

Safety Data Sheet

Antibiotic Simplex with Tobramycin

Catalogue Number: 6197-1-001

	Australian Sponsor	New Zealand Sponsor
Name:	Stryker Australia	Stryker New Zealand
Address:	8 Herbert Street St Leonards, NSW Australia 2065	515 Mt Wellington Highway, Auckland, New Zealand, 1060
Phone No:	+61 02 9467 1000	+64 09 573 1890
Fax No:	+61 02 9467 1010	+64 09 573 1891
Emergency:	Poisons Information Centre: Ph: 131 126	Poisons and hazardous chemicals emergency: Ph: 0800 764 766

Product name Antibiotic Simplex™ P with Tobramycin
Revision Date 24/10/2017
Revision 9
Supersedes date 15/05/2014



Product name Antibiotic Simplex™ P with Tobramycin

Manufactured and Distributed by: (other than the US): Howmedica International S. de R. L.
Raheen Business Park,
Limerick,
Republic of Ireland
Telephone: +353 61 498200 (Ireland)
Emergency: +353 61 498200 (Ireland) (24 Hours)

Distributed in the US by: Howmedica Osteonics Corp.,
300 Commerce Court,
Mahwah NJ 07430,
USA.
US Telephone: 1-877-946-9678
Emergency: 1-800-424-9300

Identified uses Antibiotic Simplex™ P with Tobramycin is a Medical Device for Professional Use in the Health Services only.

Antibiotic Simplex™ P with Tobramycin is a two component product containing Antibiotic Simplex™ Bone Cement Powder with Tobramycin and Surgical Simplex Liquid, which when packed together form the following product codes:

6197-9-010 Simplex™ P with Tobramycin (USA Market Full Dose)
6197-1-010 Simplex™ P with Tobramycin (CE Marked Full Dose)

Antibiotic Simplex™ P with Tobramycin is packaged in two sterile components. One component is an ampoule containing 10ml, or 20ml of a colourless, flammable liquid monomer that has a sweet slightly acrid odour and contains Methyl methacrylate (monomer), N,N-dimethyl para toluidine and Hydroquinone. The other component is a packet of 20.5g or 41g of finely divided powder containing Methyl methacrylate – styrene copolymer, Polymethyle methacrylate, Barium Sulphate (USP and EP) and Tobramycin (as sulphate).

This safety data sheet is written to provide health, safety and environmental information for professional health care people handling this product. This safety data sheet is not intended to provide information relevant to the use of this product as a medical device. Professional health care people should consult the prescribing information, information for use leaflets and product labels for further information about this medical device.

Product name Surgical Simplex P Liquid
Revision Date 24/10/2017
Revision 9
Supersedes date 15/05/2014



SECTION 1: IDENTIFICATION OF THE SUBSTANCE/MIXTURE AND OF THE COMPANY/UNDERTAKING

1.1. Product identifier

Product name Surgical Simplex P Liquid
Container size 20ml.

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

Identified uses Surgical Simplex Liquid when packed with Antibiotic Simplex™ Bone Cement Powder with Tobramycin forms the product Antibiotic Simplex™ P with Tobramycin

This product is a medical device. For Professional use only in the healthcare service.

1.3. Details of the supplier of the safety data sheet

Supplier Howmedica Intl S. de R.L.
Raheen Business Park
Limerick
Ireland
T: 0035361498200
F: 0035361229941
Contact Person Robert Mc Killican, Safetydatasheets@stryker.com
Manufacturer Howmedica Intl S. de R.L.
Raheen Business Park
Limerick
Ireland
T: 0035361498200
F: 0035361229941

1.4. Emergency telephone number

00353 61 498200 (24 hrs)

SECTION 2: HAZARDS IDENTIFICATION

2.1. Classification of the substance or mixture

2.1.1 Classification (EC 1272/2008)

Exempt from requirements – product regulated as a medical device.

2.2. Label elements

Exempt from requirements – product regulated as a medical device.

Surgical Simplex P Liquid

2.3. Other hazards

None known.

SECTION 3: COMPOSITION/INFORMATION ON INGREDIENTS

3.1 Substances

This product is a preparation.

3.2. Mixtures

Product name	Product identifier	%	Classification (EC 1272/2008)
METHYL METHACRYLATE	CAS-No.: 80-62-6 EC No.: 201-297-1	95.98	Flam. Liq. 2 - H225 Skin Irrit. 2 - H315 Skin Sens. 1 - H317 STOT SE 3 - H335
N,N-DIMETHYL-PARA-TOLUIDINE	CAS-No.: 99-97-8 EC No.: 202-805-4	2.3	Acute Tox. 3 - H301 Acute Tox. 3 - H311 Acute Tox. 3 - H331 STOT RE 2 - H373 Aquatic Chronic 3 - H412
HYDROQUINONE	CAS-No.: 123-31-9 EC No.: 204-617-8	<0.01	Acute Tox. 4 - H302 Eye Dam. 1 - H318 Skin Sens. 1 - H317 Muta. 2 - H341 Carc. 2 - H351 Aquatic Acute 1 - H400

The Full Text for all R-Phrases and Hazard Statements are Displayed in Section 16.

SECTION 4: FIRST AID MEASURES

4.1. Description of first aid measures

Inhalation	Move the exposed person to fresh air at once. Get medical attention if any discomfort continues.
Ingestion	Do not induce vomiting. Immediately rinse mouth and drink plenty of water (200-300 ml). Consult a physician for specific advice.
Skin contact	Wash skin with soap and water. Get medical attention if irritation persists after washing.
Eye contact	Immediately flush with plenty of water for up to 15 minutes. Remove any contact lenses and open eyes wide apart. Get medical attention if any discomfort continues.

Surgical Simplex P Liquid

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

General information Refer to Instructions For Use information for warnings, precautions, interactions, adverse reactions and important physician information.

4.3. Indication of any immediate medical attention and special treatment needed

Treat Symptomatically.

SECTION 5: FIREFIGHTING MEASURES

5.1. Extinguishing media

Fire can be extinguished using: Carbon dioxide (CO₂). Alcohol resistant foam. Water.

5.2. Special hazards arising from the substance or mixture

Hazardous combustion products No Data.

Unusual Fire & Explosion Hazards No Data.

Specific hazards No Data.

5.3. Advice for firefighters

Special Fire Fighting Procedures No specific recommendations.

Protective equipment for fire-fighters No specific recommendations.

SECTION 6: ACCIDENTAL RELEASE MEASURES

6.1. Personal precautions, protective equipment and emergency procedures

Wear second pair of surgical gloves, face/eye protection and suitable body protection.

6.2. Environmental precautions

Do not discharge into drains, water courses or onto the ground.

6.3. Methods and material for containment and cleaning up

Wipe up with paper towel and place in surgical waste container.

6.4. Reference to other sections

For waste disposal, see section 13.

SECTION 7: HANDLING AND STORAGE

7.1. Precautions for safe handling

For Professional use only in the healthcare service. Refer to Instructions For Use information for precautions.

7.2. Conditions for safe storage, including any incompatibilities

Store in as supplied medical device packaging in a dark room at temperature below 25°C.

7.3. Specific end use(s)

Usage Description This product is a medical device. For Professional use only in the healthcare service.

Surgical Simplex P Liquid

SECTION 8: EXPOSURE CONTROLS/PERSONAL PROTECTION

8.1. Control parameters

Name	Country	TWA 8 Hrs		STEL 15 Min		Notes
		ppm	mg/m ³	ppm	mg/m ³	
HYDROQUINONE	Ireland		0.5			GESTIS
	Australia		2			GESTIS
	France		2			GESTIS
	Canada-Québec		2			GESTIS
	USA –OSHA		2			GESTIS
METHYL METHACRYLATE	Ireland	50		100		GESTIS
	Australia	50	208	100	416	GESTIS
	France	50	205	100	410	GESTIS
	Germany	50	210	100	420	GESTIS
	Italy	50	50	100		GESTIS
	Canada-Québec	50	205			GESTIS
	USA –OSHA	100	410			GESTIS

8.2. Exposure controls

8.2.1 Engineering measures

Provide adequate ventilation.

8.2.2 Protective equipment

Eye protection

Use suitable surgical protective eye/face ware such as glasses, shields and or loupes.

Skin protection

Use suitable surgical gowns and gloves. The wearing of a second pair of surgical gloves is recommended.



8.2.3 Environmental Exposure Controls

Mixed cement should be allowed to set before disposal as chemically contaminated waste.

Surgical Simplex P Liquid

SECTION 9: PHYSICAL AND CHEMICAL PROPERTIES

9.1. Information on basic physical and chemical properties

a) Appearance	Liquid
b) Colour	Colourless
c) Odour	Characteristic. Pungent. Sweet.
d) Solubility	Miscible with: Acetone
e) Initial boiling point and boiling range (°C)	100.5 (°C) @ 760 mm Hg
f) Melting point (°C)	No Data.
g) Relative density	0.949 @ 15.5 °C
h) Bulk Density	No Data.
i) Vapour density (air=1)	No Data.
j) Vapour pressure	40 mm Hg 25 (°C)
k) Evaporation rate	No Data.
l) Evaporation Factor	No Data.
m) pH-Value, Conc. Solution	No Data.
n) Viscosity	No Data.
o) Solubility Value (G/100G H ₂ O@20°C)	1.6
p) Flash point (°C)	11.5 °C
q) Auto Ignition Temperature (°C)	No Data.
r) Flammability Limit - Lower(%)	2.1 %
s) Flammability Limit - Upper(%)	12.5 %
t) Explosive properties	No Data.
u) Oxidising properties	No Data.

9.2. Other information

No Data.

SECTION 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. Avoid contact with acids and or oxidizing materials.

10.2. Chemical stability

Stable under normal temperature conditions and recommended use.

10.3. Possibility of hazardous reactions

Reaction with: Acids. Oxidising materials.

Hazardous Polymerisation Hydroquinone has been added to this product to avoid polymerization of the liquid component of product.

10.4. Conditions to avoid

Avoid heat, flames and other sources of ignition.

Surgical Simplex P Liquid

10.5. Incompatible materials

Materials To Avoid Avoid contact with acids and oxidising substances.

10.6. Hazardous decomposition products

No Data.

SECTION 11: TOXICOLOGICAL INFORMATION

11.1. Information on toxicological effects

11.1.1 Toxicological Information

This material is harmful by inhalation. Prolonged inhalation of traces of vapour should be avoided.

11.1.2 Acute toxicity:

Acute Toxicity (Oral LD50) No Data.

Acute Toxicity (Dermal LD50) No Data.

Acute Toxicity (Inhalation LC50) No Data.

11.1.3 Skin Corrosion/Irritation:

Irritating.

11.1.4 Serious eye damage/irritation:

No Data.

11.1.5 Respiratory or skin sensitisation:

Respiratory sensitisation No Data.

Skin sensitisation No Data.

11.1.6 Germ cell mutagenicity:

Genotoxicity - In Vitro No Data.

Genotoxicity - In Vivo No Data.

11.1.7 Carcinogenicity:

Carcinogenicity No Data.

11.1.8 Specific target organ toxicity - single exposure:

STOT - Single exposure No Data.

STOT - Repeated exposure No Data.

SECTION 12: ECOLOGICAL INFORMATION

12.1 Ecotoxicity

No Data.

12.2. Toxicity

Acute Toxicity - Fish No Data.

Surgical Simplex P Liquid

Acute Toxicity - Aquatic Invertebrates No Data.

Acute Toxicity - Aquatic Plants No Data.

12.3. Persistence and degradability

Degradability No Data.

Degradability

Bioaccumulative potential No Data.

12.5. Mobility in soil

Mobility: No Data.

12.6. Results of PBT and vPvB assessment

This product does not contain any PBT or vPvB substances.

12.7. Other adverse effects

No Data.

SECTION 13: DISPOSAL CONSIDERATIONS

General information

Dispose of waste and residues in accordance with local authority requirements.

13.1. Waste treatment methods

All packaging, ampoules and residues should be disposed of as clinical waste.

SECTION 14: TRANSPORT INFORMATION

14.1. UN number

UN No. (ADR/RID/ADN) 1247

UN No. (IMDG) 1247

UN No. (ICAO) 1247

14.2. UN proper shipping name

Proper Shipping Name METHYL METHACRYLATE MONOMER, INHIBITED

Surgical Simplex P Liquid

14.3. Transport hazard class(es)

ADR/RID/ADN	Class 3
ADR/RID/ADN Class	Class 3: Flammable liquids.
ADR Label No.	Class 3
IMDG Class	Class 3
ICAO Class/Division	Class 3
Transport Labels	



14.4. Packing group

ADR/RID/ADN Packing group	II
IMDG Packing group	II
ICAO Packing group	II

14.5. Environmental hazards

Environmentally Hazardous Substance/Marine Pollutant	No.
--	-----

14.6. Special precautions for user

EMS	F-E, S-D
Emergency Action Code	3YE
Hazard No. (ADR)	339
Tunnel Restriction Code	(D/E)

14.7. Transport in bulk according to Annex II of MARPOL73/78 and the IBC Code

Not applicable.

Surgical Simplex P Liquid

SECTION 15: REGULATORY INFORMATION

SECTION 15: REGULATORY INFORMATION

15.1.1 EU Legislation

Regulation (EC) No 1272/2008 of the European Parliament and of the Council of 16 December 2008 on classification, labelling and packaging of substances and mixtures, amending and repealing Directives 67/548/EEC and 1999/45/EC, and amending Regulation (EC) No 1907/2006 with amendments.

15.1.2 National Legislation

No Data.

15.2. Chemical Safety Assessment

No chemical safety assessment has been carried out.

SECTION 16: OTHER INFORMATION

Indication of Changes	SDS update to reflect REACH and CLP Regulation requirements .
Revision Date	24/10/2017
Revision	9
Hazard Statements In Full	H225 Highly flammable liquid and vapour. H301 Toxic if swallowed. H302 Harmful if swallowed. H311 Toxic in contact with skin. H315 Causes skin irritation. H317 May cause an allergic skin reaction. H318 Causes serious eye damage. H331 Toxic if inhaled. H335 May cause respiratory irritation. H341 Suspected of causing genetic defects. H351 Suspected of causing cancer. H373 May cause damage to organs <<Organs>> through prolonged or repeated exposure. H400 Very toxic to aquatic life. H412 Harmful to aquatic life with long lasting effects.

Disclaimer

This information relates only to the specific material designated and may not be valid for such material used in combination with any other materials or in any process. Such information is, to the best of the company's knowledge and belief, accurate and reliable as of the date indicated. However, no warranty guarantee or representation is made to its accuracy, reliability or completeness. It is the user's responsibility to satisfy himself as to the suitability of such information for his own particular use.

Product Antibiotic Simplex™ Bone Cement Powder with Tobramycin
Revision Date 24/10/2017
Revision 9
Supersedes date 15/05/2014



SECTION 1: IDENTIFICATION OF THE SUBSTANCE/MIXTURE AND OF THE COMPANY/UNDERTAKING

1.1. Product identifier

Product name Antibiotic Simplex™ Bone Cement Powder with Tobramycin
Container size 41g

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

Identified uses Surgical Simplex Liquid when packed with Antibiotic Simplex™ Bone Cement Powder with Tobramycin forms the product Antibiotic Simplex™ P with Tobramycin
This product is a medical device. For Professional use only in the healthcare service.

1.3. Details of the supplier of the safety data sheet

Supplier Howmedica Intl S. de R.L.
Raheen Business Park
Limerick
Ireland
T: 0035361498200
F: 0035361229941
Contact Person Robert Mc Killican, Safetydatasheets@stryker.com
Manufacturer Howmedica Intl S. de R.L.
Raheen Business Park
Limerick
Ireland
T: 0035361498200
F: 0035361229941

1.4. Emergency telephone number

00353 61 498200 (24 hrs)

SECTION 2: HAZARDS IDENTIFICATION

2.1. Classification of the substance or mixture

2.1.1 Classification (EC 1272/2008)

Exempt from requirements – product regulated as a medical device.

2.2. Label elements

Exempt from requirements – product regulated as a medical device.

Antibiotic Simplex™ Bone Cement Powder with Tobramycin

2.3. Other hazards

None known.

SECTION 3: COMPOSITION/INFORMATION ON INGREDIENTS

3.1 Substances

This product is a preparation.

3.2. Mixtures

Product name	Product identifier	%	Classification (EC 1272/2008)
Methyl methacrylate styrene copolymer	CAS-No.: 25034-86-0 EC No.:	71-73	Eye Irrit. 2 - H319
Polymethyl methacrylate	CAS-No.: 25034-86-0 EC No.:	14-16	NC Not classified.
Barium Sulphate	CAS-No.: 7727-43-7 EC No.: 231-784-4	9-11	NC Not classified.
Tobramycin Sulphate	CAS-No.: 49842-07-1 EC No.: 256-499-2	2-3	Acute Tox. 4 - H312 Acute Tox. 4 - H332 Repr. 1B – H360

The Full Text for all R-Phrases and Hazard Statements are Displayed in Section 16.

SECTION 4: FIRST AID MEASURES

4.1. Description of first aid measures

Inhalation	Move the exposed person to fresh air at once. Get medical attention if any discomfort continues.
Ingestion	Immediately rinse mouth and provide fresh air. Get medical attention.
Skin contact	Wash skin with soap and water. Get medical attention if irritation persists after washing.
Eye contact	Immediately flush with plenty of water for up to 15 minutes. Remove any contact lenses and open eyes wide apart. Get medical attention if any discomfort continues.

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

General information	Refer to Instructions For Use information for warnings, precautions, interactions, adverse reactions and important physician information.
----------------------------	---

4.3. Indication of any immediate medical attention and special treatment needed

Treat Symptomatically.

SECTION 5: FIREFIGHTING MEASURES

Antibiotic Simplex™ Bone Cement Powder with Tobramycin

5.1. Extinguishing media

Fire can be extinguished using: Carbon dioxide (CO₂). Alcohol resistant foam. Water.

5.2. Special hazards arising from the substance or mixture

Hazardous combustion products	No Data.
Unusual Fire & Explosion Hazards	No Data.
Specific hazards	No Data.

5.3. Advice for firefighters

Special Fire Fighting Procedures	No specific recommendations.
Protective equipment for fire-fighters	No specific recommendations.

SECTION 6: ACCIDENTAL RELEASE MEASURES

6.1. Personal precautions, protective equipment and emergency procedures

Wear second pair of surgical gloves, face/eye protection and suitable body protection.

6.2. Environmental precautions

Do not discharge into drains, water courses or onto the ground.

6.3. Methods and material for containment and cleaning up

Wipe up with paper towel and place in surgical waste container.

6.4. Reference to other sections

For waste disposal, see section 13.

SECTION 7: HANDLING AND STORAGE

7.1. Precautions for safe handling

For Professional use only in the healthcare service. Refer to Instructions For Use information for precautions.

7.2. Conditions for safe storage, including any incompatibilities

Store in tightly closed original container in a dry, cool and well-ventilated place. Store under well-ventilated conditions at a temperature below 25°C.

7.3. Specific end use(s)

Usage Description	This product is a medical device. For Professional use only in the healthcare service.
--------------------------	--

SECTION 8: EXPOSURE CONTROLS/PERSONAL PROTECTION

8.1. Control parameters

Name	Country	TWA 8 Hrs		STEL 15 Min		Notes
		ppm	mg/m ³	ppm	mg/m ³	
Barium Sulphate	Ireland		2			GESTIS
	Australia		10			GESTIS
	Canada-Québec		10			GESTIS
	USA –OSHA		15			GESTIS
	Germany		4			GESTIS

8.2. Exposure controls

8.2.1 Engineering measures

Provide adequate ventilation.

8.2.2 Protective equipment

Eye protection

Use suitable surgical protective eye/face ware such as glasses, shields and or loupes.

Skin protection

Use suitable surgical gowns and gloves. The wearing of a second pair of surgical gloves is recommended.



8.2.3 Environmental Exposure Controls

Mixed cement should be allowed to set before disposal as chemically contaminated waste.

SECTION 9: PHYSICAL AND CHEMICAL PROPERTIES

9.1. Information on basic physical and chemical properties

a) Appearance	Fine powder
b) Colour	White
c) Odour	Odourless.
d) Solubility	Insoluble in Acetone
e) Initial boiling point and boiling range (°C)	No Data.
f) Melting point (°C)	No Data.
g) Relative density	0.3 @ 20 °C
h) Bulk Density	No Data.
i) Vapour density (air=1)	No Data.
j) Vapour pressure	No Data.
k) Evaporation rate	No Data.
l) Evaporation Factor	No Data.
m) pH-Value, Conc. Solution	No Data.
n) Viscosity	No Data.
o) Solubility Value (G/100G H ₂ O@20°C)	Insoluble
p) Flash point (°C)	No Data.
q) Auto Ignition Temperature (°C)	No Data.
r) Flammability Limit - Lower(%)	No Data.
s) Flammability Limit - Upper(%)	No Data.
t) Explosive properties	No Data.
u) Oxidising properties	No Data.

9.2. Other information

No Data.

SECTION 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. Avoid contact with acids and or oxidizing materials.

10.2. Chemical stability

Stable under normal temperature conditions and recommended use.

10.3. Possibility of hazardous reactions

Reaction with:	No Data.
Hazardous Polymerisation	No Data.

10.4. Conditions to avoid

No Data.

10.5. Incompatible materials

Materials To Avoid No Data.

10.6. Hazardous decomposition products

No Data.

SECTION 11: TOXICOLOGICAL INFORMATION

11.1. Information on toxicological effects

11.1.1 Toxicological Information

No Data.

11.1.2 Acute toxicity:

Acute Toxicity (Oral LD50) No Data.

Acute Toxicity (Dermal LD50) No Data.

Acute Toxicity (Inhalation LC50) No Data.

11.1.3 Skin Corrosion/Irritation:

No Data.

11.1.4 Serious eye damage/irritation:

Eye Irritant

11.1.5 Respiratory or skin sensitisation:

Respiratory sensitisation No Data.

Skin sensitisation No Data.

11.1.6 Germ cell mutagenicity:

Genotoxicity - In Vitro No Data.

Genotoxicity - In Vivo No Data.

11.1.7 Carcinogenicity:

Carcinogenicity No Data.

Antibiotic Simplex™ Bone Cement Powder with Tobramycin

11.1.8 Specific target organ toxicity - single exposure:

STOT - Single exposure	No Data.
STOT - Repeated exposure	No Data.

SECTION 12: ECOLOGICAL INFORMATION

12.1 Ecotoxicity

No Data.

12.2. Toxicity

Acute Toxicity - Fish	No Data.
Acute Toxicity - Aquatic Invertebrates	No Data.
Acute Toxicity - Aquatic Plants	No Data.

12.3. Persistence and degradability

Degradability No Data.

12.4. Degradability

Bioaccumulative potential No Data.

12.5. Mobility in soil

Mobility: No Data.

12.6. Results of PBT and vPvB assessment

This product does not contain any PBT or vPvB substances.

12.7. Other adverse effects

No Data.

SECTION 13: DISPOSAL CONSIDERATIONS

General information

Dispose of waste and residues in accordance with local authority requirements.

13.1. Waste treatment methods

All packaging, ampoules and residues should be disposed of as clinical waste.

Antibiotic Simplex™ Bone Cement Powder with Tobramycin

SECTION 14: TRANSPORT INFORMATION

This product is not covered by international regulation o the transport of dangerous goods (IMDG,IATA, ADR/IMDG, CFR 49)

14.1. UN number

UN No. (ADR/RID/ADN)	No information required.
UN No. (IMDG)	No information required.
UN No. (ICAO)	No information required.

14.2. UN proper shipping name

Proper Shipping Name	No information required.
----------------------	--------------------------

14.3. Transport hazard class(es)

ADR/RID/ADN	No information required.
ADR/RID/ADN Class	No information required.
ADR Label No.	No information required.
IMDG Class	No information required.
ICAO Class/Division	No information required.
Transport Labels	

14.4. Packing group

ADR/RID/ADN Packing group	No information required.
IMDG Packing group	No information required.
ICAO Packing group	No information required.

14.5. Environmental hazards

Environmentally Hazardous Substance/Marine Pollutant	No.
--	-----

14.6. Special precautions for user

EMS	No information required.
Emergency Action Code	No information required.
Hazard No. (ADR)	No information required.
Tunnel Restriction Code	No information required.

14.7. Transport in bulk according to Annex II of MARPOL73/78 and the IBC Code

Not applicable.

Antibiotic Simplex™ Bone Cement Powder with Tobramycin

SECTION 15: REGULATORY INFORMATION

SECTION 15: REGULATORY INFORMATION

15.1.1 EU Legislation

Regulation (EC) No 1272/2008 of the European Parliament and of the Council of 16 December 2008 on classification, labelling and packaging of substances and mixtures, amending and repealing Directives 67/548/EEC and 1999/45/EC, and amending Regulation (EC) No 1907/2006 with amendments.

15.1.2 National Legislation

No Data.

15.2. Chemical Safety Assessment

No chemical safety assessment has been carried out.

SECTION 16: OTHER INFORMATION

Indication of Changes	SDS update to reflect REACH and CLP Regulation requirements .
Revision Date	24/10/2017
Revision	9
Hazard Statements In Full	H241 Heating may cause a fire or explosion. H312 Harmful in contact with skin. H317 May cause an allergic skin reaction. H319 Causes serious eye irritation. H332 Harmful if inhaled. H360FD May damage fertility or the unborn child.

Disclaimer

This information relates only to the specific material designated and may not be valid for such material used in combination with any other materials or in any process. Such information is, to the best of the company's knowledge and belief, accurate and reliable as of the date indicated. However, no warranty guarantee or representation is made to its accuracy, reliability or completeness. It is the user's responsibility to satisfy himself as to the suitability of such information for his own particular use.