# stryker

## **MATERIAL SAFETY DATA SHEET**

## Product Name: Surgical Simplex<sup>®</sup> P Radiopaque Bone Cement

## MSDS Date Created: 29 October, 2014

	Manufacturer	Australian Supplier	New Zealand Supplier
Name:	Howmedica Intl S. de R.L.	Stryker Australia	Stryker New Zealand
Address:	Raheen Business Park	8 Herbert St,	515 Mt Wellington Highway,
	Limerick	St Leonards, NSW,	Auckland,
	Ireland	Australia, 2065	New Zealand, 1060
Phone No:	+353 61498 200	+61 02 9467 1000	+64 09 573 1890
Fax No:	+353 56229 941	+61 02 9467 1010	+64 09 573 1891

Surgical Simplex<sup>®</sup> P Radiopaque Bone Cement is a two component product containing: • Surgical Simplex<sup>®</sup> P Radiopaque Powder

- Surgical Simplex<sup>®</sup> P Liquid

This MSDS includes both components.

## 1. IDENTIFICATION OF THE MATERIAL AND SUPPLIER

#### 1.1 Product identifier

Product nameSURGICAL SIMPLEX® P LIQUIDSynonym(s)STRYKER SIMPLEX® P LIQUID

#### 1.2 Uses and uses advised against

Use(s) MEDICAL DEVICES

#### 1.3 Details of the supplier of the product

	Manufacturer	Australian Supplier	New Zealand Supplier
Name:	Howmedica Intl S. de R.L.	Stryker Australia	Stryker New Zealand
Address:	Raheen Business Park	8 Herbert St,	515 Mt Wellington Highway,
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EMERGENCY	+353 61 498200	13 11 26	0800 764 766

Contact Person: Colette Herbert, colette.herbert@stryker.com

## 2. HAZARDS IDENTIFICATION

#### 2.1 Classification of the substance or mixture

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

#### HSNO classification(s)

3.1B	Flammable liquids: high hazard.
6.1D (inhalation)	Substances that are acutely toxic - Harmful.
6.1E (oral)	Substances that are acutely toxic - May be harmful.
6.3B	Substances that are mildly irritating to the skin.
6.4A	Substances that are irritating to the eye.
6.5B	Substances that are contact sensitisers.
6.9B (inhalation repeated)	Harmful to human target organs or systems.
9.1B	Substances that are ecotoxic in the aquatic environment.
9.3C	Substances that are harmful to terrestrial vertebrates.

#### 2.2 Label elements

Signal word	
Pictogram(s)	

## DANGER



Highly flammable liquid and vapour.
May be harmful if swallowed.
Causes mild skin irritation.
May cause an allergic skin reaction.
Causes serious eye irritation.
Harmful if inhaled.
May cause damage to organs through prolonged or repeated exposure
Toxic to aquatic life with long lasting effects.
Harmful to terrestrial vertebrates.



## SURGICAL SIMPLEX® P RADIOPQUE BONE CEMENT - LIQUID

Prevention	
P102	Keep out of reach of children.
P103	Read label before use.
P210	Keep away from heat/sparks/open flames/hot surfaces. No smoking.
P233	Keep container tightly closed.
P240	Ground/bond container and receiving equipment.
P241	Use explosion-proof electrical/ventilating/lighting equipment.
P242	Use only non-sparking tools.
P243	Take precautionary measures against static discharge.
P260	Do not breathe dust/fume/gas/mist/vapours/spray.
P264	Wash thoroughly after handling.
P271	Use only outdoors or in a well-ventilated area.
P272	Contaminated work clothing should not be allowed out of the workplace.
P273	Avoid release to the environment.
P280	Wear protective gloves/protective clothing/eye protection/face protection.
Response	
P101	If medical advice is needed, have product container or label at hand.
P314	Get medical advice/attention if you feel unwell.
P321	Specific treatment is advised - see first aid instructions.
P331	Do NOT induce vomiting.
P363	Wash contaminated clothing before reuse.
P391	Collect spillage.
P303 + P361 + P353	IF ON SKIN (or hair): Remove/Take off immediately all contaminated clothing. Rinse skin with water/shower.
P304 + P340	IF INHALED: Remove to fresh air and keep at rest in a position comfortable for breathing.
P305 + P351 + P338	IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.
P332 + P337 + P313	If skin or eve irritation occurs: Get medical advice/ attention.
P370 + P378	In case of fire: Use appropriate media for extinction.
Storage	
P403 + P235	Store in a well-ventilated place. Keep cool.
Disposal	
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.

#### 2.3 Other hazards

No information provided.

## 3. COMPOSITION/ INFORMATION ON INGREDIENTS

#### 3.1 Substances / Mixtures

Ingredient	CAS Number	EC Number	Content
METHYL METHACRYLATE	80-62-6	201-297-1	95.98%
N,N-DIMETHYLTOLUDINE	99-97-8	202-805-4	2.3%
HYDROQUINONE	123-31-9	204-617-8	<1%

## 4. FIRST AID MEASURES

#### 4.1 Description of first aid measures

Еуе	If in eyes, hold eyelids apart and flush continuously with running water. Continue flushing until advised to stop by a Poisons Information Centre, 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 an Air-line respirator (in poorly ventilated areas). 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 a Poisons Information Centre or a doctor.
Ingestion	For advice, contact the emergency contact listed above or a doctor (at once). If swallowed, do not induce vomiting.
First aid facilities	No information provided.



#### 4.2 Most important symptoms and effects, both acute and delayed

See Section 11 for more detailed information on health effects and symptoms.

#### 4.3 Immediate medical attention and special treatment needed

Treat symptomatically.

#### 5. FIRE FIGHTING MEASURES

#### 5.1 Extinguishing media

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

#### 5.2 Special hazards arising from the substance or mixture

Highly flammable. May evolve toxic gases (carbon oxides, hydrocarbons) when heated to decomposition. Vapour may form explosive mixtures with air. Eliminate all ignition sources including cigarettes, open flames, spark producing switches/tools, heaters, naked lights, pilot lights, mobile phones etc. when handling. Earth containers when dispensing fluids.

#### 5.3 Advice for firefighters

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.

#### 5.4 Hazchem code

3YE

- 3 Foam
- Y Self Contained Breathing apparatus and protective gloves.
- E Evacuation of people in the vicinity of the incident should be considered.

#### 6. ACCIDENTAL RELEASE MEASURES

#### 6.1 Personal precautions, protective equipment and emergency procedures

Wear Personal Protective Equipment as detailed in Section 8 of the MSDS. Clear area of all unprotected personnel. Contact emergency services where appropriate.

#### 6.2 Environmental precautions

Prevent product from entering drains and waterways.

#### 6.3 Methods of cleaning up

Contain spillage, then cover/absorb spill with non-combustible absorbent material (vermiculite, sand, or similar), collect and place in suitable containers for disposal.

#### 6.4 Reference to other sections

See Sections 8 and 13 for exposure controls and disposal.

## 7. HANDLING AND STORAGE

#### 7.1 Precautions for safe 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.

#### 7.2 Conditions for safe storage, including any incompatibilities

Store in a cool, dry, dark, well-ventilated area, removed from direct sunlight, incompatible substances, heat or ignition sources and foodstuffs. Ensure containers are adequately labelled and protected from physical damage when not in use. Large storage areas should have appropriate ventilation and fire protection systems. Polymerises in light.

#### 7.3 Specific end use(s)

No information provided.



## 8. EXPOSURE CONTROLS / PERSONAL PROTECTION

#### 8.1 Control parameters

#### Exposure standards

Ingredient	Reference	TWA		STEL	
		ppm	mg/m³	ppm	mg/m³
Hydroquinone	WES (NZ)		2		
Methyl methacrylate	WES (NZ)	50	208	100	416

#### **Biological limits**

No biological limit values have been entered for this product.

#### 8.2 Exposure controls

**Engineering controls** Avoid inhalation. Use in well ventilated areas. Where an inhalation risk exists, mechanical explosion proof extraction ventilation is recommended. Flammable/explosive vapours may accumulate in poorly ventilated areas. Vapours are heavier than air and may travel some distance to an ignition source and flash back. Maintain vapour levels below the recommended standard.

#### **Personal Protection Equipment**

**Eye / Face:** Wear safety glasses. When using large quantities or where heavy contamination is likely, wear a faceshield. **Hands:** Wear PVA gloves.

**Body:** Wear coveralls. When using large quantities or where heavy contamination is likely, wear rubber boots and a rubber apron. If spraying, with prolonged use, or if in confined areas, wear impervious coveralls.

**Respiratory:** Wear a Type A-Class P1 (Organic gases/vapours and Particulate) respirator. At high vapour levels, wear a Type A (Organic vapour) respirator. If spraying, with prolonged use, or if in confined areas, wear an Air-line respirator.



## 9. PHYSICAL AND CHEMICAL PROPERTIES

#### 9.1 Information on basic physical and chemical properties

Appearance	COLOURLESS LIQUID
Odour	CHARACTERISTIC ODOUR
Odour threshold	NOT AVAILABLE
рН	NOT AVAILABLE
Melting point	NOT AVAILABLE
Boiling point	100.5°C
Flash point	11.5°C
Evaporation rate	NOT AVAILABLE
Flammability	HIGHLY FLAMMABLE
Upper explosion limit	12.5 % (Methyl methacrylate)
Lower explosion limit	2.1 % (Methyl methacrylate)
Vapour pressure	40 mm Hg @ 25°C
Vapour density	NOT AVAILABLE
Solubility (water)	INSOLUBLE
Partition coefficient	NOT AVAILABLE
Autoignition temperature	NOT AVAILABLE
Decomposition temperature	NOT AVAILABLE
Viscosity	NOT AVAILABLE
Explosive properties	NOT AVAILABLE
Oxidising properties	NOT AVAILABLE
Specific gravity	NOT AVAILABLE
9.2 Other information	
Relative density	0.949 @ 15.5°C
% Volatiles	NOT AVAILABLE
Density	NOT AVAILABLE



## **10. STABILITY AND REACTIVITY**

#### 10.1 Reactivity

In the supplied state, the product is stable and non-reactive. At the time of use, the powder and liquid are mixed, the mixture is designed to result in the exothermic polymeric formation of a soft pliable, dough like mass which as the reaction progresses becomes a hard cement like complex.

#### 10.2 Chemical stability

Stable under recommended conditions of storage.

#### 10.3 Possibility of hazardous reactions

Hydroquine has been added to this product to avoid polymerization of the liquid component of product.

#### 10.4 Conditions to avoid

Avoid heat, sparks, open flames and other ignition sources.

#### 10.5 Incompatible materials

May polymerise in contact with oxidising agents (e.g. nitrates), acids (e.g. nitric acid), amines, UV light, alkalis (e.g. sodium hydroxide), or if heated. Polymerisation may generate heat with potential for fire-explosion.

#### 10.6 Hazardous decomposition products

May evolve carbon oxides and hydrocarbons when heated to decomposition.

## **11. TOXICOLOGICAL INFORMATION**

#### 11.1 Information on toxicological effects

Health hazard summary	Harmful - 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. Chronic exposure may result in fatigue, headache, sleep disturbances, irritability, loss of memory and pains in the extremities. May cause sensitisation by skin contact. Harmful: possible risk of irreversible effects through inhalation, in contact with skin and if swallowed.		
Eye	Irritant. Contact may result in irritation, lacrimation, pain, redness, conjunctivitis and violent itching. May result in burns with prolonged contact.		
Inhalation	Harmful - irritant. Over exposure may rest fatigue. High level exposure may result in and respiratory failure.	sult in irritation of the nose and throat, coughing, headache and n breathing difficulties, chemical pneumonitis, pulmonary oedema	
Skin	Irritant. Contact may result in drying and de skin with harmful effects. May cause sensiti	efatting of the skin, rash and dermatitis. May be absorbed through sation by skin contact.	
Ingestion	Toxic. Ingestion may result in nausea, von may result in dizziness, drowsiness, liver a may cause chemical pneumonitis and pulm	niting, abdominal pain and diarrhoea. Ingestion of large quantities and kidney damage, and unconsciousness. Aspiration or inhalation onary oedema.	
Toxicity data	METHYL METHACRYLATE (80-6 LCLo (inhalation) LD50 (ingestion) LD50 (skin) TCLo (inhalation)	2-6) 17500 mg/kg/4.5 hours (rabbit) 3625 mg/kg (mouse) > 5000 mg/kg (rabbit) 125 ppm (human - behavioural effect)	
	N,N-DIMETHYLTOLUDINE (99-97 LD50 (intraperitoneal)	7-8) 212 mg/kg (mouse)	
	HYDROQUINONE (123-31-9) LD50 (ingestion) LD50 (intraperitoneal) LD50 (intravenous) LD50 (subcutaneous) LDL0 (ingestion) LDL0 (intraperitoneal) LDL0 (intravenous) LDL0 (subcutaneous) TDL0 (ingestion)	70 mg/kg (cat) 100 mg/kg (mouse) 115 mg/kg (rat) 182 mg/kg (mouse) 29 mg/kg (human) 200 mg/kg (guinea pig) 50 mg/kg (cat) 100 mg/kg (dog) 170 mg/kg (human)	

## **12. ECOLOGICAL INFORMATION**



#### 12.1 Toxicity

Toxic to aquatic organisms.

#### 12.2 Persistence and degradability

No information provided.

#### 12.3 Bioaccumulative potential

No information provided.

#### 12.4 Mobility in soil

No information provided.

#### 12.5 Other adverse effects

If emitted into the atmosphere it will rapidly photodegrade. If released into soil or water methyl methacrylate will be principally lost by volatilisation, though in soil some leaching to groundwater will occur. Will biodegrade at a moderate rate. Not expected to bioconcentrate in fish.

## 13. DISPOSAL CONSIDERATIONS

#### 13.1 Waste treatment methods

**Waste disposal** Mix components together (small amounts), absorb with sand, vermiculite or similar and dispose of to an approved landfill site. Ensure protective equipment is worn when mixing. Do not seal containers/tins until reaction is complete. Contact the manufacturer/supplier for additional information (if required). Prevent contamination of drains and waterways as environmental damage may result.

Legislation Dispose of in accordance with relevant local legislation.

## 14. TRANSPORT INFORMATION

#### CLASSIFIED AS A DANGEROUS GOOD ACCORDING TO LAND TRANSPORT RULE: DANGEROUS GOODS 2005; NZS 5433:2012, UN, IMDG OR IATA



	LAND TRANSPORT (NZS 5433)	SEA TRANSPORT (IMDG / IMO)	AIR TRANSPORT (IATA / ICAO)
14.1 UN Number	1247	1247	1247
14.2 Proper Shipping Name	METHYL METHACRYLATE MONOMER, INHIBITED	METHYL METHACRYLATE MONOMER, INHIBITED	METHYL METHACRYLATE MONOMER, INHIBITED
14.3 Transport hazard class	3	3	3
14.4 Packing Group	ll	I	I

**14.5 Environmental hazards** Not a Marine Pollutant

14.6 Special precautions for user

Hazchem code3YEEMSF-E, S-D

## **15. REGULATORY INFORMATION**

## 15.1 Safety, health and environmental regulations/legislation specific for the substance or mixtureApproval codeHSR002495Group standardAdditives, Intermediates, Process Chemicals and Raw Materials (Flammable) Group Standard 2006



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

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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 in conjunction with SURGICAL SIMPLEX<sup>®</sup> P RADIOPAQUE POWDER. Please consult the appropriate MSDS before use.

ACRYLIC - ACRYLAMIDE RESINS: These resins are generally of low toxicity. Toxicity increases with presence of significant concentrations of acrylic - acrylamide monomers. These monomers have been linked with the development of skin sensitisation.

RESPIRATORS: In general the use of respirators should be limited and engineering controls employed to avoid exposure. If respiratory equipment must be worn ensure correct respirator selection and training is undertaken. Remember that some respirators may be extremely uncomfortable when used for long periods. The use of air powered or air supplied respirators should be considered where prolonged or repeated use is necessary.

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#### Abbreviations

ACGIH	American Conference of Governmental Industrial Hygienists
CAS #	Chemical Abstract Service number - used to uniquely identify chemical compounds
CCID	Chemical Classification and Information Database (HSNO)
CNS	Central Nervous System
EC No.	EC No - European Community Number
EPA	Environmental Protection Authority [New Zealand]
GHS	Globally Harmonized System
HSNO	Hazardous Substances and New Organisms
IARC	International Agency for Research on Cancer
LC50	Lethal Concentration, 50% / Median Lethal Concentration
LD50	Lethal Dose, 50% / Median Lethal Dose
mg/m³	Milligrams per Cubic Metre
OEL	Occupational Exposure Limit
PEL	Permissible Exposure Limit
pН	relates to hydrogen ion concentration using a scale of 0 (high acidic) to 14 (highly alkaline).
ppm	Parts Per Million
REACH	Regulation on Registration, Evaluation, Authorisation and Restriction of Chemicals
STEL	Short-Term Exposure Limit
STOT-RE	Specific target organ toxicity (repeated exposure)
STOT-SE	Specific target organ toxicity (single exposure)
TLV	Threshold Limit Value
TWA	Time Weighted Averag



## 1. IDENTIFICATION OF THE MATERIAL AND SUPPLIER

#### 1.1 Product identifier

Product name SURGICAL SIMPLEX® P RADIOPAQUE POWDER

Synonym(s) STRYKER SURGICAL SIMPLEX<sup>®</sup> P RADIOPAQUE POWDER

#### 1.2 Uses and uses advised against

Use(s)

MEDICAL APPLICATIONS • ORTHOPAEDIC APPLICATIONS • TWO COMPONENT PACK

#### 1.3 Details of the supplier of the product

	Manufacturer	Australian Supplier	New Zealand Supplier
Name:	Howmedica Intl S. de R.L.	Stryker Australia	Stryker New Zealand
Address:	Raheen Business Park	8 Herbert St,	515 Mt Wellington Highway,
	Limerick	St Leonards, NSW,	Auckland,
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EMERGENCY	+353 61 498200	13 11 26	0800 764 766

Contact Person: Colette Herbert, colette.herbert@stryker.com

## 2. HAZARDS IDENTIFICATION

#### 2.1 Classification of the substance or mixture

NOT CLASSIFIED AS HAZARDOUS ACCORDING TO SAFE WORK AUSTRLIA CRITERIA AND HAZARDOUS SUBSTANCES [CLASSIFICATION] REGULATIONS 2001

#### HSNO classification(s)

None allocated.

#### 2.2 Label elements

No signal word, pictograms, hazard or precautionary statements have been allocated.

#### 2.3 Other hazards

No information provided.

## 3. COMPOSITION/ INFORMATION ON INGREDIENTS

#### 3.1 Substances / Mixtures

Ingredient	CAS Number	EC Number	Content
POLY(STYRENE-CO-METHYL METHACRYLATE)	25034-86-0	-	90%
BARIUM SULPHATE	7727-43-7	231-784-4	10%

## 4. FIRST AID MEASURES

## 4.1 Description of first aid measures

EyeIf in eyes, hold eyelids apart and flush continuously with running water. Continue flushing until advised to stop by a Poisons Information Centre, a doctor, or for at least 15 minutes.InhalationIf inhaled, remove from contaminated area. Apply artificial respiration if not breathing.SkinIf 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 a Poisons Information Centre or a doctor.IngestionFor 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.First aid facilitiesNo information provided.		
InhalationIf inhaled, remove from contaminated area. Apply artificial respiration if not breathing.SkinIf 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 a Poisons Information Centre or a doctor.IngestionFor 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.First aid facilitiesNo information provided.	Eye	If in eyes, hold eyelids apart and flush continuously with running water. Continue flushing until advised to stop by a Poisons Information Centre, a doctor, or for at least 15 minutes.
SkinIf 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 a Poisons Information Centre or a doctor.IngestionFor 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.First aid facilitiesNo information provided.	Inhalation	If inhaled, remove from contaminated area. Apply artificial respiration if not breathing.
IngestionFor 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.First aid facilitiesNo information provided.	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 a Poisons Information Centre or a doctor.
First aid facilities No information provided.	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.
	First aid facilities	No information provided.



## SURGICAL SIMPLEX® P RADIOPAQUE BONE CEMENT - POWDER

#### 4.2 Most important symptoms and effects, both acute and delayed

Adverse effects not expected from this product under normal conditions of use.

#### 4.3 Immediate medical attention and special treatment needed

Treat symptomatically.

#### 5. FIRE FIGHTING MEASURES

#### 5.1 Extinguishing media

Use an extinguishing agent suitable for the surrounding fire.

#### 5.2 Special hazards arising from the substance or mixture

Non flammable. May evolve toxic gases (carbon oxides, hydrocarbons) when heated to decomposition. Finely divided dust may form explosive mixtures with air.

#### 5.3 Advice for firefighters

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.

#### 5.4 Hazchem code

None allocated.

## 6. ACCIDENTAL RELEASE MEASURES

#### 6.1 Personal precautions, protective equipment and emergency procedures

Wear Personal Protective Equipment (PPE) as detailed in Section 8 of the MSDS. Clear area of all unprotected personnel. Contact emergency services where appropriate.

#### 6.2 Environmental precautions

Prevent product from entering drains and waterways.

#### 6.3 Methods of cleaning up

Contain spillage, then collect and place in suitable containers for reuse or disposal. Avoid generating dust.

#### 6.4 Reference to other sections

See Sections 8 and 13 for exposure controls and disposal.

## 7. HANDLING AND STORAGE

#### 7.1 Precautions for safe 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.

#### 7.2 Conditions for safe storage, including any incompatibilities

Store in a cool, dry, well ventilated area, removed from incompatible substances, heat or ignition sources and foodstuffs. Ensure containers are adequately labelled, protected from physical damage and sealed when not in use. Check regularly for leaks or spills. Large storage areas should have appropriate ventilation systems.

#### 7.3 Specific end use(s)

No information provided.



## 8. EXPOSURE CONTROLS / PERSONAL PROTECTION

#### 8.1 Control parameters

#### Exposure standards

Ingredient	Reference	TWA		STEL	
		ppm	mg/m³	ppm	mg/m³
Barium sulphate	WES (NZ)		10		

#### **Biological limits**

No biological limit values have been entered for this product.

#### 8.2 Exposure controls

Engineering controls Avoid inhalation. Use in well ventilated areas. Maintain dust levels below the recommended exposure standard.

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



## 9. PHYSICAL AND CHEMICAL PROPERTIES

#### 9.1 Information on basic physical and chemical properties

Appearance	FINE WHITE POWDER
Odour	ODOURLESS
Odour threshold	NOT AVAILABLE
рН	NOT AVAILABLE
Melting point	NOT AVAILABLE
Boiling point	NOT AVAILABLE
Flash point	NOT RELEVANT
Evaporation rate	NOT AVAILABLE
Flammability	NON FLAMMABLE
Upper explosion limit	NOT RELEVANT
Lower explosion limit	NOT RELEVANT
Vapour pressure	NOT AVAILABLE
Vapour density	NOT AVAILABLE
Solubility (water)	INSOLUBLE
Partition coefficient	NOT AVAILABLE
Autoignition temperature	NOT AVAILABLE
Decomposition temperature	NOT AVAILABLE
Viscosity	NOT AVAILABLE
Explosive properties	NOT AVAILABLE
Oxidising properties	NOT AVAILABLE
Specific gravity	NOT AVAILABLE
9.2 Other information	
Relative density	0.3 @ 20°C
% Volatiles	NOT AVAILABLE

## **10. STABILITY AND REACTIVITY**



## SURGICAL SIMPLEX® P RADIOPAQUE BONE CEMENT - POWDER

#### 10.1 Reactivity

In the supplied state, the product is stable and non-reactive. At the time of use, the powder and liquid are mixed, the mixture is designed to result in the exothermic polymeric formation of a soft pliable, dough like mass which as the reaction progresses becomes a hard cement like complex. Avoid contact with acids and or oxidizing materials.

#### 10.2 Chemical stability

Stable under recommended conditions of storage.

#### 10.3 Possibility of hazardous reactions

Polymerization is not expected to occur.

#### 10.4 Conditions to avoid

Avoid heat, sparks, open flames and other ignition sources.

#### 10.5 Incompatible materials

Incompatible with oxidising agents (e.g. hypochlorites) and acids (e.g. nitric acid).

#### 10.6 Hazardous decomposition products

May evolve carbon oxides and hydrocarbons when heated to decomposition.

## 11. TOXICOLOGICAL INFORMATION

#### 11.1 Information on toxicological effects

Acute toxicity	This product is expected to be of low toxicity. Under normal conditions of use, adverse health effects are not anticipated.
Skin	Not classified as a skin irritant. Contact may result in mild irritation.
Eye	Not classified as an eye irritant. Contact may cause discomfort, lacrimation and redness.
Sensitization	This product is not known to be a skin or respiratory sensitiser.
Mutagenicity	No evidence of mutagenic effects.
Carcinogenicity	No evidence of carcinogenic effects.
Reproductive	No evidence of reproductive effects.
STOT – single exposure	No known effects from this product.
STOT – repeated exposure	No known effects from this product.
Aspiration	This product does not present an aspiration hazard.

## **12. ECOLOGICAL INFORMATION**

#### 12.1 Toxicity

No information provided.

#### 12.2 Persistence and degradability

No information provided.

#### 12.3 Bioaccumulative potential

No information provided.

#### 12.4 Mobility in soil

No information provided.

#### 12.5 Other adverse effects

No information provided.

## **13. DISPOSAL CONSIDERATIONS**

#### 13.1 Waste treatment methods

Waste disposal

Collect and place in sealable containers and dispose of to an approved landfill site. Contact the manufacturer/supplier for additional information (if 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 5433:2012, UN, IMDG OR IATA

	LAND TRANSPORT (NZS 5433)	SEA TRANSPORT (IMDG / IMO)	AIR TRANSPORT (IATA / ICAO)
14.1 UN Number	None Allocated	None Allocated	None Allocated
14.2 Proper Shipping Name	None Allocated	None Allocated	None Allocated
14.3 Transport hazard class	None Allocated	None Allocated	None Allocated
14.4 Packing Group	None Allocated	None Allocated	None Allocated

14.5 Environmental hazards No information provided

14.6 Special precautions for user

Hazchem code None Allocated

## 15. REGULATORY INFORMATION

15.1 Safety, health and environmental regulations/legislation specific for the substance or mixture

Approval	code	None allocated.

 Group standard
 None allocated.

 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 in conjunction with Surgical Simplex<sup>®</sup> P Liquid. Please consult the appropriate SDS before use.

RESPIRATORS: In general the use of respirators should be limited and engineering controls employed to avoid exposure. If respiratory equipment must be worn ensure correct respirator selection and training is undertaken. Remember that some respirators may be extremely uncomfortable when used for long periods. The use of air powered or air supplied respirators should be considered where prolonged or repeated use is necessary.



## SURGICAL SIMPLEX® P RADIOPAQUE BONE CEMENT - POWDER

Abbreviation	s
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ACGIH	American Conference of Governmental Industrial Hygienists
CAS #	Chemical Abstract Service number - used to uniquely identify chemical compounds
CCID	Chemical Classification and Information Database (HSNO)
CNS	Central Nervous System
EC No.	EC No - European Community Number
EPA	Environmental Protection Authority [New Zealand]
GHS	Globally Harmonized System
HSNO	Hazardous Substances and New Organisms
IARC	International Agency for Research on Cancer
LC50	Lethal Concentration, 50% / Median Lethal Concentration
LD50	Lethal Dose, 50% / Median Lethal Dose
mg/m³	Milligrams per Cubic Metre
OEL	Occupational Exposure Limit
PEL	Permissible Exposure Limit
рН	relates to hydrogen ion concentration using a scale of 0 (high acidic) to 14 (highly alkaline).
ppm	Parts Per Million
REACH	Regulation on Registration, Evaluation, Authorisation and Restriction of Chemicals
STEL	Short-Term Exposure Limit
STOT-RE	Specific target organ toxicity (repeated exposure)
STOT-SE	Specific target organ toxicity (single exposure)
TLV	Threshold Limit Value
TWA	Time Weighted Average

**Revision history** 

Revision	Description
1.0	Initial MSDS Creation

## **END OF MSDS**

