KERR

Material Safety Data Sheet

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

Revision Date: 21st May 2009

SECTION 1

Product & Company identification

1.1 Product name

OPTIBOND FL PRIMER

1.2 <u>Uses/Application</u>:

Dental adhesive.

1.3 Company (Name, address and info phone number)

KERR ITALIA S.r.l.

Via Passanti, 332

84018 Scafati (SA) - Italy

Free Phone: 00-800-41-050-505

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 <u>Hazard classification</u> (according to communitarian directives 67/548/EEC & 99/45/EC) Highly flammable; Sensitizing; Irritating.

2.2 Other hazard

Uncured material may be harmful if swallowed.

SECTION 3

Composition/Information on Ingredients

(according to communitarian directives 67/548/EEC, 99/45/EC & 2001/58/EC)

3.1 <u>Hazardous ingredients</u>

HAZARDOUS	%	HAZARD	RISK	CAS N.	EINECS
INGREDIENTS		SYMBOLS	PHRASES		N.
HydroxyEthylMethAcrylate	25-30	Xi	36/38-43	868-77-9	212-782-2
(HEMA)					
Ethyl Alcohol	20-25	F	11	64-17-5	200-578-6

3.2 Other non-hazardous ingredients

None.

SECTION 4

First aid measures

- 4.1 Treatment for eye contact: Flush with water for 15 minutes. If irritation persists, seek medical attention.
- 4.2 Treatment for skin contact: Wash skin thoroughly with soap and water. Use hand cream.
- 4.3 Treatment for inhalation (breathing): Remove to fresh air. If irritation persists, seek medical attention.
- <u>4.4 Treatment for ingestion (swallowing)</u>: Do not give liquids if person is unconscious. Seek medical attention.

SECTION 5

Fire-fighting Measures

- 5.1 Suitable extinguishing media: Carbon dioxide and dry chemical foam.
- 5.2 Forbidden extinguishing media: Unknown.
- 5.3 Special fire fighting measures: None. Wear self-contained breathing apparatus and full protective gear.
- <u>5.4 Unusual fire and explosion hazards:</u> Heat can cause polymerization of the product and formation of hazardous vapours.
- 5.5 Special protection equipment: Sealed overall against liquids and gases.

SECTION 6

Accidental Release Measures

- 6.1 Personal Precautions: Adopt the same precautions listed in section 8.
- 6.2 Environmental Precautions: Keep spilled material out of sewers.
- <u>6.3 Reclaiming Methods:</u> Dilute with water, wipe up with cloth and transfer to suitable container for disposal. Dispose of in accordance with local regulations.

SECTION 7

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

- 7.1 Handling Precautions: Handle away from sources of ignition. Adopt precautions listed in section 8.
- 7.2 Precautions in case of Fire and Explosion: Extinguish all ignition sources.
- 7.3 Storage Conditions: Store in a cool, dry place, away from heat, light and ignition sources.
- 7.4 Suggested container(s): The original containers provided by manufacturer.
- 7.5 Indication for Combined Storage: Avoid contact with strong oxidizing agents.
- 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.

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SECTION 8		
Exposure controls/personal protection		
8.1 Exposure Limits:	TWA/TLV: 1000 ppm (Ethanol)	
8.2 Exposure control measures		
8.2.1 Precautionary Meast (according to communita	ures: ırian directives 89/686/EEC & article 4 of 98/24/EC)	
Ventilation:	Local Exhaust Ventilation: Sufficient to keep vapours under exposure limits. Special Ventilation: None required. Mechanical (General) Ventilation: Good general ventilation recommended. Other Ventilation: None required.	
Respiratory Protection:	Avoid breathing of vapours of the material. In case of high vapours concentration, use a mask with a filter against organic vapours.	
Hands Protection:	Nitrile or Vinyl gloves are sufficient for short contact and for small quantity handling. Otherwise, impervious rubber or PVA gloves are recommended.	
Eyes Protection:	Safety glasses may be used.	
Skin Protection:	Handle in accordance with good personal hygiene and safety practices. These practices include avoiding unnecessary exposure to uncured material.	
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		
Appearance: Pale yellow liquid.	Odour: Fruity odour.	
9.2 Information related to health, safety and envi	ronment	
<u>pH</u> : Not established (N/E)	Relative density: N/E	
Boiling point: N/E	Specific gravity: 0,96 g/ml	
Flash point: 18°C (Ethyl Alcohol)	Solubility: Soluble	
<u>Flammability</u> : Flammable.	Partition coefficient n-octanol/water: N/E	
Lower Explosivity Limit (L.E.L.): N/E	<u>Viscosity</u> : N/E	
<u>Upper Explosivity Limit (U.E.L.)</u> : N/E	<u>Vapor density (air = 1)</u> : N/E	
Oxidizing properties: None	Evaporation rate (n-butane = 1): N/E	
Vapour pressure: N/E	Melting point: N/E	
9.3 Other information (according to communitarian directive 94/9/EC):		
Miscibility: Not available	Conducibility: Not available	
Solubility in Lipids: Not available	Gases Group: Not applicable	

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SECTION 10

Stability and Reactivity

Stability: Stable if stored as directed.

10.1 Conditions to avoid: Heat, sparks and open flame.

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

10.3 Hazardous decomposition products: Carbon Oxides.

Other precautions:

Hazardous Polymerization Products: Not determined

Safety significance in case of change in physical appearance: Unknown

Stabilizers: The product is stabilized with non-hazardous polymerization inhibitors.

SECTION 11

Toxicological Information

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

None.

Effects and hazards of eye contact: May cause irritation and damage if not removed promptly.

Effects and hazards of skin contact: Irritating. May cause sensitization in sensitive individuals.

Effects and hazards of Inhalation (Breathing): May cause irritation to the throat and respiratory tract.

<u>Effects and hazards of Ingestion (Swallowing</u>): May cause severe irritation to the digestive tract, abdominal pain, nausea. Uncured material may be harmful if swallowed.

Effects for prolonged Exposure: Not applicable.

Toxic-kinetic effects: Unknown.

Effects on metabolism: Unknown.

<u>Toxicological data for ingredients:</u>

HEMA	LD ₅₀ (oral rat)	> 5000 mg/Kg
	LD ₅₀ (skin rabbit)	> 3000 mg/Kg
	LC ₅₀ (inhalation rat/3 weeks)	> 0,5 mg/Kg

Ethyl Alcohol	LC ₅₀ (inhalation mouse/4hrs)	39g/m ³
	LC ₅₀ (inhalation rat/10hrs)	20000ppm
	LD _{Lo} (intraperitoneal dog)	3000mg/Kg
	LD ₅₀ (intraperitoneal guinea pig)	3414mg/Kg
	LD ₅₀ (intraperitoneal hamster)	5068mg/Kg
	LD ₅₀ (intraperitoneal mammal)	4300mg/Kg
	LD ₅₀ (intraperitoneal mouse)	933mg/Kg
	LD ₅₀ (intraperitoneal rat)	3750mg/Kg
	LD ₅₀ (intraperitoneal rabbit)	963mg/Kg
	LD _{Lo} (intravenous cat)	3945mg/Kg
	LD _{Lo} (intravenous chicken)	8216mg/Kg
	LD _{Lo} (intravenous dog)	1600mg/Kg
	LD ₅₀ (intravenous mouse)	1973mg/Kg
	LD ₅₀ (intravenous rat)	1440mg/Kg
	LD ₅₀ (intravenous rabbit)	2374mg/Kg
	LD _{Lo} (oral cat)	6000mg/Kg
	LD _{Lo} (oral child)	2000mg/Kg
	LD _{Lo} (oral dog)	5500mg/Kg
	LD ₅₀ (oral guinea pig)	5560mg/Kg
	LD _{Lo} (oral human)	1400mg/Kg
	TD _{Lo} (oral man)	700mg/Kg
	TD _{Lo} (oral man)	50mg/Kg
	TD _{Lo} (oral man)	1430mg/Kg
	LD ₅₀ (oral mouse)	7500mg/Kg
	LD ₅₀ (oral rat)	7060 mg/Kg
	LD ₅₀ (oral rabbit)	6300mg/Kg
	TD _{Lo} (oral woman)	6300mg/Kg
	LD _{Lo} (subcutaneous chicken)	5g/Kg
	LD _{Lo} (subcutaneous dog)	6000mg/Kg
	LD _{Lo} (subcutaneous frog)	7100mg/Kg
	LD _{Lo} (subcutaneous infant)	19440mg/Kg
	LD _{Lo} (subcutaneous mouse)	4g/Kg
	LD _{Lo} (subcutaneous pigeon)	5g/Kg
	LD _{Lo} (skin rabbit)	20g/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:

HEMA	LC ₅₀ (Fish, Oryzias Latipes)	> 100 mg/l (OCSE 203, 96h)
Easily biodegradable: 84%	LC ₅₀ (Fish, Oryzias Latipes)	> 100 mg/l (OCSE 204, 14 days)
(OCSE 301D, closed bottle test, 28 days)	NOEC (Daphnia magna)	24,1 mg/l (OCSE 202/2, 21 days)
	EC ₅₀ (Daphnia magna)	380 mg/l (OCSE 202/1, 48h)
	EC ₅₀ (Selenastrum Copricornutum)	345 mg/l (OCSE 201, 72h)
	EC ₅₀ (Pseudomonas fluorescens)	> 3000 mg/l (DEV LB, 16h)
Ethanol	LC ₅₀ (Oncorhynchus mykiss):	10400-13000 mg/l (96hrs)
	LC ₅₀ (Pimephales promelas):	15300 mg/l (96hrs)
	LC ₅₀ (Other fishes):	10000 mg/l (24hrs)
	LC ₅₀ (Daphnia magna):	9,3 mg/l (48hrs)

SECTION 13

Disposal considerations

Dispose of in accordance with local regulations.

SECTION 14

Transport information

14.1 Sea transportation (IMDG)

<u>UN number</u>: 1170 <u>Class</u>: 3 <u>Packing group</u>: II <u>EMS-No</u>: F-E, S-D

Stowage/segregation: Category A; <u>Limited Quantity</u>: 1 Lt

Proper shipping name: Ethanol or Ethanol in solution.

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14.2 Air transportation (ICAO/IATA)

UN number: 1170 Class: 3 Packing group: II Label: 3

<u>Maximum quantities</u>: 5 Lt (Passenger Aircraft); 60 Lt (Cargo Aircraft only) Limited Quantity: 1 Lt Proper shipping name: Ethanol or Ethanol in solution.

14.3 Transportation by Road/Railway (RID/ADR)

<u>UN number</u>: 1170 <u>Class</u>: 3 <u>Packing group</u>: II (3°b); Hazard identific. n°: 33 <u>Label</u>: 3

<u>Limited Quantity</u> LQ4: (3 Lt/30 Kg for combined, 1 Lt/20Kg for bandaged trays/pallets).

Proper shipping name: Ethanol or Ethanol in solution.

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

Highly flammable.

43 May cause sensitisation by skin.

36/38 Irritating to eyes and skin.

16.1.1 Safety phrases of all ingredients

- 1/2 Keep locked up and out of reach of children.
- 16 Keep away from sources of ignition No Smoking!
- 26 In case of contact with eyes, rinse immediately with plenty of water and seek medical advice.
- 28 After contact with skin, wash immediately with plenty of water.

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.

<u>Document modification history</u>: First version in compliance of Community Regulation 2006/1907/EC (R.E.A.Ch.)

CAUTION: PRODUCT FOR PROFESSIONAL USE

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