

MATERIAL SAFETY DATA SHEET

Product Name: OP-1 Implant

MSDS Date Created: 25 November, 2014

	Manufacturer	Australian Supplier:	New Zealand Supplier:
Name:	Stryker Biotech	Stryker Australia	Stryker New Zealand
Address:	9 Technology Drive West Lebanon, NH 03784	8 Herbert St, St Leonards, NSW, Australia, 2065	515 Mt Wellington Highway, Auckland, New Zealand, 1060
Phone No:	+603 298 3000	+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:** OP-1 Implant**Synonym(s):** Osteogenic Protein 1**Use(s):** MEDICAL APPLICATIONS/ORTHOPAEDIC APPLICATIONS

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EMERGENCY	0800 424 9300	13 11 26	0800 764 766

2. HAZARDS IDENTIFICATION

NOT CLASSIFIED AS HAZARDOUS ACCORDING TO HAZARDOUS SUBSTANCES [CLASSIFICATION] REGULATIONS 2001 AND SAFEWORK AUSTRALIA CRITERIA

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
BOVINE TYPE I COLLAGEN	N/A	>50%
RECOMBINANT HUMAN OSTEOGENIC PROTEIN	N/A	<50%

4. FIRST AID MEASURES

Eye If in eyes, 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. Apply artificial respiration if not breathing.

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 Never give anything by mouth to a victim who is unconscious or is having convulsions. Do not induce vomiting. If ingestion of a large amount does occur, seek medical attention.

Advice to Doctor Treat symptomatically

5. FIRE FIGHTING MEASURES

Flammability Non flammable. May evolve toxic gases if strongly heated.

Fire and Explosion Evacuate area and contact emergency services.

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

Hazchem Code None Allocated

6. ACCIDENTAL RELEASE MEASURES

Spillage Minimize generation of dust. Use high efficiency particulate filter vacuum or wet methods to pick up material. Place material in a closed container.

7. STORAGE AND HANDLING

Storage Protect from heat, light and moisture. Store between +2 and +8 degrees Celcius.

Handling Before use carefully read the product label. Use of safe work practices are recommended to avoid eye or skin contact and inhalation. Observe good personal hygiene, including washing hands before eating. Prohibit eating, drinking and smoking in contaminated areas.

8. EXPOSURE CONTROLS/ PERSONAL PROTECTION

Exposure Stds No exposure standard(s) allocated.

Engineering Controls Avoid inhalation. Use in well ventilated areas. Where an inhalation risk exists, use under a fume cupboard.

PPE Wear dust-proof goggles and rubber or PVC gloves. When handling large quantities, wear coveralls. Where a dust inhalation risk exists, wear a Class P1 (Particulate) respirator.



9. PHYSICAL AND CHEMICAL PROPERTIES

Appearance	OFF-WHITE POWDER	Solubility (Water)	INSOLUBLE
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	NOT AVAILABLE	Lower Explosion Limit	NOT RELEVANT
Evaporation Rate	NOT AVAILABLE		

10. STABILITY AND REACTIVITY

Chemical Stability	Not determined
Incompatibility	Not determined
Hazardous Decomposition Products	Not determined
Polymerization	Polymerization is not expected to occur.

11. TOXICOLOGICAL INFORMATION

Carcinogenicity Not listed as a carcinogen by NTP, OSHA, ACGIH, NIOSH

Acute/Chronic Toxicity Evaluation of this product in animal and human studies has not demonstrated acute or chronic toxic effects or other adverse safety issues

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 Ensure product is covered with moist soil to prevent dust generation and dispose of to approved Council landfill. Contact the manufacturer if additional information is required.

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 Not Available

Group Name Not Available

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 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.

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.

END OF MSDS