

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 SOLO PLUS

1.2 Uses/Application:

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 Hazard classification (according to communitarian directives 67/548/EEC & 99/45/EC)

Harmful; Sensitizing; Highly flammable.

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.
HydroxyEthylMethAcrylate (HEMA)	15-20	Xi	36/38-43	868-77-9	212-782-2
Ethyl Alcohol	20-25	F	11	64-17-5	200-578-6
Disodium Hexafluorosilicate	0,8-1,2	T	23/24/25	16893-85-9	240-934-8

3.2 Other non-hazardous ingredients

Inert fillers.

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.
- 4.4 Treatment for ingestion (swallowing): 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. Use water spray to cool containers.
- 5.4 Unusual fire and explosion hazards: High temperature might generate hazardous vapours of hydrofluoric acid.
- 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.
- 6.3 Reclaiming Methods: 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: Keep 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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Material Safety Data Sheet for: OPTIBOND SOLO PLUS

SECTION 8**Exposure controls/personal protection**

8.1 Exposure Limits: TWA/TLV : 1000 ppm (Ethyl Alcohol)

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> : Sufficient to keep vapours under exposure limits. <u>Special Ventilation</u> : None required. <u>Mechanical (General) Ventilation</u> : Good general ventilation recommended. <u>Other Ventilation</u> : 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 paste.Odour: Fruity odour.**9.2 Information related to health, safety and environment**pH: Not established (N/E)Relative density: N/EBoiling point: N/ESpecific gravity: ~1.25 g/mlFlash point: 18°C (Ethyl Alcohol)Solubility: PartialFlammability: Flammable.Partition coefficient n-octanol/water: N/ELower Explosivity Limit (L.E.L.): N/EViscosity: N/EUpper Explosivity Limit (U.E.L.): N/EVapor density (air = 1): N/EOxidizing properties: NoneEvaporation rate (n-butane = 1): N/EVapour pressure: N/EMelting point: N/E**9.3 Other information (according to communitarian directive 94/9/EC):**Miscibility: Not availableConducibility: Not availableSolubility in Lipids: Not availableGases Group: Not applicable

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 mild irritation.

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.

Effects and hazards of Ingestion (Swallowing): 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.

Toxicological data for ingredients:

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
DISODIUM HEXAFLUOROSILICATE	LD ₅₀ (oral rat & rabbit)	125 mg/Kg
	LD ₅₀ (oral mouse)	70 mg/l

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Ethyl Alcohol	LC ₅₀ (inhalation mouse/4hrs)	39g/m ³
	LC ₅₀ (inhalation rat/10hrs)	20000ppm
	LD _{L0} (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 _{L0} (intravenous cat)	3945mg/Kg
	LD _{L0} (intravenous chicken)	8216mg/Kg
	LD _{L0} (intravenous dog)	1600mg/Kg
	LD ₅₀ (intravenous mouse)	1973mg/Kg
	LD ₅₀ (intravenous rat)	1440mg/Kg
	LD ₅₀ (intravenous rabbit)	2374mg/Kg
	LD _{L0} (oral cat)	6000mg/Kg
	LD _{L0} (oral child)	2000mg/Kg
	LD _{L0} (oral dog)	5500mg/Kg
	LD ₅₀ (oral guinea pig)	5560mg/Kg
	LD _{L0} (oral human)	1400mg/Kg
	TD _{L0} (oral man)	700mg/Kg
	TD _{L0} (oral man)	50mg/Kg
	TD _{L0} (oral man)	1430mg/Kg
	LD ₅₀ (oral mouse)	7500mg/Kg
	LD ₅₀ (oral rat)	7060 mg/Kg
	LD ₅₀ (oral rabbit)	6300mg/Kg
	TD _{L0} (oral woman)	6300mg/Kg
	LD _{L0} (subcutaneous chicken)	5g/Kg
	LD _{L0} (subcutaneous dog)	6000mg/Kg
	LD _{L0} (subcutaneous frog)	7100mg/Kg
	LD _{L0} (subcutaneous infant)	19440mg/Kg
	LD _{L0} (subcutaneous mouse)	4g/Kg
	LD _{L0} (subcutaneous pigeon)	5g/Kg
	LD _{L0} (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

KERR**Material Safety Data Sheet for: OPTIBOND SOLO PLUS****Aquatic toxicity data for ingredients:**

HEMA Easily biodegradable: 84% (OCSE 301D, closed bottle test, 28 days)	LC ₅₀ (Fish, Oryzias Latipes)	> 100 mg/l (OCSE 203, 96h)
	LC ₅₀ (Fish, Oryzias Latipes)	> 100 mg/l (OCSE 204, 14 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)
Disodium Hexafluorosilicate	LC ₅₀ (Fishes)	10-100 mg/l (after 48 hours)
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)UN number: 1170 Class: 3 Packing group: II EMS-No: F-E, S-DStowage/segregation: Category A; Limited Quantity: 1 LtProper shipping name: Ethanol or Ethanol in solution.14.2 Air transportation (ICAO/IATA)UN number: 1170 Class: 3 Packing group: II Label: 3Maximum quantities: 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)UN number: 1170 Class: 3 Packing group: II (3^b); Hazard identific. n°: 33 Label: 3Limited Quantity 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

- 11 Highly flammable.
 43 May cause sensitisation by skin.
 36/38 Irritating to eyes and skin.
 23/24/25 Toxic by inhalation, in contact with the skin and if swallowed

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.
 45 In case of accident or if you feel unwell, seek medical advice immediately (show the label where possible)

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.

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Material Safety Data Sheet for: **OPTIBOND SOLO PLUS**

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.

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Material Safety Data Sheet

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

Revision Date: 29th September 2008

SECTION 1

Product & Company identification

1.1 Product name

GEL ETCHANT

1.2 Uses/Application:

Dental Etching paste.

1.3 Company (Name, address and info phone number)

Kerr Corporation

1717 West Collins Avenue

92867 Orange – CALIFORNIA (U.S.A.)

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 Hazard classification (according to communitarian directives 67/548/EEC & 99/45/EC)

Corrosive.

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.
ortho-Phosphoric acid (H ₃ PO ₄)	36 - 39	C	34	7664-38-2	231-633-2

3.2 Other non-hazardous ingredients

Pigments.

SECTION 4**First aid measures**

- 4.1 Treatment for eye contact: Wash eyes with plenty of water for at least 15 minutes, lifting lower and upper eyelids occasionally. Get medical attention.
- 4.2 Treatment for skin contact: Immediately flush skin with plenty of water. Get medical attention.
- 4.3 Treatment for inhalation (breathing): Remove to fresh air Get medical attention.
- 4.4 Treatment for ingestion (swallowing): Do not induce vomiting. Give large quantities of water and get medical attention.

SECTION 5**Fire-fighting Measures**

- 5.1 Suitable extinguishing media: None; not considered to be a fire hazard.
- 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 particular.

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.
- 6.3 Reclaiming Methods: Absorb spills with inert material and transfer to suitable container for disposal.

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

- 7.1 Handling Precautions: Avoid contact with skin, eyes, soft tissues and unnecessary exposure to the product.
- 7.2 Precautions in case of Fire and Explosion: At high temperatures toxic fumes of phosphoric acid and phosphorous oxides can be generated.
- 7.3 Storage Conditions: Store at room temperature.
- 7.4 Suggested container(s): The original containers provided by manufacturer.
- 7.5 Indication for Combined Storage: Avoid contact with strong caustics, metals, sulphides and sulphites.
- 7.6 Environmental precautions: Keep spilled material out of sewers.
- 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:* (H_3PO_4): TWA/TLV 0,25 ppm (1 mg/m³); STEL: 0,75 ppm (3 mg/m³)

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> : Good general ventilation should be sufficient. <u>Special Ventilation</u> : None required. <u>Mechanical (General) Ventilation</u> : Good general ventilation recommended. <u>Other Ventilation</u> : None required.
Respiratory Protection:	None particular.
Hands Protection:	Impervious rubber gloves recommended
Eyes Protection:	May be used safety glasses.
Skin Protection:	Handle in accordance with good personal hygiene and safety practices. These practices include avoiding unnecessary exposure to the product.
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: Purple gel.

Odour: Odourless.

9.2 Information related to health, safety and environment

pH: 0.5 – 1.5

Relative density: N/E

Boiling point: 100°C

Specific gravity: 1,2 g/ml

Flash point: Not applicable (N/A)

Solubility: Soluble in water

Flammability: Not flammable.

Partition coefficient n-octanol/water: N/E

Lower Explosivity Limit (L.E.L.): N/A

Viscosity: N/E

Upper Explosivity Limit (U.E.L.): N/A

Vapor density (air = 1): 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: Similar to water

Solubility in Lipids: Not available

Gases Group: Not applicable

SECTION 10**Stability and Reactivity**

Stability: Stable.

10.1 Conditions to avoid: Excessive heat.

10.2 Materials to avoid (incompatibility): Strong caustics, metals, sulphides and sulphites.

10.3 Hazardous decomposition products: Toxic fumes of phosphoric acid.

Other precautions:

Hazardous Polymerization Products: None

Safety significance in case of change in physical appearance: Unknown

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: Corrosive. May cause redness, pain and eye burns.

Effects and hazards of skin contact: Corrosive. May cause redness, pain and burns.

Effects and hazards of Inhalation (Breathing): Inhalation is not an expected hazard unless product is misted or heated at high temperatures.

Effects and hazards of Ingestion (Swallowing): Corrosive. May cause sore throat and burns of the mouth and throat.

Effects for prolonged Exposure: May cause burns to the respiratory tract, contact with soft tissues may cause burns.

Toxic-kinetic effects: Unknown.

Effects on metabolism: Unknown.

Toxicological data for ingredients:

ortho-Phosphoric acid (H_3PO_4)	LD_{50} (oral rat)	1530 mg/Kg
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SECTION 12**Ecological Information**

The product is not considered as environmentally hazardous. However, if released in massive quantities in the environment, may cause pH change with adverse effects on aquatic life.

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 with local regulations.

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

UN number: 1805 Class: 8 Packing group: III EMS-No: F-A, S-B

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

Proper shipping name: Phosphoric acid in (aqueous/gel) solution.

14.2 Air transportation (ICAO/IATA)

UN number: 1805 Class: 8 Packing group: III Labels: 8

Maximum quantities: 5 Lt (Passenger Aircraft); 60 Lt (Cargo Aircraft only)

Limited Quantity: 1 Lt Proper shipping name: Phosphoric acid in (aqueous/gel) solution.

14.3 Transportation by Road/Railway (RID/ADR)

UN number: 1805 Class: 8 Packing group: III Kemler n°: 80 Labels: 8

Limited Quantity: LQ7 (5 Lt/30 Kg for combined, 5 Lt/20 Kg for bandaged trays).

External package type: carton (4G) both for simple and combined packages;

Proper shipping name: Phosphoric acid in (aqueous/gel) 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

34 Causes burns.

16.1.1 Safety phrases of all ingredients

26 In case of contact with eyes, rinse immediately with plenty of water and seek medical advice.

45 In case of accident or if you feel unwell, seek medical advice immediately (show the label where possible)

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

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.

Kerr™

Safety Data Sheet HERCULITE XRV (all shades)

SECTION 1: IDENTIFICATION OF THE SUBSTANCE/MIXTURE AND OF THE COMPANY/UNDERTAKING

1.1. Product identifier

Product name : HERCULITE XRV (all shades)

1.2. Relevant identified uses of the substance or mixture and uses advised against

Relevant identified uses

Main use category : Professional use
Function or use category : Dental materials.

Uses advised against

No additional information available

1.3. Details of the supplier of the safety data sheet

Supplier

Kerr Italia S.r.l.
Via Passanti, 332
84018 Scafati (SA) - Italy
T +39-081-850-8311
E-mail: safety@kerrhawe.com

Manufacturer

Kerr Italia S.r.l.
Via Passanti, 332
84018 Scafati (SA) - Italy
T +39-081-850-8311
E-mail: safety@kerrhawe.com

Contact person : safety@kerrhawe.com - tel. 00-800-41-050-505 (08.00-17.00)

1.4. Emergency telephone number

Emergency number : CHEMTREC® Emergency Call Center. Emergency Telephone Number (for USA only) 001-800-424-9300 International and Maritime Telephone Number +1 (703) 527-3887

Country	Organisation/Company	Address	Emergency number
United Kingdom	National Poisons Information Service (Newcastle Unit)	Claremont Place Newcastle-upon-Tyne, Newcastle	+44 191 2606182/+44 191 2606180 24H

SECTION 2: HAZARDS IDENTIFICATION

2.1. Classification of the substance or mixture

Classification according to Regulation (EC) No. 1272/2008 [CLP]

Skin Sens. 1 H317

Full text of classification categories and H statements : see section 16

2.2. Label elements

Labelling according to Regulation (EC) No. 1272/2008 [CLP]

Hazard pictograms (CLP) :



GHS07

Signal word (CLP) : Warning
Hazardous ingredients : hexamethylene diacrylate, hexane-1,6-diol diacrylate
Hazard statements (CLP) : H317 - May cause an allergic skin reaction
Precautionary statements (CLP) : P261 - Avoid breathing spray, vapours, gas, fume, mist
P272 - Contaminated work clothing should not be allowed out of the workplace
P280 - Wear eye protection
P302+P352 - IF ON SKIN: Wash with plenty of soap and water
P333+P313 - If skin irritation or rash occurs: Get medical advice/attention
P362+P364 - Take off contaminated clothing and wash it before reuse
P501 - Dispose of contents/container to ...

Extra phrases

: The product is seen as a medical device and therefore not subject to labelling (EU-regulation 1907/2006, article 2, paragraph 6c).

2.3. Other hazards

Other hazards not contributing to the classification : None under normal conditions.

This substance/mixture does not meet the PBT criteria of REACH regulation, annex XIII

This substance/mixture does not meet the vPvB criteria of REACH regulation, annex XIII

SECTION 3: COMPOSITION/INFORMATION ON INGREDIENTS

3.1. Substance

Not applicable

3.2. Mixture

Name	Product identifier	%	Classification according to Regulation (EC) No. 1272/2008 [CLP]
hexamethylene diacrylate, hexane-1,6-diol diacrylate	(CAS No) 13048-33-4 (EC no) 235-921-9 (EC index no) 607-109-00-8 (REACH-no) 01-2119484737-22	=>2-<3	Eye Irrit. 2, H319 Skin Irrit. 2, H315 Skin Sens. 1, H317
titanium dioxide	(CAS No) 13463-67-7 (EC no) 236-675-5 (REACH-no) 01-2119489379-17	< 0.1	Not classified
zinc oxide	(CAS No) 1314-13-2 (EC no) 215-222-5 (EC index no) 030-013-00-7 (REACH-no) 01-2119463881-32	< 0.1	Aquatic Acute 1, H400 Aquatic Chronic 1, H410
methacrylate ester monomer			Not classified
pigment	(REACH-no) N/A		Not classified

Full text of H-statements: see section 16

SECTION 4: FIRST AID MEASURES

4.1. Description of first aid measures

First-aid measures general : If medical advice is needed, have product container or label at hand.

First-aid measures after inhalation : Remove victim to fresh air and keep at rest in a position comfortable for breathing. Get medical advice/attention if you feel unwell.

First-aid measures after skin contact : Gently wash with plenty of soap and water. If skin irritation occurs: Get medical advice/attention.

First-aid measures after eye contact : IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing. Get medical advice/attention if you feel unwell.

First-aid measures after ingestion : If swallowed, rinse mouth with water (only if the person is conscious). Call a POISON CENTER or doctor/physician if you feel unwell.

4.2. Most important symptoms and effects, both acute and delayed

Symptoms/injuries after skin contact : May cause an allergic skin reaction.

4.3. Indication of any immediate medical attention and special treatment needed

No specific measures identified.

SECTION 5: FIREFIGHTING MEASURES

5.1. Extinguishing media

Suitable extinguishing media : Use extinguishing media appropriate for surrounding fire. Foam, carbon dioxide (CO2) and powder.

Unsuitable extinguishing media : Do not use a heavy water stream.

5.2. Special hazards arising from the substance or mixture

Fire hazard : Non flammable.

Explosion hazard : Product is not explosive.

Hazardous decomposition products in case of fire : Carbon dioxide. Carbon monoxide.

5.3. Advice for firefighters

Firefighting instructions : Use water spray or fog for cooling exposed containers.

Protection during firefighting : Do not enter fire area without proper protective equipment, including respiratory protection.

SECTION 6: ACCIDENTAL RELEASE MEASURES**6.1. Personal precautions, protective equipment and emergency procedures**

General measures : Avoid contact with skin and eyes. Wear chemically protective gloves, lab coat or apron to prevent prolonged or repeated skin contact.

For non-emergency personnel

Protective equipment : See Heading 8.
Emergency procedures : Evacuate unnecessary personnel.

For emergency responders

No additional information available

6.2. Environmental precautions

Avoid release to the environment.

6.3. Methods and material for containment and cleaning up

For containment : Collect all waste in suitable and labelled containers and dispose according to local legislation.

Methods for cleaning up : Large spills: scoop solid spill into closing containers.

6.4. Reference to other sections

For further information refer to section 13.

SECTION 7: HANDLING AND STORAGE**7.1. Precautions for safe handling**

Precautions for safe handling : Do not eat, drink or smoke when using this product. Keep away from heat, hot surfaces, sparks, open flames and other ignition sources. No smoking.

7.2. Conditions for safe storage, including any incompatibilities

Storage conditions : Keep away from heat, hot surfaces, sparks, open flames and other ignition sources. No smoking. Keep container tightly closed. Store in original container.

Incompatible materials : Oxidizing substances. reducing materials. Organic peroxides. Amines.

Storage area : Store in a well-ventilated place.

7.3. Specific end use(s)

Consult the supplier for further information.

SECTION 8: EXPOSURE CONTROLS/PERSONAL PROTECTION**8.1. Control parameters**

No additional information available

8.2. Exposure controls

Appropriate engineering controls : Ensure good ventilation of the work station.

Personal protective equipment : Gloves. Safety glasses.

Hand protection : Wear suitable gloves. Nitrile rubber gloves. Layer thickness : 0,09mm. Breakthrough time : >480 min. STANDARD EN 374.

Eye protection : Safety glasses. STANDARD EN 166.

Skin and body protection : Wear suitable protective clothing

Respiratory protection : Respiratory protection not applicable



Other information : Do not eat, drink or smoke during use.

SECTION 9: PHYSICAL AND CHEMICAL PROPERTIES**9.1. Information on basic physical and chemical properties**

Physical state : Liquid
Appearance : Paste.
Colour : No data available
Odour : Fruity.
Odour threshold : No data available
pH : No data available

Relative evaporation rate (butylacetate=1)	: No data available
Melting point	: No data available
Freezing point	: No data available
Boiling point	: No data available
Flash point	: No data available
Auto-ignition temperature	: No data available
Decomposition temperature	: No data available
Flammability (solid, gas)	: No data available
Vapour pressure	: No data available
Relative vapour density at 20 °C	: No data available
Relative density	: No data available
Density	: 2.4 g/cm ³
Solubility	: Material insoluble in water.
Log Pow	: No data available
Viscosity, kinematic	: No data available
Viscosity, dynamic	: No data available
Explosive properties	: Product is not explosive.
Oxidising properties	: No data available
Explosive limits	: No data available

9.2. Other information

No additional information available

SECTION 10: STABILITY AND REACTIVITY

10.1. Reactivity

The product is non-reactive under normal conditions of use, storage and transport.

10.2. Chemical stability

Stable under normal conditions.

10.3. Possibility of hazardous reactions

May polymerize.

10.4. Conditions to avoid

No flames, no sparks. Eliminate all sources of ignition.

10.5. Incompatible materials

Oxidizing agent. reducing materials. Organic peroxides. Amines.

10.6. Hazardous decomposition products

No decomposition if stored normally.

SECTION 11: TOXICOLOGICAL INFORMATION

11.1. Information on toxicological effects

Acute toxicity : Not classified

titanium dioxide (13463-67-7)

LD50 oral rat	> 100000
LD50 dermal rabbit	> 10000
LC50 inhalation rat (Dust/Mist - mg/l/4h)	> 4.68 mg/l/4h

zinc oxide (1314-13-2)

LD50 oral rat	> 5000 mg/kg
LD50 oral	> 7950 mg/kg Oral, mouse
LD50 dermal rabbit	> 2000 mg/kg
LC50 inhalation rat (mg/l)	0.57 mg/l/4h

hexamethylene diacrylate, hexane-1,6-diol diacrylate (13048-33-4)

LD50 oral rat	5000 mg/kg
LD50 dermal rabbit	3600 mg/kg

Skin corrosion/irritation	: Not classified Contact during a long period may cause slight irritation
Serious eye damage/irritation	: Not classified Liquid splashes in the eye may cause irritation
Respiratory or skin sensitisation	: May cause an allergic skin reaction.
Germ cell mutagenicity	: Not classified

Carcinogenicity	: Not classified
Reproductive toxicity	: Not classified
Specific target organ toxicity (single exposure)	: Not classified
	By prolonged exposure : May cause minor irritation to the respiratory tract and to other mucous membranes
Specific target organ toxicity (repeated exposure)	: Not classified
Aspiration hazard	: Not classified

SECTION 12: ECOLOGICAL INFORMATION

12.1. Toxicity

Ecology - general	: The product is not considered harmful to aquatic organisms or to cause long-term adverse effects in the environment.
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titanium dioxide (13463-67-7)	
LC50 fish 1	> 1000 (96 hours - Fundulus heteroclitus)
EC50 Daphnia 1	> 1000 (48 hours - Daphnia magna)
zinc oxide (1314-13-2)	
LC50 fish 1	1.1 mg/l 96 h (Onchorhynchus mykiss)
EC50 Daphnia 1	24.6 48 h (Daphnia magna)

12.2. Persistence and degradability

HERCULITE XRV (all shades)	
Persistence and degradability	No data available.

12.3. Bioaccumulative potential

HERCULITE XRV (all shades)	
Bioaccumulative potential	No data.
zinc oxide (1314-13-2)	
Bioconcentration factor (BCF REACH)	92
hexamethylene diacrylate, hexane-1,6-diol diacrylate (13048-33-4)	
Bioconcentration factor (BCF REACH)	46.77

12.4. Mobility in soil

HERCULITE XRV (all shades)	
Ecology - soil	Material insoluble in water.

12.5. Results of PBT and vPvB assessment

HERCULITE XRV (all shades)	
This substance/mixture does not meet the PBT criteria of REACH regulation, annex XIII	
This substance/mixture does not meet the vPvB criteria of REACH regulation, annex XIII	
Component	
titanium dioxide (13463-67-7)	This substance/mixture does not meet the PBT criteria of REACH regulation, annex XIII This substance/mixture does not meet the vPvB criteria of REACH regulation, annex XIII

12.6. Other adverse effects

Other adverse effects	: None to our knowledge.
Additional information	: No other effects known

SECTION 13: DISPOSAL CONSIDERATIONS

13.1. Waste treatment methods

Regional legislation (waste)	: Dispose as hazardous waste.
Waste treatment methods	: Recover the product with absorbent material. Dispose of contents/container in accordance with licensed collector's sorting instructions.
Waste disposal recommendations	: Dispose in a safe manner in accordance with local/national regulations.
Ecology - waste materials	: Avoid release to the environment.
European List of Waste (LoW) code	: 18 01 06* - chemicals consisting of or containing dangerous substances

SECTION 14: TRANSPORT INFORMATION

In accordance with ADR / RID / IMDG / IATA / ADN

14.1. UN number

Not regulated for transport

14.2. UN proper shipping name

14.3. Transport hazard class(es)

14.4. Packing group

14.5. Environmental hazards

Dangerous for the environment : No

Other information : No supplementary information available

14.6. Special precautions for user

14.7. Transport in bulk according to Annex II of MARPOL 73/78 and the IBC Code

Not applicable

SECTION 15: REGULATORY INFORMATION

15.1. Safety, health and environmental regulations/legislation specific for the substance or mixture

EU-Regulations

Contains no REACH substances with Annex XVII restrictions

Contains no substance on the REACH candidate list

Contains no REACH Annex XIV substances

National regulations

EC-regulation 453/2010/EC, 1907/2006/EC (REACH), 1272/2008/EC (CLP), 790/2009/EC. Transport of dangerous goods (ADR/RID, IMDG, IATA/ICAO). Workplace exposure limits.

15.2. Chemical safety assessment

No chemical safety assessment has been carried out for the substance or the mixture by the supplier

SECTION 16: OTHER INFORMATION

Indication of changes:

Regulatory information.

2.1	Classification according to Directive 67/548/EEC [DSD] or 1999/45/EC [DPD]	Removed	
2.1	Hazard statements (CLP)	Added	Skin Sens. 1: H317
2.2	Hazard statements (CLP)	Added	Skin Sens. 1: H317
2.2	Signal word (CLP)	Added	Warning
2.2	Hazard symbols	Added	GHS07
3.2	Classification according to Directive 67/548/EEC [DSD] or 1999/45/EC [DPD]	Removed	

Data sources : EC-regulation 453/2010/EC, 1907/2006/EC (REACH), 1272/2008/EC (CLP), 790/2009/EC. Transport of dangerous goods (ADR/RID, IMDG, IATA/ICAO). Workplace exposure limits.

Date of issue : 28/01/2004

Revision date : 25/09/2015

Supersedes : 13/05/2013

Signature : A. Åsebø Murel

Full text of H- and EUH-statements:

Aquatic Acute 1	Hazardous to the aquatic environment — Acute Hazard, Category 1
Aquatic Chronic 1	Hazardous to the aquatic environment — Chronic Hazard, Category 1
Eye Irrit. 2	Serious eye damage/eye irritation, Category 2
Skin Irrit. 2	Skin corrosion/irritation, Category 2
Skin Sens. 1	Sensitisation — Skin, Category 1
H315	Causes skin irritation
H317	May cause an allergic skin reaction
H319	Causes serious eye irritation
H400	Very toxic to aquatic life
H410	Very toxic to aquatic life with long lasting effects

The information in this safety data sheet is based on information from the manufacturer/supplier, present European and national legislation, and presupposes that the product is used within the specified area of application.