECTION 6**Accidental Release Measures**

- 6.1 Personal Precautions: Impervious gloves, safety glasses, lab coat or apron.
- 6.2 Environmental Precautions: Prevent product from going into sewers and water sources by diking or impounding.
- 6.3 Reclaiming Methods: Using appropriate safety equipment, mop up or soak up with absorbent material, such as sand or clay.

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

- 7.1 Handling Precautions: Adopt same precautions listed in section 8
- 7.2 Precautions in case of Fire and Explosion: Unknown.
- 7.3 Storage Conditions: Store in tightly closed containers, away from ignition sources.
- 7.4 Suggested container(s): Original sealed containers provided by manufacturer.
- 7.5 Indication for Combined Storage: Strong oxidizing agents.
- 7.6 Environmental precautions: Do not allow product to reach sewers and rivers.
- 7.7 Other Precautions: Use according to directions.

SECTION 8	
Exposure controls/personal protection	
8.1 Exposure Limits:	(Naphtha): TLV: 100 ppm; STEL: 200 ppm; PEL: 500 ppm
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: Appropriate. Special Ventilation: None. Mechanical (General) Ventilation: None. Other Ventilation: None.
Respiratory Protection:	Avoid vapor inhalation. In case of dangerous high concentration use a respirator with approved filter.
Hands Protection:	Impervious gloves, nitrilic type.
Eyes Protection:	Safety glasses.
Skin Protection:	Handle in accordance with good personal hygiene and safety practices.
Other Protective Equipments:	Eyewash. It would be better use a lab coat.
<i>Measures listed in this paragraph are to be considered as indications and NOT prescriptions (89/656/EEC)</i>	
8.2.2 Environment exposure control measures Not Applicable.	

SECTION 9	
Physical and Chemical Properties	
9.1 General information	
Appearance: Colourless liquid.	Odour: Petroleum odour.
9.2 Information related to health, safety and environment	
pH: Not determined (N/D)	Relative density: Not applicable (N/A)
Boiling point: 177°C	Specific gravity: 0,803 g/ml
Flash point: 50°C (TCC)	Solubility: Slight
Flammability: Yes.	Partition coefficient n-octanol/water: N/A
Lower Explosivity Limit (L.E.L.): 1%	Viscosity: N/E
Upper Explosivity Limit (U.E.L.): 6%	Vapour density (air = 1): 4,8 ÷ 5,3
Oxidizing properties: None	Evaporation rate (n-butyl Acetate = 1): < 0,1
Vapour pressure: < 5mm Hg @ 38°C	Melting point: N/A
9.3 Other information (according to communitarian directive 94/9/EC):	
Miscibility: N/D	Conducibility: N/A
Solubility in Lipids: N/D	Gases Group: N/A

SECTION 10

Stability and Reactivity

Stability: Stable if stored as directed.

10.1 Conditions to avoid: Heat and ignition sources.

10.2 Materials to avoid (incompatibility): Strong oxidizing agents.

10.3 Hazardous decomposition products: Thermal decomposition may yield carbon monoxide.

Other precautions:

Hazardous Polymerization Products: Will not occur.

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

Stabilizers: The product does not contain stabilizers.

SECTION 11

Toxicological Information

CMR effects (Carcinogenicity, Mutagenicity and toxicity for reproduction):

No (See asterisk note in section 3.1 related to Naphta, EC number 265-150-3).

Effects and hazards of eye contact: May cause irritation.

Effects and hazards of skin contact: Repeated or prolonged contact may cause drying and defatting of skin and sensitisation.

Effects and hazards of Inhalation (Breathing): May cause headache, dizziness, nausea and anaesthetic effects.

Effects and hazards of Ingestion (Swallowing): Low order of oral toxicity; however, minute amount aspirated into lungs during ingestion may cause severe pulmonary injury.

Effects for prolonged Exposure: Unknown.

Toxic-kinetic effects: Unknown.

Effects on metabolism: Unknown.

Toxicological data for ingredients:

(R)-p-mentha-1,8-diene	LD ₅₀ (oral rat)	> 4800 mg/Kg
	LD ₅₀ (skin rabbit)	> 5000 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: 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**

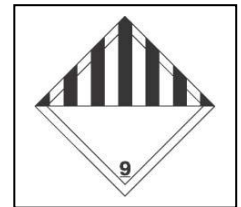
Dispose of in accordance of local regulations.

SECTION 14**Transport information**14.1 Sea transportation (IMDG)

UN number: 3082 Class: 9 Packing group: III EMS-No: F-A, S-F

Stowage/segregation: Category A; Limited Quantity: 5Lt

Proper shipping name: Environmentally hazardous substance, liquid, n.o.s.

14.2 Air transportation (ICAO/IATA)

UN number: 3082; Class: 9; Packing group: III; Label: 9

Maximum quantities: No limits (both for Passenger Aircraft and Cargo Aircraft only)

Limited Quantity: 30Kg G; Proper shipping name: Environmentally hazardous substance, liquid, n.o.s.

14.3 Transportation by Road/Railway (RID/ADR)

UN number: 3082; Class: 9; Packing group: III; Hazard identification n°: 90 Label: 9

Proper shipping name: Environmentally hazardous substance, liquid, n.o.s.

Limited Quantity: LQ7 (5Lt/30Kg for combined, 5Lt/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 (Other) Risk phrases

- 65 Harmful: may cause lung damage if swallowed
 10 Flammable.
 38 Irritating to skin.
 43 May cause sensitization by skin contact.
 50/53 Very toxic to aquatic organisms, may cause long-term adverse effects in the aquatic environment.

16.1.1 (Other) Safety phrases

- 2 Keep out of the reach of children.
 24 Avoid contact with skin.
 37 Wear suitable gloves.
 45 In case of accident or if you feel unwell, seek medical advice immediately (show the label where possible).
 53 Avoid exposure — obtain special instructions before use.
 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.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.
2008/58/EC:	Commission Directive 2008/58/EC of 21 August 2008 amending, for the purpose of its adaptation to technical progress, for the 30th time, Council Directive 67/548/EEC on the approximation of the laws, regulations and administrative provisions relating to the classification, packaging and labelling of dangerous substances.

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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