

**Product name** Antibiotic Simplex Bone Cement with Erythromycin/Colistin  
**Revision Date** 11/01/2017  
**Revision** 9  
**Supersedes date** 15/05/2014



**Product name** Antibiotic Simplex Bone Cement with Erythromycin/Colistin

**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 Bone Cement with Erythromycin/Colistin is a Medical Device for Professional Use in the Health Services only.

Antibiotic Simplex Bone Cement with Erythromycin/Colistin is a two component product containing Antibiotic Simplex™ bone cement powder with Erythromycin/Colistin and Surgical Simplex P Liquid, which when packed together form the following product codes:

**6196-9-010** Antibiotic Simplex Bone Cement with Erythromycin/Colistin

Antibiotic Simplex Bone Cement with Erythromycin/Colistin 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 pare toluidine and Hydroquinone. The other component is a packet of 20.5g or 41g of finely divided powder containing Methyl methacrylate – styrene copolymer, Polymethyl methacrylate, Barium Sulphate USP and EP, Erythromycin Glucoheptonate USP and Colistin Sulphomate Sodium EP.

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 11/01/2017  
Revision 9  
Supersedes date 15/05/2014



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

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### 1.1. Product identifier

Product name Surgical Simplex P Liquid  
Container size 10ml, 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 Erythromycin/Colistin forms the product Antibiotic Simplex Bone Cement with Erythromycin/Colistin.  
  
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)

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## SECTION 2: HAZARDS IDENTIFICATION

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### 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.

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## SECTION 3: COMPOSITION/INFORMATION ON INGREDIENTS

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### 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<br>EC No.: 201-297-1  | 95.98 | Flam. Liq. 2 - H225<br>Skin Irrit. 2 - H315<br>Skin Sens. 1 - H317<br>STOT SE 3 - H335                                        |
| N,N-DIMETHYL-PARA-TOLUIDINE | CAS-No.: 99-97-8<br>EC No.: 202-805-4  | 2.3   | Acute Tox. 3 - H301<br>Acute Tox. 3 - H311<br>Acute Tox. 3 - H331<br>STOT RE 2 - H373<br>Aquatic Chronic 3 - H412             |
| HYDROQUINONE                | CAS-No.: 123-31-9<br>EC No.: 204-617-8 | <0.01 | Acute Tox. 4 - H302<br>Eye Dam. 1 - H318<br>Skin Sens. 1 - H317<br>Muta. 2 - H341<br>Carc. 2 - H351<br>Aquatic Acute 1 - H400 |

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

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## SECTION 4: FIRST AID MEASURES

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### 4.1. Description of first aid measures

|                     |                                                                                                                                                                     |
|---------------------|---------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| <b>Inhalation</b>   | Move the exposed person to fresh air at once. Get medical attention if any discomfort continues.                                                                    |
| <b>Ingestion</b>    | Do not induce vomiting. Immediately rinse mouth and drink plenty of water (200-300 ml). Consult a physician for specific advice.                                    |
| <b>Skin contact</b> | Wash skin with soap and water. Get medical attention if irritation persists after washing.                                                                          |
| <b>Eye contact</b>  | 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.

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## SECTION 5: FIREFIGHTING MEASURES

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### 5.1. Extinguishing media

Fire can be extinguished using: Carbon dioxide (CO<sub>2</sub>). 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.

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## SECTION 6: ACCIDENTAL RELEASE MEASURES

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### 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.

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## SECTION 7: HANDLING AND STORAGE

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### 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

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### SECTION 8: EXPOSURE CONTROLS/PERSONAL PROTECTION

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#### 8.1. Control parameters

| Name                | Country       | TWA 8 Hrs |                   | STEL 15 Min |                   | Notes  |
|---------------------|---------------|-----------|-------------------|-------------|-------------------|--------|
|                     |               | ppm       | mg/m <sup>3</sup> | ppm         | mg/m <sup>3</sup> |        |
| 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

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### SECTION 9: PHYSICAL AND CHEMICAL PROPERTIES

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#### 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 <sub>2</sub> 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.

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### SECTION 10: STABILITY AND REACTIVITY

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#### 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** Hydroquine 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.

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## SECTION 11: TOXICOLOGICAL INFORMATION

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### 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.

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## SECTION 12: ECOLOGICAL INFORMATION

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### 12.1 Ecotoxicity

No Data.

## Surgical Simplex P Liquid

### 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 Bioaccumulative potential

|                           |          |
|---------------------------|----------|
| 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.

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## SECTION 13: DISPOSAL CONSIDERATIONS

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### 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.

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## SECTION 14: TRANSPORT INFORMATION

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### 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.

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## SECTION 15: REGULATORY INFORMATION

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### 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.

## Surgical Simplex P Liquid

### 15.2. Chemical Safety Assessment

No chemical safety assessment has been carried out.

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### SECTION 16: OTHER INFORMATION

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|                                  |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                    |
|----------------------------------|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| <b>Indication of Changes</b>     | SDS update to reflect REACH and CLP Regulation requirements .                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                      |
| <b>Revision Date</b>             | 11/01/2017                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                         |
| <b>Revision</b>                  | 9                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                  |
| <b>Hazard Statements In Full</b> | H225 Highly flammable liquid and vapour.<br>H301 Toxic if swallowed.<br>H302 Harmful if swallowed.<br>H311 Toxic in contact with skin.<br>H315 Causes skin irritation.<br>H317 May cause an allergic skin reaction.<br>H318 Causes serious eye damage.<br>H331 Toxic if inhaled.<br>H335 May cause respiratory irritation.<br>H341 Suspected of causing genetic defects.<br>H351 Suspected of causing cancer.<br>H373 May cause damage to organs <<Organs>> through prolonged or repeated exposure.<br>H400 Very toxic to aquatic life.<br>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 Erythromycin/Colistin  
**Revision Date** 11/01/2017  
**Revision** 9  
**Supersedes date** 15/05/2014



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

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### 1.1. Product identifier

**Product name** Antibiotic Simplex™ bone cement powder with Erythromycin/Colistin  
**Container size** 20.5g, 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 Erythromycin/Colistin forms the product Antibiotic Simplex Bone Cement with Erythromycin/Colistin.  
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)

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## SECTION 2: HAZARDS IDENTIFICATION

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### 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 Erythromycin/Colistin

### 2.3. Other hazards

None known.

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## SECTION 3: COMPOSITION/INFORMATION ON INGREDIENTS

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### 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<br>EC No.:           | 73-75 | Eye Irrit. 2 - H319            |
| Polymethyl methacrylate               | CAS-No.: 25034-86-0<br>EC No.:           | 14-16 | NC Not classified.             |
| Barium Sulphate                       | CAS-No.: 7727-43-7<br>EC No.: 231-784-4  | 9-11  | NC Not classified.             |
| Erythromycin Glucoheptonate           | CAS-No.: 23067-13-2<br>EC No.: 245-407-6 | 1-2   | NC Not classified.             |
| Colistin Sulphomethate Sodium         | CAS-No.: 8068-28-8<br>EC No.: 232-516-9  | <1    | Repr. 2 - H361<br>Lact. - H362 |

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

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## SECTION 4: FIRST AID MEASURES

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### 4.1. Description of first aid measures

|                     |                                                                                                                                                                     |
|---------------------|---------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| <b>Inhalation</b>   | Move the exposed person to fresh air at once. Get medical attention if any discomfort continues.                                                                    |
| <b>Ingestion</b>    | Immediately rinse mouth and provide fresh air. Get medical attention.                                                                                               |
| <b>Skin contact</b> | Wash skin with soap and water. Get medical attention if irritation persists after washing.                                                                          |
| <b>Eye contact</b>  | 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

|                            |                                                                                                                                           |
|----------------------------|-------------------------------------------------------------------------------------------------------------------------------------------|
| <b>General information</b> | 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.

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## SECTION 5: FIREFIGHTING MEASURES

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### 5.1. Extinguishing media

Fire can be extinguished using: Carbon dioxide (CO<sub>2</sub>). Alcohol resistant foam. Water.

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

|                                             |          |
|---------------------------------------------|----------|
| <b>Hazardous combustion products</b>        | No Data. |
| <b>Unusual Fire &amp; Explosion Hazards</b> | No Data. |
| <b>Specific hazards</b>                     | No Data. |

### 5.3. Advice for firefighters

|                                               |                              |
|-----------------------------------------------|------------------------------|
| <b>Special Fire Fighting Procedures</b>       | No specific recommendations. |
| <b>Protective equipment for fire-fighters</b> | No specific recommendations. |

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## SECTION 6: ACCIDENTAL RELEASE MEASURES

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### 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.

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## 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)

|                          |                                                                                        |
|--------------------------|----------------------------------------------------------------------------------------|
| <b>Usage Description</b> | 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 <sup>3</sup> | ppm         | mg/m <sup>3</sup> |        |
| 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.

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## SECTION 9: PHYSICAL AND CHEMICAL PROPERTIES

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### 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 <sub>2</sub> 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.

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## 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.

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### SECTION 11: TOXICOLOGICAL INFORMATION

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#### 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 Erythromycin/Colistin

### 11.1.8 Specific target organ toxicity - single exposure:

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

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## SECTION 12: ECOLOGICAL INFORMATION

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### 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.

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## SECTION 13: DISPOSAL CONSIDERATIONS

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### 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.

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## SECTION 14: TRANSPORT INFORMATION

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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.

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**SECTION 15: REGULATORY INFORMATION**

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**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.

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**SECTION 16: OTHER INFORMATION**

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|                                  |                                                                                                                                                   |
|----------------------------------|---------------------------------------------------------------------------------------------------------------------------------------------------|
| <b>Indication of Changes</b>     | SDS update to reflect REACH and CLP Regulation requirements .                                                                                     |
| <b>Revision Date</b>             | 11/01/2017                                                                                                                                        |
| <b>Revision</b>                  | 9                                                                                                                                                 |
| <b>Hazard Statements In Full</b> | H361fd Suspected of damaging fertility or the unborn child.<br>H362 May cause harm to breast-fed children.<br>H319 Causes serious eye irritation. |

**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.