

SAFETY DATA SHEET

Herculite® Ultra

Section 1. Identification

Product name : Herculite® Ultra
Other means of : Not available.

identification

Product type : Paste.

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

Product use : Dental product: Composite

Manufacturer : Kerr Australia Pty Limited

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North Ryde, NSW 2113

Australia

Telephone no.: 1 800 643 603

Email general queries: kerraust.orders@sybrondental.com

Emergency telephone number (with hours of operation) : 61 401 690 670 (24 hours)

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Section 2. Hazards identification

HSNO Classification : 6.1 - ACUTE TOXICITY (oral) - Category D

6.1 - ACUTE TOXICITY (dermal) - Category E

6.3 - SKIN IRRITATION - Category A

6.4 - EYE IRRITATION - Category A (Irritant) 6.5 - SENSITIZATION - Category B (Skin)

6.8 - REPRODUCTIVE AND DEVELOPMENTAL TOXICITY (Fertility) - Category B

6.8 - REPRODUCTIVE AND DEVELOPMENTAL TOXICITY (Unborn child) -

Category B

9.1 - AQUATIC ECOTOXICITY - Category C

Percentage of the mixture consisting of ingredient(s) of unknown toxicity: 46.5% Percentage of the mixture consisting of ingredient(s) of unknown hazards to the

aquatic environment: 100%

Health effects are based on the uncured material.

This material is classified as hazardous according to criteria in the Hazardous Substances (Minimum Degrees of Hazard) Regulations 2001 and has been classified according to the Hazardous Substances (Classifications) Regulations 2001.

This material is not classified as a dangerous good according to criteria in New Zealand Standard 5433:2007 Transport of Dangerous Goods on Land.

GHS label elements

Signal word : Warning

Hazard statements: Harmful if swallowed.

May be harmful in contact with skin.

Causes skin irritation.
Causes serious eye irritation.
May cause an allergic skin reaction.

Suspected of damaging fertility or the unborn child. Harmful to aquatic life with long lasting effects.

Precautionary statements



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Section 2. Hazards identification

Prevention

: Obtain special instructions before use. Do not handle until all safety precautions have been read and understood. Use personal protective equipment as required. Wear protective gloves. Wear eye or face protection. Avoid release to the environment. Avoid breathing vapour. Do not eat, drink or smoke when using this product. Wash thoroughly after handling. Contaminated work clothing should not be allowed out of the workplace.

Response

: IF SWALLOWED: Rinse mouth. IF ON SKIN: Take off contaminated clothing and wash before reuse. Wash with plenty of soap and water. IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing. Wash hands after handling. IF exposed or concerned: Call a POISON CENTER or doctor/physician if you feel unwell. Get medical advice/attention.

Storage

: Store locked up.

Disposal

: Dispose of contents and container in accordance with all local, regional, national and international regulations.

Symbol





Other hazards which do not : None known.

result in classification

Section 3. Composition/information on ingredients

Substance/mixture : Mixture Other means of

identification

: Not available.

CAS number/other identifiers

CAS number : Not applicable.

EC number : Mixture. : Not available. **Product code**

Ingredient name	%	CAS number
Enamel / Dentin	>=90	-
glass, oxide, chemicals	>=35 - <50	65997-17-3
Silica, amorphous, fumed, crystfree	>=10 - <15	112945-52-5
Silanamine, 1,1,1-trimethyl-N-(trimethylsilyl)-, hydrolysis products with	>=10 - <15	68909-20-6
silica		
7,7,9(or 7,9,9)-trimethyl-4,13-dioxo-3,14-dioxa-5,12-diazahexadecane-1,	>=10 - <20	72869-86-4
16-diyl bismethacrylate		
2,2-bis(acryloyloxymethyl)butyl acrylate	>=10 - <20	15625-89-5
3-trimethoxysilylpropyl methacrylate	>=1 - <5	2530-85-0
2-ethylhexyl 4-(dimethylamino)benzoate	<1	21245-02-3

There are no additional ingredients present which, within the current knowledge of the supplier and in the concentrations applicable, are classified as hazardous to health or the environment and hence require reporting in this section.

Occupational exposure limits, if available, are listed in Section 8.

Section 4. First-aid measures

Description of necessary first aid measures

Inhalation

: No special measures required. If inhaled, remove to fresh air. Get medical attention if symptoms occur.

Ingestion

: Wash out mouth with water. If material has been swallowed and the exposed person is conscious, give small quantities of water to drink. Stop if the exposed person feels sick as vomiting may be dangerous. Get medical attention if adverse health effects persist or are severe.



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Section 4. First-aid measures

Skin contact : No special measures required. In case of contact, immediately flush skin with plenty

of water. Get medical attention if symptoms occur.

Eye contact: No special measures are required. In case of contact with eyes, rinse immediately

with plenty of water. Get medical attention if symptoms occur.

Most important symptoms/effects, acute and delayed

Potential acute health effects

Inhalation : Exposure to decomposition products may cause a health hazard. Serious effects

may be delayed following exposure.

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

Skin contact : May be harmful in contact with skin. Causes skin irritation. May cause an allergic

skin reaction.

Eye contact : Causes serious eye irritation.

Over-exposure signs/symptoms

Inhalation : Adverse symptoms may include the following:

reduced foetal weight increase in foetal deaths skeletal malformations

Ingestion : Adverse symptoms may include the following:

reduced foetal weight increase in foetal deaths skeletal malformations

Skin : Adverse symptoms may include the following:

irritation redness

reduced foetal weight increase in foetal deaths skeletal malformations

Eyes : Adverse symptoms may include the following:

pain or irritation watering redness

Indication of immediate medical attention and special treatment needed, if necessary

Specific treatments: Not available.

Notes to physician : In case of inhalation of decomposition products in a fire, symptoms may be delayed.

The exposed person may need to be kept under medical surveillance for 48 hours.

Protection of first-aiders : In case of major fire and large quantities: No action shall be taken involving any

personal risk or without suitable training. It may be dangerous to the person providing aid to give mouth-to-mouth resuscitation. Wash contaminated clothing

thoroughly with water before removing it, or wear gloves.

See toxicological information (Section 11)

Section 5. Fire-fighting measures

Extinguishing media

Suitable: Use an extinguishing agent suitable for the surrounding fire.

Not suitable : None known.

Specific hazards arising from the chemical

: In a fire or if heated, a pressure increase will occur and the container may burst. This material is harmful to aquatic life with long lasting effects. Fire water contaminated with this material must be contained and prevented from being

discharged to any waterway, sewer or drain.

Hazardous thermal decomposition products

: Decomposition products may include the following materials:

carbon dioxide carbon monoxide nitrogen oxides metal oxide/oxides

Hazchem code : Not available.

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Section 5. Fire-fighting measures

Special precautions for firefighters : In case of major fire and large quantities: Promptly isolate the scene by removing all persons from the vicinity of the incident if there is a fire. No action shall be taken involving any personal risk or without suitable training.

Special protective equipment for fire-fighters

: Fire-fighters should wear appropriate protective equipment and self-contained breathing apparatus (SCBA) with a full face-piece operated in positive pressure mode.

Section 6. Accidental release measures

Personal precautions, protective equipment and emergency procedures : Low release. For professional use only. Handling of product in very small amounts or in situations where release is highly unlikely

Environmental precautions

: Low release. Avoid dispersal of spilt material and runoff and contact with soil, waterways, drains and sewers. Inform the relevant authorities if the product has caused environmental pollution (sewers, waterways, soil or air). Water polluting material. May be harmful to the environment if released in large quantities.

Methods and material for containment and cleaning up

Small spill

: Small Quantity. For professional use only. Absorb with an inert material and place in an appropriate waste disposal container.

Large spill

: Small Quantity. For professional use only. Absorb with an inert material and place in an appropriate waste disposal container.

Section 7. Handling and storage

Precautions for safe handling

: No special measures are required for small quantities under normal and intended conditions of product use. For professional use only. Put on appropriate personal protective equipment (see Section 8). Handle with care and dispose of in a safe manner.

Conditions for safe storage, including any incompatibilities

Store in accordance with local regulations. Store in original container protected from direct sunlight in a dry, cool and well-ventilated area, away from incompatible materials (see Section 10) and food and drink. Keep container tightly closed and sealed until ready for use. Containers that have been opened must be carefully resealed and kept upright to prevent leakage. Do not store in unlabelled containers. Use appropriate containment to avoid environmental contamination.

Section 8. Exposure controls/personal protection

Control parameters

Occupational exposure limits

Ingredient name	Exposure limits
glass, oxide, chemicals	NZ OSH (New Zealand, 2/2013). WES-TWA: 5 f/ml 8 hours. Form: inhalable fiber WES-TWA: 1 f/ml 8 hours. Form:
Silica, amorphous, fumed, crystfree	respirable fiber EH40/2005 WELs (United Kingdom (UK), 12/2011). TWA: 6 mg/m³ 8 hours. Form: inhalable
Silanamine, 1,1,1-trimethyl-N-(trimethylsilyl)-, hydrolysis products with silica	dust TWA: 2.4 mg/m³ 8 hours. Form: respirable dust ACGIH TLV (United States). TWA: 10 mg/m³ 8 hours. Form: Inhalable TWA: 3 mg/m³ 8 hours. Form: Respirable

Recommended monitoring procedures

: If this product contains ingredients with exposure limits, personal, workplace atmosphere or biological monitoring may be required to determine the effectiveness of the ventilation or other control measures and/or the necessity to use respiratory protective equipment. Reference should be made to appropriate monitoring standards. Reference to national guidance documents for methods for the determination of hazardous substances will also be required.



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Section 8. Exposure controls/personal protection

Appropriate engineering controls

Environmental exposure controls

: No special measures are required for small quantities under normal and intended conditions of product use.

: No special measures are required for small quantities under normal and intended conditions of product use.

Individual protection measures

Hygiene measures

: No special measures are required for small quantities under normal and intended conditions of product use.

Respiratory protection

: No special measures are required for small quantities under normal and intended conditions of product use.

Hand protection

Chemical-resistant, impervious gloves complying with an approved standard should be worn at all times when handling chemical products if a risk assessment indicates this is necessary. Considering the parameters specified by the glove manufacturer, check during use that the gloves are still retaining their protective properties. It should be noted that the time to breakthrough for any glove material may be different for different glove manufacturers. In the case of mixtures, consisting of several substances, the protection time of the gloves cannot be accurately estimated.

Eye protection

: Safety eyewear complying with an approved standard should be used when a risk assessment indicates this is necessary to avoid exposure to liquid splashes, mists, gases or dusts. If contact is possible, the following protection should be worn, unless the assessment indicates a higher degree of protection: chemical splash goggles.

Skin protection

: No special measures are required for small quantities under normal and intended conditions of product use.

Section 9. Physical and chemical properties

Appearance

Physical state : Liquid. [Paste.]

Colour : Various

Odour : Fruity ester-like **Odour threshold** : Not available. : Not available. pН **Melting point** : Not available. : Not available. **Boiling point** : Not available. Flash point : Not applicable. **Burning rate Burning time** : Not applicable. : Not available. **Evaporation rate** : Not available. Flammability (solid, gas) : Not available. Lower and upper explosive

(flammable) limits

Vapour pressure : Not available.
Vapour density : Not available.

Relative density : 2.5

Solubility: Insoluble in the following materials: cold water and hot water.

Partition coefficient: n-

octanol/water

: Not available.

Auto-ignition temperature : Not available.

Decomposition temperature : Not available.

SADT : Not available.

Viscosity : Not available.

Aerosol product



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Section 9. Physical and chemical properties

Type of aerosol : Not applicable.

Heat of combustion : Not available.

Ignition distance : Not applicable.

Enclosed space ignition - : Not applicable.

Time equivalent

Enclosed space ignition - Deflagration density

: Not applicable.

Flame height : Not applicable.
Flame duration : Not applicable.

Section 10. Stability and reactivity

Chemical stability : The product is stable.

Possibility of hazardous reactions

: Under normal conditions of storage and use, hazardous reactions will not occur.

Conditions to avoid : Keep away from heat and direct sunlight. Heat can cause polymerization with rapid

release of energy.

Incompatible materials : Reactive or incompatible with the following materials: oxidizing materials and

reducing materials.

Incompatible with peroxides. Amines.

Hazardous decomposition

products

: Under normal conditions of storage and use, hazardous decomposition products

should not be produced.

Under normal conditions of storage and use, hazardous polymerisation will not

occur.

Section 11. Toxicological information

Information on the likely routes of exposure

Inhalation : Exposure to decomposition products may cause a health hazard. Serious effects

may be delayed following exposure.

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

Skin contact : May be harmful in contact with skin. Causes skin irritation. May cause an allergic

skin reaction.

Eye contact : Causes serious eye irritation.

Symptoms related to the physical, chemical and toxicological characteristics

Inhalation : Adverse symptoms may include the following:

reduced foetal weight increase in foetal deaths skeletal malformations

Ingestion : Adverse symptoms may include the following:

reduced foetal weight increase in foetal deaths skeletal malformations

Skin contact: Adverse symptoms may include the following:

irritation redness

reduced foetal weight increase in foetal deaths skeletal malformations

Eye contact : Adverse symptoms may include the following:

pain or irritation watering

redness

Delayed and immediate effects and also chronic effects from short and long term exposure

Acute toxicity



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Section 11. Toxicological information

Product/ingredient name	Result	Species	Dose	Exposure
Enamel / Dentin	LD50 Dermal	Rabbit	>2000 mg/kg	-
	LD50 Oral	Rat	>1000 mg/kg	-
Silica, amorphous, fumed, crystfree	LD50 Oral	Rat	3160 mg/kg	-
2,2-bis(acryloyloxymethyl) butyl acrylate	LD50 Dermal	Rabbit	5170 mg/kg	-
	LD50 Oral	Rat	5709 mg/kg	-
3-trimethoxysilylpropyl methacrylate	LD50 Oral	Rat	23504 mg/kg	-

Conclusion/Summary

: Based on the criteria of the protocol, this product is considered non-cytotoxic per ISO 10993-5.

Irritation/Corrosion

Product/ingredient name	Result	Species	Score	Exposure	Observation
2,2-bis(acryloyloxymethyl) butyl acrylate	Eyes - Moderate irritant	Rabbit	-	100 milligrams	-
	Skin - Moderate irritant	Rabbit	-	24 hours 500 milligrams	-
3-trimethoxysilylpropyl methacrylate	Eyes - Mild irritant	Rabbit	-	24 hours 500 milligrams	-
	Skin - Mild irritant	Rabbit	-	24 hours 500 milligrams	-

Sensitisation

3	Route of exposure	Species	Result
Enamel / Dentin	skin	Guinea pig	Not sensitizing

Potential chronic health effects

General

: No known significant effects or critical hazards.

Inhalation

: No known significant effects or critical hazards.

Ingestion

: No known significant effects or critical hazards.

Skin contact

: Once sensitized, a severe allergic reaction may occur when subsequently exposed

to very low levels.

Eye contact

: No known significant effects or critical hazards.

Carcinogenicity

: No known significant effects or critical hazards.

Mutagenicity

: No known significant effects or critical hazards.

Teratogenicity

: Suspected of damaging the unborn child.

Developmental effects

: No known significant effects or critical hazards.

Fertility effects

: Suspected of damaging fertility.

Chronic toxicity

Not available.

Carcinogenicity

Not available.

Mutagenicity

Product/ingredient name	Test	Experiment	Result
Enamel / Dentin	-	Subject: Bacteria	Negative

Teratogenicity

Not available.

Reproductive toxicity

Not available.

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Section 11. Toxicological information

Specific target organ toxicity

Not available.

Aspiration hazard

Not available.

Numerical measures of toxicity

Acute toxicity estimates

Route	ATE value
	805.7 mg/kg 3723.1 mg/kg

Section 12. Ecological information

Ecotoxicity

: This material is harmful to aquatic life with long lasting effects.

Aquatic and terrestrial toxicity

Not available.

Persistence/degradability

Not available.

Bioaccumulative potential

Product/ingredient name	LogPow	BCF	Potential
7,7,9(or 7,9,9)-trimethyl-4, 13-dioxo-3,14-dioxa-5, 12-diazahexadecane-1, 16-diyl bismethacrylate	3	-	low
2,2-bis(acryloyloxymethyl) butyl acrylate	0.67	-	low
3-trimethoxysilylpropyl methacrylate	2.1	-	low
2-ethylhexyl 4- (dimethylamino)benzoate	5.77	-	high

Mobility in soil

Soil/water partition coefficient (Koc)

: Not available.

Other adverse effects : No known significant effects or critical hazards.

Section 13. Disposal considerations

Disposal methods

: The generation of waste should be avoided or minimised wherever possible.

Disposal of this product, solutions and any by-products should at all times comply with the requirements of environmental protection and waste disposal legislation and any regional local authority requirements.

Section 14. Transport information

Regulatory information	UN number	Proper shipping name	Classes	PG*	Label	Additional information
New Zealand Class	Not regulated.	-	-	-		-
ADG Class	Not regulated.	-	-	-		-
UN Class	Not regulated.	-	-	-		-
ADR/RID Class	Not regulated.	-	-	_		-



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Section 14. Transport information

IATA Class	Not regulated.	-	-	-	-
IMDG Class	Not regulated.	-	-	-	-

PG*: Packing group

Section 15. Regulatory information

New Zealand Inventory of Chemicals (NZIoC)

: Not determined.

HSNO Approval Number HSNO Group Standard Not available.Not available.

HSNO Classification

: 6.1 - ACUTE TOXICITY (oral) - Category D

6.1 - ACUTE TOXICITY (dermal) - Category E

6.3 - SKIN IRRITATION - Category A

6.4 - EYE IRRITATION - Category A (Irritant) 6.5 - SENSITIZATION - Category B (Skin)

6.8 - REPRODUCTIVE AND DEVELOPMENTAL TOXICITY (Fertility) - Category B 6.8 - REPRODUCTIVE AND DEVELOPMENTAL TOXICITY (Unborn child) -

Category B

9.1 - AQUATIC ECOTOXICITY - Category C

Australia inventory (AICS)

Safety, health and environmental regulations specific for the product

Not determined.

: No known specific national and/or regional regulations applicable to this product (including its ingredients).

Section 16. Other information

History

Date of issue/Date of

revision

: 22/12/2014.

Date of previous issue

: No previous validation.

Version
Prepared by

: 1 : IHS

Key to abbreviations

: ADN = European Provisions concerning the International Carriage of Dangerous

Goods by Inland Waterway

ADR = The European Agreement concerning the International Carriage of

Dangerous Goods by Road ATE = Acute Toxicity Estimate BCF = Bioconcentration Factor

GHS = Globally Harmonized System of Classification and Labelling of Chemicals

IATA = International Air Transport Association

IBC = Intermediate Bulk Container

IMDG = International Maritime Dangerous Goods

LogPow = logarithm of the octanol/water partition coefficient

MARPOL 73/78 = International Convention for the Prevention of Pollution From Ships, 1973 as modified by the Protocol of 1978. ("Marpol" = marine pollution)
RID = The Regulations concerning the International Carriage of Dangerous Goods

by Rail

UN = United Nations

References : GHS - Globally Harmonized System of Classification and Labeling of Chemicals

International transport regulations

Indicates information that has changed from previously issued version.

Notice to reader



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Section 16. Other information

To the best of our knowledge, the information contained herein is accurate. However, neither the abovenamed supplier, nor any of its subsidiaries, assumes any liability whatsoever for the accuracy or completeness of the information contained herein.

Final determination of suitability of any material is the sole responsibility of the user. All materials may present unknown hazards and should be used with caution. Although certain hazards are described herein, we cannot guarantee that these are the only hazards that exist.

