

SAFETY DATA SHEETS

This SDS packet was issued with item:

074264941

The safety data sheets (SDS) in this packet apply to one or more components included in the items listed below. Items listed below may require one or more SDS. Please refer to invoice for specific item number(s).

074265005 070371872 074264420 074264784 074264800 074264818 074264826 074264834 074264842 074264859
074264867 074264875 074264883 074264891 074264909 074264917 074264925 074264933 074264958 074264966
074264974 074264982 074264990 074265013 074265021 074265039 074265047 074265054

KERR

Material Safety Data Sheet

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

Revision Date: 05th September 2008

SECTION 1

Product & Company identification

1.1 Product name

HERCULITE XRV (all shades)

1.2 Uses/Application:

Dental restorative material.

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)

None (Enamel & Dentin shades);

Sensitizing (Incisal shade only).

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 Hazardous ingredients

HAZARDOUS INGREDIENTS	%	HAZARD SYMBOLS	RISK PHRASES	CAS N.	EINECS N.
1,6 Hexanediol Diacrylate*	2 - 3	Xi	36/38-43	13048-33-4	235-921-9
Zinc Oxide (ZnO)	< 0,1	N	50-53	1314-13-2	215-222-5

* Contained only in Incisal shade.

3.2 Other non-hazardous ingredients

Uncured Methacrylate Ester Monomers, Titanium Dioxide (TiO₂) and pigments.

SECTION 4**First aid measures**

- 4.1 Treatment for eye contact: Flush with water for 15 minutes including under eyelids.
- 4.2 Treatment for skin contact: Wash thoroughly with soap and water.
- 4.3 Treatment for inhalation (breathing): Remove to fresh air - get medical attention if discomfort persists.
- 4.4 Treatment for ingestion (swallowing): Rinse mouth out with water - do not induce vomiting. Seek medical attention

SECTION 5**Fire-fighting Measures**

- 5.1 Suitable extinguishing media: Chemical foam, CO₂, dry chemical.
- 5.2 Forbidden extinguishing media: Unknown.
- 5.3 Special fire fighting measures: None. Wear a self contained breathing apparatus.
- 5.4 Unusual fire and explosion hazards: Heat can cause polymerization with rapid release of energy.
- 5.5 Special protection equipment: Sealed overall against liquids and gases.

SECTION 6**Accidental Release Measures**

- 6.1 Personal Precautions: Follow recommended precautions listed in other sections.
- 6.2 Environmental Precautions: Material should not be allowed to drain into sewers.
- 6.3 Reclaiming Methods: Absorb with inert material. Prevent spilled material to reach sewers.

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. Avoid exposure to excessive heat.
- 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): Original sealed containers provided by manufacturer.
- 7.5 Indication for Combined Storage: Avoid the contact with reducing and oxidizing agents, peroxides and amines.
- 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:	TiO₂ PEL/TLV: 3,1ppm (10mg/m ³); ZnO TWA: 0,6ppm (2 mg/m ³); STEL: 3 ppm (10 mg/m ³)
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 to control airborne levels of vapours released by uncured material. <u>Special Ventilation:</u> None required. <u>Mechanical (General) Ventilation:</u> Good general ventilation recommended. <u>Other Ventilation:</u> None required.
Respiratory Protection:	Avoid prolonged or excessive breathing of vapours of uncured material
Hands Protection:	Impervious rubber gloves recommended when contacting uncured material
Eyes Protection:	Not required if used as directed. 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.
<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

<u>Appearance:</u> Pigmented paste	<u>Odour:</u> Fruity ester-like odour.
9.2 Information related to health, safety and environment	
<u>pH:</u> Not available	<u>Relative density:</u> Not determined
<u>Boiling point:</u> Not determined (N/D)	<u>Specific gravity:</u> 2,4 g/ml
<u>Flash point:</u> Not determined	<u>Solubility:</u> Insoluble
<u>Flammability:</u> Not flammable.	<u>Partition coefficient n-octanol/water:</u> N/D
<u>Lower Explosivity Limit (L.E.L.):</u> N/A	<u>Viscosity:</u> Not determined
<u>Upper Explosivity Limit (U.E.L.):</u> N/A	<u>Vapour density (air = 1):</u> Not determined
<u>Oxidizing properties:</u> None	<u>Evaporation rate (n-butane = 1):</u> Not determined
<u>Vapour pressure:</u> Not determined	<u>Melting point:</u> Not determined
9.3 Other information (according to communitarian directive 94/9/EC):	
<u>Miscibility:</u> Not determined	<u>Conducibility:</u> Not determined
<u>Solubility in Lipids:</u> Not determined	<u>Gases Group:</u> N/A

SECTION 10**Stability and Reactivity**

Stability: Stable if stored as directed.

10.1 Conditions to avoid: Heat, light, aging and contamination.

10.2 Materials to avoid (incompatibility): Reducing and oxidizing agents, peroxides and amines.

10.3 Hazardous decomposition products: Carbon oxides.

Other precautions:

Hazardous Polymerization Products: May occur

Safety significance in case of change in physical appearance: None

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

SECTION 11**Toxicological Information**

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

No

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

Effects and hazards of skin contact: Prolonged or repeated exposure to uncured material may cause irritation or skin rash especially in sensitive individuals.

Effects and hazards of Inhalation (Breathing): Prolonged or excessive inhalation may cause respiratory tract irritation.

Effects and hazards of Ingestion (Swallowing): Uncured material may be harmful if swallowed.

Effects for prolonged Exposure: Unknown.

Toxic-kinetic effects: Unknown.

Effects on metabolism: Unknown.

Toxicological data for ingredients:

Titanium Dioxide	LD ₅₀ (oral rat)	> 20000 mg/Kg
	LD ₅₀ (skin rabbit)	> 10000 mg/Kg
	LC ₅₀ (inhalation rat/4hrs)	> 6,8 mg/l
ZnO (Acute toxicity):	LD ₅₀ (oral mouse)	7950 mg/Kg
	LD ₅₀ (skin rat)	> 2000 mg/Kg
	LD _{Lo} (oral human)	500 mg/Kg
	LC ₅₀ (inhalation rat/4hrs)	> 5700 mg/m ³ (4 hrs)

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:

Titanium Dioxide	LC ₅₀ (Leuciscus Idus)	> 1000 mg/l (48 hours)
	EC ₅₀ (Daphnia magna, crustacea)	> 3 mg/l (30days)
	EC ₅₀ (Pseudomonas fluorescens)	> 10000 mg/l (24 hours)
ZnO	EC ₅₀ (Daphnia magna)	> 1000 mg/l (48 hrs)
	LC ₅₀ (Oncorhynchus mykiss)	1,1 mg/l (96 hrs)
	LC ₅₀ (Lepomis macrochirus)	> 320 mg/l (96 hrs)
	LC ₅₀ (Pimephales promelas)	2246 mg/l (96 hrs)
	EC ₅₀ (Selenastrum capricornutum)	0,17 mg/l (72 hr; Lisec 1997)

SECTION 13**Disposal considerations**

Unpolymerized (uncured) material may be hazardous waste. 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

- 43 May cause sensitisation by skin contact.
 36/38 Irritating to eyes and skin.
 50 Very toxic to aquatic organisms.
 53 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.
 26 In case of contact with eyes, rinse immediately with plenty of water and seek medical advice.
 39 Wear eye/face protection.

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.

SAFETY DATA SHEET

Section 1. Product And Company Identification

Product Name: Herculite XRV

Product Use: Dental product: Composite

Manufacturer: Kerr Corporation
1717 W. Collins Ave.
Orange, CA 92867-5422
U.S.A.

Information Phone Number: 1-800-841-1428 (Customer Service)

Chemical Emergency Phone Number (Chemical Spills, Leaks, Fire, Exposure or Accident only):
CHEMTREC 1-800-424-9300 (in the US) 1-703-527-3887 (Outside the US)

SDS Date of Preparation/Revision: January 3, 2019

Section 2. Hazards Identification

GHS Classification:

Acute Oral Toxicity Category 4

Skin Irritation Category 2

Eye Irritation Category 2A

Specific Target Organ Toxicity Single Exposure Category 3

Label Elements:

Warning!



Hazard Phrases

Harmful if swallowed.

Causes serious eye irritation.

Causes skin irritation.

May cause respiratory irritation.

Precautionary Phrases:

Do not breathe dust or vapors.

Wash thoroughly after handling.

Do not eat, drink or smoke when using this product.

Use only outdoors or in a well-ventilated area.

Wear protective gloves/protective clothing/eye protection/face protection.

IF SWALLOWED: Call a POISON CENTER or doctor/physician if you feel unwell. Rinse mouth.

IF ON SKIN: Wash with plenty of soap and water.

IF INHALED: Remove victim to fresh air and keep at rest in a position comfortable for breathing.

IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.
Store locked up.
Dispose of contents and container in accordance with local and national regulations.

Section 3. Composition/Information on Ingredients

Component	CAS No.	Amount
7,7,9(or 7,9,9)-trimethyl-4,13-dioxo-3,14-dioxo-5,12-diazahexadecane-1,16-diyl bismethacrylate	72869-86-4	5-10%
Poly(oxy-1,2-ethanediyl), α,α' -[(1-methylethylidene)di-4,1-phenylene]bis[ω -[(2-methyl-1-oxo-2-propen-1-yl)oxy]-	41637-38-1	5-10%
1,6-hexanediyl bismethacrylate	6606-59-3	5-10%
2,2'-ethylenedioxydiethyl dimethacrylate	109-16-0	5-10%
Hexamethylene diacrylate	13048-33-4	1-5%
3-trimethoxysilylpropyl methacrylate	2530-85-0	1-5%

Section 4. First Aid Measures

Inhalation: Immediately remove victim to fresh air. If breathing is difficult, oxygen should be administered by qualified personnel. If breathing has stopped, administer artificial respiration. Get immediate medical attention.

Skin Contact: Flush thoroughly with water. Get medical attention if irritation or symptoms of exposure develop. Remove and launder contaminated clothing before re-use.

Eye Contact: Rinse thoroughly with water. Get medical attention if irritation occurs and persists.

Ingestion: Do NOT induce vomiting. Rinse mouth with water. Never give anything by mouth to an unconscious or convulsing person. Keep the victim calm and warm. Get immediate medical attention.

Most important symptoms and effects, acute and delayed: Causes serious eye irritation and skin irritation. May cause respiratory irritation. Exposure to decomposition products may cause a health hazard. Serious effects may be delayed following exposure. Harmful if swallowed. Irritating to mouth, throat and stomach.

Indication of immediate medical attention and special treatment, if needed: None required under normal conditions of use.

Section 5. Fire Fighting Measures

Suitable (and Unsuitable) Extinguishing Media: Use any media appropriate for the surrounding fire. Cool fire exposed containers with water.

Specific Hazards Arising from the Chemical: Combustion may produce carbon dioxide, carbon monoxide, nitrogen oxides, and metal oxides.

Special Protective Equipment and Precautions for Fire-fighters: Firefighters should wear positive pressure self-contained breathing apparatus and full protective clothing for fires in areas where chemicals are used or stored. Cool fire-exposed containers with water. Contain water used in firefighting from entering sewers or natural waterways.

Section 6: Accidental Release Measures

Personal precautions, Protective equipment, and Emergency procedures: Evacuate spill area and keep unprotected personnel away. Avoid contact with eyes, skin and clothing. Wear appropriate protective clothing and equipment.

Environmental Precautions: Avoid releases to the environment. Report spill as required by local and federal regulations.

Methods and Materials for Containment and Cleaning up: Prompt cleanup and removal are necessary. Absorb spills with an inert material and place in an appropriate waste disposal container.

Section 7. Handling and Storage

Precautions for Safe Handling: Prevent contact with eyes, skin and clothing. Always wear impervious gloves, chemical safety goggles and protective clothing when handling this material. Wash thoroughly with soap and water after handling. Do not eat, drink or smoke in the work area. Remove and wash contaminated clothing before reuse.

Empty containers retain product residues which can be hazardous. Follow all SDS precautions when handling empty containers.

Conditions for Safe Storage, Including any Incompatibilities: Store in a cool, dry, well-ventilated area away from direct sunlight. Keep in the original container or an approved alternative made from a compatible material, kept tightly closed when not in use. Containers that have been opened must be carefully resealed and kept upright to prevent leakage. Do not store in unlabeled containers.

Section 8. Exposure Controls / Personal Protection

Exposure Limits

Chemical	Exposure Limit
7,7,9(or 7,9,9)-trimethyl-4,13-dioxo-3,14-dioxa-5,12-diazahexadecane-1,16-diyl bismethacrylate	None Established
Poly(oxy-1,2-ethanediyl), α,α' -[(1-methylethylidene)di-4,1-phenylene]bis[ω -(2-methyl-1-oxo-2-propen-1-yl)oxy]-	None Established
1,6-hexanediyl bismethacrylate	None Established
2,2'-ethylenedioxydiethyl dimethacrylate	None Established
Hexamethylene diacrylate	1 mg/m ³ TWA AIHA WEEL
3-trimethoxysilylpropyl methacrylate	None Established

Appropriate Engineering Controls: Use with adequate general or local exhaust ventilation to maintain exposure levels below the occupational exposure limits.

Respiratory Protection: None under normal use conditions with adequate ventilation. For operations where the occupational exposure limits are exceeded, an approved respirator with particulate cartridges is recommended. Equipment selection depends on contaminant type and concentration. Select in accordance with applicable regulations and good industrial hygiene practice. For firefighting, use self-contained breathing apparatus.

Hand protection: Impervious gloves are suggested to prevent skin contact. Contact your glove supplier for selection assistance.

Eye Protection: Chemical safety goggles are recommended if contact is possible.

Skin Protection: Wear protective clothing as needed to avoid skin contact and contamination of personal clothing.

Hygiene measures: Suitable eye and skin washing facilities should be available in the work area.

Section 9. Physical and Chemical Properties

Appearance:	Various colored paste	Odor:	Fruity
Odor Threshold:	Not available	pH:	Not available
Melting/Freezing Point:	Not available	Boiling Point/Range:	Not available
Flash Point:	Not flammable	Evaporation Rate:	Not available
Flammability: (Solid, Gas)	Not applicable	Flammability Limits:	LEL: Not applicable UEL: Not applicable
Vapor Pressure:	Not available	Vapor Density:	Not available
Relative Density:	2.5	Solubilities:	Insoluble in water
Partition Coefficient: (N-Octanol/Water)	Not available	Autoignition Temperature:	Not available
Decomposition Temperature:	Not available	Viscosity:	Not available

Section 10. Stability and Reactivity

Reactivity: The product is not expected to be reactive.

Chemical Stability: Stable under normal storage and handling conditions.

Possibility of Hazardous Reactions: Hazardous polymerization will not occur.

Conditions to avoid: Avoid high temperatures, flames, sparks, and all sources of ignition. Heat can cause polymerization with rapid release of energy.

Incompatible Materials: Oxidizing materials, reducing materials, peroxide, amine.

Hazardous decomposition products: None if stored normally.

Section 11. Toxicological Information

Potential Health Effects:

Inhalation: May cause respiratory irritation. Exposure to decomposition products may cause a health hazard.

Skin Contact: Causes skin irritation.

Eye Contact: Causes serious eye irritation.

Ingestion: Harmful if swallowed. Irritating to mouth, throat and stomach.

Chronic Hazards: None expected.

Skin Sensitization: May cause an allergic skin reaction.

Respiratory Sensitization: No data available. This product is not expected to cause respiratory sensitization.

Germ Cell Mutagenicity: None of the components are mutagenic.

Carcinogen: None of the components are listed as a carcinogen or potential carcinogen by IARC, NTP, ACGIH, or OSHA.

Developmental / Reproductive Toxicity: None of the components have been shown to cause reproductive or developmental toxicity.

Specific Target Organ Toxicity (Single Exposure): By prolonged exposure, may cause minor irritation to the respiratory tract and to other mucous membranes.

Specific Target Organ Toxicity (Repeated Exposure): No data available.

Aspiration Toxicity: Not an aspiration hazard.

Acute Toxicity Values:

2,2'-ethylenedioxydiethyl dimethacrylate: LD50 Oral rat: 10837 mg/kg

Hexamethylene diacrylate: LD50 Oral rat: 5000 mg/kg; LD50 Dermal rabbit: 3600 mg/kg

3-trimethoxysilylpropyl methacrylate: LD50 Oral rat: 23504 mg/kg

Section 12. Ecological Information

Toxicity: No data available

Persistence and degradability: Biodegradation is not applicable to inorganic substances.

Bioaccumulative Potential:

7,7,9(or 7,9,9)-trimethyl-4,13-dioxo-3,14-dioxo-5,12-diazaheptadecane-1,16-diyl bismethacrylate:

log P_{ow} 3, potential for bioaccumulative is low

Poly(oxy-1,2-ethanediyl), α,α' -[(1-methylethylidene)di-4,1-phenylene]bis[ω -[(2-methyl-1-oxo-2-propen-1-yl)oxy]- has a BCF of 2372, log P_{ow} 3.43 to 5.62, potential for bioaccumulative is high

2,2'-ethylenedioxydiethyl dimethacrylate: log P_{ow} 1.88, potential for bioaccumulative is low

Hexamethylene diacrylate: log P_{ow} 2.81, potential for bioaccumulative is low

3-trimethoxysilylpropyl methacrylate : log P_{ow} 2.1, potential for bioaccumulative is low

Mobility in Soil: No data available.

Other Adverse Effects: No data available.

Section 13. Disposal Considerations

Disposal: For unused product, dispose of in accordance with Federal and local regulations.

Container Disposal: Dispose of empty container in accordance with Federal and local regulations.

Section 14. Transport Information

	UN Number	UN Proper Shipping Name	Hazard Class(s)	Packing Group	Environmental Hazards
US DOT	None	Not Regulated			None
EU ADR/RID	None	Not Regulated			None
IMDG	None	Not Regulated			None
IATA/ICAO	None	Not Regulated			None

Special Precautions for User: Transport within user's premises: always transport in closed containers that are upright and secure. Ensure that persons transporting the product know what to do in the event of an accident or spillage.

Transport in Bulk According to Annex II MARPOL 73/78 and the IBC Code: Not applicable – product is transported only in packaged form.

Section 15. Regulatory Information

U.S. Federal Regulations:

EPA SARA 311/312 Hazard Classification: Refer to Section 2 for OSHA Hazard Classification.

EPA SARA 313: This Product Contains the Following Chemicals Subject to Annual Release Reporting Requirements Under SARA Title III, Section 313 (40 CFR 372): None

Protection Of Stratospheric Ozone: This product is not known to contain or to have been manufactured with ozone depleting substances as defined in 40 CFR Part 82, Appendix A to Subpart A.

CERCLA SECTION 103: This product is not subject to CERCLA reporting requirements; however, many states have more stringent release reporting requirements. Report spills required under federal, state and local regulations.

International Inventories

US EPA TSCA Inventory: All of the components of this product are listed on the Toxic Substances Control Act (TSCA) Chemical Substances Inventory or exempt.

Canada CEPA: All of the components of this material are listed on the DSL or exempt.

Section 16. Other Information

Effective Date: January 3, 2019



Supersedes Date: February 26, 2015

Revision Summary: All Sections – New SDS format

The information and recommendations set forth herein are taken from sources believed to be accurate as of the date of preparation, however, KERR Corporation makes no warranty with respect to the accuracy or suitability of the recommendations, and assumes no liability to any use thereof.