MATERIAL SAFETY DATA SHEET

Product Name: Vitoss™ Scaffold

MSDS Date Created: 02 December, 2014

	Manufacturer	Australian Supplier	New Zealand Supplier
Name:	Orthovita Inc. (dba Stryker Orthobiologics)	Stryker Australia	Stryker New Zealand
Address:	45 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 **Vitoss™ Scaffold**

Synonym(s) BETA-TCP • CALCIUM PHOSPHATE • CALCIUM PHOSPHATE TRIBASIC • TCP • VITOSS SCAFFOLD

Use(s) ORTHOPAEDIC APPLICATIONS

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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. NOT CLASSIFIED AS HAZARDOUS ACCORDING TO THE SAFEWORK AUSTRALIA CRITERIA.

HSNO CLASSIFICATION

6.1E Substances that are acutely toxic.

9.1D Substances that are slightly harmful to the aquatic environment or are otherwise designed for biocidal action.

HAZARD STATEMENT

H303 May be harmful if swallowed.

H401 Toxic to aquatic life.

H402 Harmful to aquatic life.

H413 May cause long lasting harmful effects to aquatic life.

PREVENTION STATEMENT

P102 Keep out of reach of children (applies only where the substance is available to the general public).

P103 Read label before use (applies only where the substance is available to the general public).

P273 Avoid release to the environment. This statement does not apply where this is the intended use.

RESPONSE STATEMENT

P101 If medical advice is needed, have product container or label at hand (applies only where the substance is available to the general public).

P312 Call the emergency contact listed above or a doctor/physician if you feel unwell.

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 THE 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
TRICALCIUM PHOSPHATE	7758-87-4	100%

4. FIRST AID MEASURES

Eye Flush eyes with plenty of water for at least 15 minutes, occasionally lifting the upper and lower lids. Get medical aid.

Inhalation Remove from exposure to fresh air immediately. If not breathing, give artificial respiration. If breathing is difficult,

give oxygen. Get medical aid if cough or other symptoms appear.

Skin Flush skin with plenty of soap and water for at least 15 minutes while removing contaminated clothing and shoes. Get medical aid if irritation develops or persists. Was clothing before reuse.

Ingestion Never give anything by mouth to an unconscious person. Get medical aid. Do NOT induce vomiting. Allow the victim to rinse his mouth and then to drink 2-4 cups of water, and see medical advice.

Advice to Doctor Treat symptomatically

First Aid Facilities Eye wash facilities should be available.

5. FIRE FIGHTING MEASURES

General Information: As in any fire, wear a self-contained breathing apparatus in pressure-demand, MSHA/NIOSH (approved or equivalent), and full protective gear. During a fire, irritating and highly toxic gases may be generated by thermal decomposition or combustion. Vapors may be heavier than air. They can spread along the ground and collect in low or confined areas.

Extinguishing Media: Substance is noncombustible; use agent most appropriate to extinguish surrounding fire. In case of fire use water spay, dry chemical, carbon dioxide, or appropriate foam.

Autoignition Temperature: N/A

Flash Point: N/A. Estimated Health: ; Flammability: ;Reactivity: Explosion Limits, Lower: Not available. Upper: Not available.

6. ACCIDENTAL RELEASE MEASURES

Prevention: Use proper personal protective equipment as indicated in section 8.

Response: Vacuum or sweep up material and place into a suitable disposal container. Reduce airborne dust and prevent scattering by moistening with water. Clean up spills immediately, observing precautions in the Protective Equipment section. Avoid generating dusty conditions. Provide ventilation.

7. STORAGE AND HANDLING

Storage Keep container closed when not in use. Store in a tightly closed container. Store in a cool, dry, well-ventilated area away from incompatible substances.

Handling Wash thoroughly after handling. Wash hands before eating. Use with adequate ventilation. Avoid contact with eyes, skin and clothing. Keep container tightly closed. Avoid ingestion and inhalation.

8. EXPOSURE CONTROLS/ PERSONAL PROTECTION

Exposure Stds No exposure standard(s) allocated.

Engineering Controls Avoid inhalation. Use in well ventilated areas.

PPE Wear dust-proof goggles and rubber or PVC gloves. When using large quantities or where heavy contamination is likely, wear: coveralls. Where an inhalation risk exists, wear: a Class P1 (Particulate) respirator.

9. PHYSICAL AND CHEMICAL PROPERTIES

Appearance	POROUS WHITE SOLID	**Solubility (Water)**	SLIGHTLY SOLUBLE
Odour	SLIGHT ODOUR	**Specific Gravity**	NOT AVAILABLE
pH	NOT AVAILABLE	**% Volatiles**	NOT AVAILABLE
Vapour Pressure	NOT AVAILABLE	**Flammability**	NON FLAMMABLE
Vapour Density	NOT AVAILABLE	**Flash Point**	NOT RELEVANT
Boiling Point	NOT AVAILABLE	**Upper Explosion Limit**	NOT RELEVANT
Melting Point	1670°C	**Lower Explosion Limit**	NOT RELEVANT
Evaporation Rate	NOT AVAILABLE		

10. STABILITY AND REACTIVITY

Chemical Stability	Stable under recommended conditions of storage.
Conditions to Avoid	Avoid heat, sparks, open flames and other ignition sources.
Material to Avoid	Incompatible with oxidising agents (eg. hypochlorites) and acids (eg. nitric acid).
Hazardous Decomposition Products	May evolve toxic gases (phosphorus oxides) when heated to decomposition. May also evolve phosphine and calcium oxides when heated to decomposition.
Polymerization	Polymerization is not expected to occur.

11. TOXICOLOGICAL INFORMATION

Health Hazard Summary	Low toxicity. Use safe work practices to avoid eye or skin contact and inhalation.
Eye	Irritant. Contact may result in irritation, lacrimation, pain and redness.
Inhalation	Low irritant. Over exposure may result in irritation of the nose and throat, with coughing.
Skin	Low to moderate irritant. Prolonged or repeated contact may result in irritation and rash.
Ingestion	Low toxicity. Ingestion of large quantities may result in nausea, vomiting and gastrointestinal irritation. Ingestion of large quantities may also result in serious disturbances in calcium metabolism.
Toxicity Data	No LD50 data available for this product.

12. ECOLOGICAL INFORMATION

Environment	Limited ecotoxicity data was available for this product at the time this report was prepared. Ensure appropriate measures are taken to prevent this product from entering the environment.

13. DISPOSAL CONSIDERATIONS

Waste Disposal	Dispose of to an approved landfill site. Contact the manufacturer for additional information.
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 THE 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	HSR002806
Group Name	Phosphoric acid, calculim salt (2:3)
HSNO Controls	**Refer to the ERMA website for more information: www.ermanz.govt.nz**
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

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 (highly alkaline). ppm - Parts Per Million.
RTECS - Registry of Toxic Effects of Chemical Substances.
TWA/ES - Time Weighted Average or Exposure Standard.

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 Chem Alert 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 Chem Alert 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.

Revision history

Revision	Description
1.0	Initial MSDS Creation

END OF MSDS