MATERIAL SAFETY DATA SHEET

Product Name: Cortoss® Bone Augmentation Material

MSDS Date Created: 25 November, 2014

	Manufacturer	Australian Supplier	New Zealand Supplier
Name:	Orthovita Inc. (dba Stryker Orthobiologics)	Stryker Australia	Stryker New Zealand
Address:	77 Great Valley Parkway Malverns, PA 19355	8 Herbert St, St Leonards, NSW, Australia, 2065	515 Mt Wellington Highway, Auckland, New Zealand, 1060
Phone No:	+610 640 1775	+61 02 9467 1000	+64 09 573 1890
Fax No:	-	+61 02 9467 1010	+64 09 573 1891

1. IDENTIFICATION OF THE MATERIAL AND SUPPLIER

Product Name Cortoss® Bone Augmentation Material

Synonym(s) None

Use ORTHOPAEDIC APPLICATIONS

	Manufacturer	Australian Supplier:	New Zealand Supplier:
Name:	Orthovita Inc. (dba Stryker Orthobiologics)	Stryker Australia	Stryker New Zealand
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Contact Person: John Urtz, john.urtz@stryker.com

2. HAZARDS IDENTIFICATION

CLASSIFIED AS HAZARDOUS ACCORDING TO HAZARDOUS SUBSTANCES [CLASSIFICATION] REGULATIONS 2001 AND SAFE WORK AUSTRALIA CRITERIA

HSNO CLASSIFICATION

6.5B	Substances that are contact sensitisers.
6.8C	Substances that produce toxic human reproductive or developmental effects on or via lactation.

HAZARD STATEMENT

H317	May cause an allergic skin reaction.
H362	May cause harm to breast-fed children.

PREVENTION STATEMENT

P103	Read label before use (applies only where the substance is available to the general public).
P201	Obtain special instructions before use.
P260	Do not breathe dust/fume/gas/mist/vapours/spray.
P261	Avoid breathing dust/fume/gas/mist/vapours/spray.
P263	Avoid contact during pregnancy/while nursing.
P264	Wash thoroughly after handling.
P270	Do not eat, drink or smoke when using this product.
P272	Contaminated work clothing should not be allowed out of the workplace.
P280	Wear protective gloves/protective clothing/eye protection/face protection.

RESPONSE STATEMENT

P321	Specific treatment is advised - see first aid instructions.
P363	Wash contaminated clothing before reuse.
P302 + P352	IF ON SKIN: Wash with plenty of soap and water.
P308 + P313	IF exposed or concerned: Get medical advice/ attention.
P333 + P313	If skin irritation or rash occurs: Get medical advice/attention.

DISPOSAL STATEMENT

P501	In the case of a substance that is in compliance with a HSNO approval other than a Part 6A (Group Standards) approval, a label must provide a description of one or more appropriate and achievable methods for the disposal of a substance in accordance with the Hazardous Substances (Disposal) Regulations 2001. This may also include any method of disposal that must be avoided.

NOT CLASSIFIED AS A DANGEROUS GOOD ACCORDING TO LAND TRANSPORT RULE: DANGEROUS GOODS 2005; NZS 5433:2007, UN, IMDG OR IATA; OR ADG CODE

UN No.	None Allocated	**DG Class**	None Allocated	**Subsidiary Risk(s)**	None Allocated
Packing Group	None Allocated	**Hazchem Code**	None Allocated	**EPG**	None Allocated

3. COMPOSITION/ INFORMATION ON INGREDIENTS

Ingredient	CAS No.	Content
BENZOYL PEROXIDE	94-36-0	<1%
BUTYLATED HYDROXYTOLUENE	128-37-0	<1%
SILANE TREATED BARIUM BOROALUMINOSILICATE	Not Available	25-50%
SILANE TREATED GLASS	Not Available	25-50%
(1-METHYLETHYLIDENE)BIS[4,1-PHENYLENEOXY(2-HYDROXY-3,1-PROPANEDIYL)] BISMETHACRYLATE	1565-94-2	<25%
ETHOXYLATED BISPHENOL A DIMETHACRYLATE	41637-38-1	<25%
TRIETHYLENE GLYCOL DIMETHACRYLATE	109-16-0	<25%
DIMETHYL SILOXANE, WITH SILICONE	67762-90-7	5-15%
2,2'-(P-TOLYIMINO)DIETHANOL	3077-12-1	<1%
OXYBENZONE	131-57-7	<1%

4. FIRST AID MEASURES

Eye If in eyes, remove any contact lenses, hold eyelids apart and flush the eye continuously with running water. Continue flushing until advised to stop by the emergency contact listed above or a doctor, or for at least 15 minutes.

Inhalation If inhaled, remove from contaminated area. To protect rescuer, use a Type A (Organic vapour) respirator or Air-line respirator (in poorly ventilated areas). Apply artificial respiration if not breathing. Seek medical attention immediately.

Skin If skin or hair contact occurs, remove contaminated clothing and flush skin and hair with running water. Continue flushing with water until advised to stop by the emergency contact listed above or a doctor.

Ingestion For advice, contact the emergency contact listed above or a doctor (at once). If swallowed, do not induce vomiting. Ingestion is considered unlikely due to product form.

5. FIRE FIGHTING MEASURES

Flammability Combustible. May evolve toxic gases (carbon oxides, benzene, phenyls, styrene) when heated to decomposition. Styrene will polymerise readily at elevated temperatures and may violently rupture sealed containers. Benzoyl peroxide may evolve benzoic acid, carbon oxides, benzene, biphenyls, phenyl benzoate and terphenyls when heated to decomposition (> 65°C).

Fire and Explosion Evacuate area and contact emergency services. Toxic gases may be evolved in a fire situation. Remain upwind and notify those downwind of hazard. Wear full protective equipment including Self Contained Breathing Apparatus (SCBA) when combating fire. Use waterfog to cool intact containers and nearby storage areas.

Extinguishing Dry agent, carbon dioxide or foam. Prevent contamination of drains or waterways.

Hazchem Code None Allocated

6. ACCIDENTAL RELEASE MEASURES

Spillage If spilt/ containers damaged (bulk), use personal protective equipment. Ventilate area where possible. Contain spillage, then cover / absorb spill with non-combustible absorbant material (vermiculite, sand, or similar), collect and place in suitable containers for disposal. Eliminate all ignition sources. Prevent spill entering drains or waterways.

7. STORAGE AND HANDLING

Storage Store must be stored refrigerated (2-8ºC or 35-46ºF) in a dry location. Storing the material outside these parameter may result in a longer set time and/or compromise the mechanical or chemical characteristics of the product (ie. Failure to set or pre-polymerization in the cartridge).

Handling Do not breath dust. Prohibit contact with eyes, skin or clothing. Use PPE and safe work practices. Utilize good personal hygience practices, wash hands and exposed skin thoroughly with soap and water after use.

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8. EXPOSURE CONTROLS/ PERSONAL PROTECTION

Ingredient	CAS Number	Exposure Guideline
Bisphenol-a-glycidal Dimethacrylate	001565-94-2	Not Available
Bisphenol-a-ethoxy Dimethacrylate	41637-38-1	Not Available
Dihydroxyethyl-para-toluidine	3077-12-1	PEL-TWA = 10 mg/m^3 (Respirable Dust)
Silane-Treated Combeite Glass Ceramic	N/A	PEL-TWA = 15 mg/m^3 (Total Dust) PEL-TWA = 5 mg/m^3 (Respirable Dust) TLV-TWA = 10 mg/m^3
Triethylene Glycol Dimethacrylate	109-16-0	Not Available
Silane-Treated Amorphous Silica	67762-90-7	PEL-TWA = 15 mg/m^3 (Total Dust) PEL-TWA = 5 mg/m^3 (Respirable Dust) TLV-TWA = 10 mg/m^3
Silane-Treated Barium-Boroaluminosilicate Glass	N/A	Not Available
Benzoyl Peroxide	94-36-0	OSHA PEL-TWA = 5 mg/m^3 ACGIH TLV-TWA = 5 mg/m^3
2-Hydroxy-4-Methoxy-Benzophenone	000131-57-7	Not Available
Butylated hydroxy toluene	128-37-0	Not Available

Engineering Controls

Avoid inhalation. Use in well ventilated areas. If capsules/ cartridges are damaged (bulk), mechanical explosion proof extraction ventilation is recommended. Maintain vapour levels below the recommended exposure standard.

PPE

Wear splash-proof goggles and barrier gloves. Where an inhalation risk exists, wear: a Type A (Organic vapour) respirator. With prolonged use, wear: coveralls.

9. PHYSICAL AND CHEMICAL PROPERTIES

Appearance	TWO PASTES AND OFF-WHITE SOLID	**Solubility (Water)**	INSOLUBLE
Odour	SLIGHT ACRYLIC ODOUR	**Specific Gravity**	1.7 to 1.9
pH	12	**% Volatiles**	NOT AVAILABLE
Vapour Pressure	NOT AVAILABLE	**Flammability**	COMBUSTIBLE
Vapour Density	NOT AVAILABLE	**Flash Point**	> 200°C
Boiling Point	NOT AVAILABLE	**Upper Explosion Limit**	NOT AVAILABLE
Melting Point	NOT AVAILABLE	**Lower Explosion Limit**	NOT AVAILABLE
Evaporation Rate	NOT AVAILABLE		

10. STABILITY AND REACTIVITY

The product is stable under normal handling and storage conditions. Avoid humid environments, as this may create sodium hydroxide that affects the polymer matrix. Avoid contact with strong acids.

11. TOXICOLOGICAL INFORMATION

Health Hazard Summary Low to moderate toxicity - irritant. This product has the potential to cause adverse health effects with over exposure. Use safe work practices to avoid eye or skin contact and inhalation. Potential sensitising agent. Due to the nature of use and encapsulation, the risk of exposure to vapours or of skin contamination is reduced. Benzoyl peroxide is not classifiable as to its carcinogenicity in humans (IARC Group 3).

Eye Irritant. Contact may result in irritation, lacrimation, pain, redness and conjunctivitis. May result in burns with prolonged contact. Due to product form and nature of use, the potential for exposure is reduced.

Inhalation Irritant. Over exposure may result in respiratory irritation, coughing, nausea, dizziness and headache. Due to product form, an inhalation hazard is not anticipated with normal use.

Skin Irritant. Contact may result in irritation, redness, pain and rash. May cause sensitisation by skin contact. However, due to product form / nature of use, skin contact is considered unlikely.

Ingestion Ingestion is considered unlikely due to product form. If the container is broken, ingestion may result in nausea, vomiting, and abdominal pain.

Toxicity Data

BENZOYL PEROXIDE (94-36-0)
- Carcinogenicity: Not classifiable as to its carcinogenicity (IARC Group 3)
- LD50 (Ingestion): 5700 mg/kg (mouse)
- LD50 (Intraperitoneal): 250 mg/kg (mouse)
- LD50 (Skin): > 1000 mg/kg (mammal)
- TDLo (Skin): 24000 mg/kg/30 weeks intermittently (mouse)

BUTYLATED HYDROXYTOLUENE (128-37-0)
- LD50 (Ingestion): 650 mg/kg (mouse)
- LD50 (Intraperitoneal): 138 mg/kg (mouse)
- LD50 (Intravenous): 180 mg/kg (mouse)
- LDLo (Ingestion): 940 mg/kg (cat)
- TDLo (Ingestion): 80 mg/kg (woman)

TRIETHYLENE GLYCOL DIMETHACRYLATE (109-16-0)
- LD50 (Ingestion): 10750 mg/kg (mouse)

OXYBENZONE (131-57-7)
- LD50 (Ingestion): 7400 mg/kg (rat)

12. ECOLOGICAL INFORMATION

Environment ATMOSPHERE: Methyl methacrylate will photodegrade (half-life 2.7 hours (urban areas) and > 3 hours (rural areas)). SOIL: Expected to volatilise from soil surface and leach into the groundwater where its fate is unknown. WATER: Principally lost by volatilisation (typical half-life: 6.3 hours). No appreciable adsorption to sediment or particulate matter will occur. BIOLOGICAL: Will biodegrade at a moderate rate. Not expected to bioconcentrate in fish. Aquatic Toxicity: TLm (fathead minnow) is 150 ppm/96 hour. Benzoyl peroxide is expected to have low mobility in soil, and volatilisation from both moist and dry soil surfaces should be important. If released into the atmosphere, benzoyl peroxide will exist both in the vapour and particulate phases in the ambient atmosphere. It is expected to volatilise from water surfaces, and may bioconcentrate in aquatic organisms.

13. DISPOSAL CONSIDERATIONS

Waste Disposal For small quantities, mix with other component/s, absorb with sand, vermiculite or similar and dispose of to an approved landfill site. Contact the manufacturer for additional information. Ensure protective equipment is worn when mixing. Prevent contamination of drains or waterways as aquatic life may be threatened and environmental damage may result.

Legislation Dispose of in accordance with relevant local legislation.

14. TRANSPORT INFORMATION

NOT CLASSIFIED AS A DANGEROUS GOOD ACCORDING TO LAND TRANSPORT RULE: DANGEROUS GOODS 2005; NZS 5433:2007, UN, IMDG OR IATA; OR ADG CODE

Shipping Name	None Allocated				
UN No.	None Allocated	**DG Class**	None Allocated	**Subsidiary Risk(s)**	None Allocated
Packing Group	None Allocated	**Hazchem Code**	None Allocated	**EPG**	None Allocated

15. REGULATORY INFORMATION

Approval Code HSR002670

Group Name Surface Coatings and Colourants (Subsidiary Hazard) Group Standard 2006

HSNO Controls **Refer to the ERMA website for more information: www.ermanz.govt.nz**

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Inventory Listing(s)

AUSTRALIA: AICS (Australian Inventory of Chemical Substances)
All components are listed on AICS, or are exempt

NEW ZEALAND: NZIoC (New Zealand Inventory of Chemicals)
All components are listed on the NZIoC inventory, or are exempt

16. OTHER INFORMATION

Additional Information

This product is used for the treatment of nonunion of tibia of at least 9 month duration, secondary to trauma, in skeletally mature patients, in cases where previous treatment with autograft has failed or use of autograft is unfeasible.

ORGANIC PEROXIDES: Fires involving organic peroxides can be intense and move rapidly due to product rapid decomposition with release of oxygen and may involve explosions. If spilt on combustible materials it may spontaneously ignite. A diluent is often added to organic peroxides to reduce shock sensitivity.

IARC - GROUP 2B - POSSIBLE HUMAN CARCINOGEN. This product contains an ingredient which has demonstrated sufficient evidence to have been classified by the International Agency for Research into Cancer (IARC) as possibly carcinogenic to humans and whose use should be strictly monitored and controlled.

HEALTH EFFECTS FROM EXPOSURE:
It should be noted that the effects from exposure to this product will depend on several factors including: frequency and duration of use; quantity used; effectiveness of control measures; protective equipment used and method of application. Given that it is impractical to prepare a report which would encompass all possible scenarios, it is anticipated that users will assess the risks and apply control methods where appropriate.

PERSONAL PROTECTIVE EQUIPMENT GUIDELINES:
The recommendation for protective equipment contained within this report is provided as a guide only. Factors such as method of application, working environment, quantity used, product concentration and the availability of engineering controls should be considered before final selection of personal protective equipment is made.

Abbreviations

ADB	Air Dry Basis
BEI	Biological Exposure Indice(s)
CAS #	Chemical Abstract Service number – used to uniquely identify chemical compounds
CNS	Central Nervous System
EINECS	European Inventory of Existing Commercial Chemical Substances
IARC	International Agency for Research on Cancer
M	Moles per litre, a unit of concentration
mg/m3	Milligrams per cubic metre
NOS	Not otherwise specified
NTP	National Toxicology Program
OSHA	Occupational Safety and Health Administration
pH	Relates to hydrogen ion concentration using a scale of 0 (high acidic) to 14 (high alkaline)
ppm	Parts per million
RTECS	Registry of Toxic Effects of Chemical Substances
TWA/ES	Time weighted average or exposure standard

Revision history

Revision	Description
1.0	Initial MSDS Creation

END OF MSDS

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