

# SAFETY DATA SHEET



## Gentamicin (8%) Injection Formulation



Version 3.0      Revision Date: 2020/10/10      SDS Number: 1845019-00008      Date of last issue: 2020/03/23  
Date of first issue: 2017/07/25

---

### 1. PRODUCT AND COMPANY IDENTIFICATION

Chemical product name : Gentamicin (8%) Injection Formulation

#### Supplier's company name, address and phone number

Company name of supplier : Organon & Co.

Address : 30 Hudson Street, 33rd floor  
Jersey City, New Jersey, U.S.A 07302

Telephone : 551-430-6000

E-mail address : EHSSTEWARD@organon.com

Emergency telephone number : 215-631-6999

#### Recommended use of the chemical and restrictions on use

Recommended use : Pharmaceutical

---

### 2. HAZARDS IDENTIFICATION

#### GHS classification of chemical product

Reproductive toxicity : Category 1A

Specific target organ toxicity - repeated exposure (Oral) : Category 2 (Kidney, inner ear)

Short-term (acute) aquatic hazard : Category 1

Long-term (chronic) aquatic hazard : Category 2

#### GHS label elements

Hazard pictograms :



Signal word : Danger

Hazard statements : H360D May damage the unborn child.  
H373 May cause damage to organs (Kidney, inner ear) through prolonged or repeated exposure if swallowed.  
H400 Very toxic to aquatic life.  
H411 Toxic to aquatic life with long lasting effects.

Precautionary statements :

#### Prevention:

P201 Obtain special instructions before use.

P202 Do not handle until all safety precautions have been read and understood.

---

## Gentamicin (8%) Injection Formulation

Version 3.0      Revision Date: 2020/10/10      SDS Number: 1845019-00008      Date of last issue: 2020/03/23  
Date of first issue: 2017/07/25

P260 Do not breathe mist or vapours.  
P273 Avoid release to the environment.  
P280 Wear protective gloves/ protective clothing/ eye protection/ face protection.

**Response:**

P308 + P313 IF exposed or concerned: Get medical advice/ attention.  
P391 Collect spillage.

**Storage:**

P405 Store locked up.

**Disposal:**

P501 Dispose of contents/ container to an approved waste disposal plant.

**Other hazards which do not result in classification**

None known.

**3. COMPOSITION/INFORMATION ON INGREDIENTS**

Substance / Mixture : Mixture

**Components**

| Chemical name  | CAS-No.   | Concentration (% w/w) | ENCS No. |
|----------------|-----------|-----------------------|----------|
| Gentamicin     | 1403-66-3 | 8                     |          |
| Benzyl alcohol | 100-51-6  | 1.5                   | 3-1011   |

**4. FIRST AID MEASURES**

General advice : In the case of accident or if you feel unwell, seek medical advice immediately.  
When symptoms persist or in all cases of doubt seek medical advice.

If inhaled : If inhaled, remove to fresh air.  
Get medical attention.

In case of skin contact : In case of contact, immediately flush skin with soap and plenty of water.  
Remove contaminated clothing and shoes.  
Get medical attention.  
Wash clothing before reuse.  
Thoroughly clean shoes before reuse.

In case of eye contact : Flush eyes with water as a precaution.  
Get medical attention if irritation develops and persists.

If swallowed : If swallowed, DO NOT induce vomiting.  
Get medical attention.  
Rinse mouth thoroughly with water.

Most important symptoms and effects, both acute and delayed : May damage the unborn child.  
May cause damage to organs through prolonged or repeated exposure if swallowed.

Protection of first-aiders : First Aid responders should pay attention to self-protection,

## Gentamicin (8%) Injection Formulation

|         |                |               |                                 |
|---------|----------------|---------------|---------------------------------|
| Version | Revision Date: | SDS Number:   | Date of last issue: 2020/03/23  |
| 3.0     | 2020/10/10     | 1845019-00008 | Date of first issue: 2017/07/25 |

---

Notes to physician : and use the recommended personal protective equipment when the potential for exposure exists (see section 8).  
: Treat symptomatically and supportively.

---

**5. FIREFIGHTING MEASURES**

Suitable extinguishing media : Water spray  
Alcohol-resistant foam  
Carbon dioxide (CO<sub>2</sub>)  
Dry chemical

Unsuitable extinguishing media : None known.

Specific hazards during fire-fighting : Vapours may form explosive mixtures with air.  
Exposure to combustion products may be a hazard to health.

Hazardous combustion products : Carbon oxides

Specific extinguishing methods : Use extinguishing measures that are appropriate to local circumstances and the surrounding environment.  
Use water spray to cool unopened containers.  
Remove undamaged containers from fire area if it is safe to do so.  
Evacuate area.

Special protective equipment for firefighters : In the event of fire, wear self-contained breathing apparatus.  
Use personal protective equipment.

---

**6. ACCIDENTAL RELEASE MEASURES**

Personal precautions, protective equipment and emergency procedures : Use personal protective equipment.  
Follow safe handling advice (see section 7) and personal protective equipment recommendations (see section 8).

Environmental precautions : Avoid release to the environment.  
Prevent further leakage or spillage if safe to do so.  
Prevent spreading over a wide area (e.g. by containment or oil barriers).  
Retain and dispose of contaminated wash water.  
Local authorities should be advised if significant spillages cannot be contained.

Methods and materials for containment and cleaning up : Soak up with inert absorbent material.  
For large spills, provide dyking or other appropriate containment to keep material from spreading. If dyked material can be pumped, store recovered material in appropriate container.  
Clean up remaining materials from spill with suitable absorbent.  
Local or national regulations may apply to releases and disposal of this material, as well as those materials and items employed in the cleanup of releases. You will need to determine which regulations are applicable.  
Sections 13 and 15 of this SDS provide information regarding certain local or national requirements.

## Gentamicin (8%) Injection Formulation

Version 3.0      Revision Date: 2020/10/10      SDS Number: 1845019-00008      Date of last issue: 2020/03/23  
 Date of first issue: 2017/07/25

**7. HANDLING AND STORAGE****Handling**

- Technical measures : See Engineering measures under EXPOSURE CONTROLS/PERSONAL PROTECTION section.
- Local/Total ventilation : If sufficient ventilation is unavailable, use with local exhaust ventilation.
- Advice on safe handling : Do not get on skin or clothing.  
 Do not breathe mist or vapours.  
 Do not swallow.  
 Avoid contact with eyes.  
 Wash skin thoroughly after handling.  
 Handle in accordance with good industrial hygiene and safety practice, based on the results of the workplace exposure assessment  
 Keep container tightly closed.  
 Do not eat, drink or smoke when using this product.  
 Take care to prevent spills, waste and minimize release to the environment.
- Avoidance of contact : Oxidizing agents
- Hygiene measures : If exposure to chemical is likely during typical use, provide eye flushing systems and safety showers close to the working place.  
 When using do not eat, drink or smoke.  
 Wash contaminated clothing before re-use.  
 The effective operation of a facility should include review of engineering controls, proper personal protective equipment, appropriate degowning and decontamination procedures, industrial hygiene monitoring, medical surveillance and the use of administrative controls.

**Storage**

- Conditions for safe storage : Keep in properly labelled containers.  
 Store locked up.  
 Keep tightly closed.  
 Store in accordance with the particular national regulations.
- Materials to avoid : Do not store with the following product types:  
 Strong oxidizing agents
- Packaging material : Unsuitable material: None known.

**8. EXPOSURE CONTROLS/PERSONAL PROTECTION****Threshold limit value and permissible exposure limits for each component in the work environment**

| Components  | CAS-No.   | Value type (Form of exposure) | Control parameters / Permissible concentration | Basis          |
|---|-----------|-------------------------------|--|----------------|
| Gentamicin  | 1403-66-3 | TWA                           | 0.1 mg/m <sup>3</sup> (OEB 2)                  | Internal       |
| Benzyl alcohol  | 100-51-6  | OEL-C                         | 25 mg/m <sup>3</sup>                           | JP OEL<br>JSOH |
| Further information: Skin sensitizing agent; Group 2 substances |           |                               |  |                |

## Gentamicin (8%) Injection Formulation

|         |                |               |                                 |
|---------|----------------|---------------|---------------------------------|
| Version | Revision Date: | SDS Number:   | Date of last issue: 2020/03/23  |
| 3.0     | 2020/10/10     | 1845019-00008 | Date of first issue: 2017/07/25 |

|| \_\_\_\_\_ | which probably induce allergic reactions in humans. |

**Engineering measures** : Use appropriate engineering controls and manufacturing technologies to control airborne concentrations (e.g., drip-less quick connections).  
All engineering controls should be implemented by facility design and operated in accordance with GMP principles to protect products, workers, and the environment.  
Laboratory operations do not require special containment.

**Personal protective equipment**

Respiratory protection : If adequate local exhaust ventilation is not available or exposure assessment demonstrates exposures outside the recommended guidelines, use respiratory protection.

Filter type : Combined particulates and organic vapour type

Hand protection

Material : Chemical-resistant gloves

Eye protection : Wear safety glasses with side shields or goggles.  
If the work environment or activity involves dusty conditions, mists or aerosols, wear the appropriate goggles.  
Wear a faceshield or other full face protection if there is a potential for direct contact to the face with dusts, mists, or aerosols.

Skin and body protection : Work uniform or laboratory coat.

**9. PHYSICAL AND CHEMICAL PROPERTIES**

Physical state : liquid

Colour : colourless

Odour : No data available

Odour Threshold : No data available

Melting point/freezing point : No data available

Boiling point, initial boiling point and boiling range : No data available

Flammability (solid, gas) : Not applicable

Flammability (liquids) : Not applicable

Lower explosion limit and upper explosion limit / flammability limit  
Upper explosion limit / Upper flammability limit : No data available

Lower explosion limit / Lower flammability limit : No data available

Flash point : > 93.3 °C

# SAFETY DATA SHEET



## Gentamicin (8%) Injection Formulation



|         |                |               |                                 |
|---------|----------------|---------------|---------------------------------|
| Version | Revision Date: | SDS Number:   | Date of last issue: 2020/03/23  |
| 3.0     | 2020/10/10     | 1845019-00008 | Date of first issue: 2017/07/25 |

---

|  |   |  |
|--|---|--|
| Decomposition temperature              | : | No data available  |
| pH                                     | : | No data available  |
| Evaporation rate                       | : | No data available  |
| Auto-ignition temperature              | : | No data available  |
| Viscosity                              | : |  |
| Viscosity, kinematic                   | : | No data available  |
| Solubility(ies)                        | : |  |
| Water solubility                       | : | No data available  |
| Partition coefficient: n-octanol/water | : | No data available  |
| Vapour pressure                        | : | No data available  |
| Density and / or relative density      | : |  |
| Relative density                       | : | No data available  |
| Density                                | : | No data available  |
| Relative vapour density                | : | No data available  |
| Explosive properties                   | : | Not explosive  |
| Oxidizing properties                   | : | The substance or mixture is not classified as oxidizing. |
| Molecular weight                       | : | No data available  |
| Particle characteristics               | : |  |
| Particle size                          | : | No data available  |

---

### 10. STABILITY AND REACTIVITY

|                                    |   |   |
|------------------------------------|---|---|
| Reactivity                         | : | Not classified as a reactivity hazard.  |
| Chemical stability                 | : | Stable under normal conditions.   |
| Possibility of hazardous reactions | : | Vapours may form explosive mixture with air.<br>Can react with strong oxidizing agents. |
| Conditions to avoid                | : | None known.   |
| Incompatible materials             | : | Oxidizing agents  |
| Hazardous decomposition products   | : | No hazardous decomposition products are known.  |

---

### 11. TOXICOLOGICAL INFORMATION

|  |   |  |
|--|---|--|
| Information on likely routes of exposure | : | Inhalation<br>Skin contact<br>Ingestion<br>Eye contact |
|--|---|--|

## Gentamicin (8%) Injection Formulation

|         |                |               |                                 |
|---------|----------------|---------------|---------------------------------|
| Version | Revision Date: | SDS Number:   | Date of last issue: 2020/03/23  |
| 3.0     | 2020/10/10     | 1845019-00008 | Date of first issue: 2017/07/25 |

---

**Acute toxicity**

Not classified based on available information.

**Product:**

Acute oral toxicity : Acute toxicity estimate: > 2,000 mg/kg  
Method: Calculation method

Acute inhalation toxicity : Acute toxicity estimate: > 5 mg/l  
Exposure time: 4 h  
Test atmosphere: dust/mist  
Method: Calculation method

**Components:****Gentamicin:**

|   |   |  |
|---|---|--|
| Acute oral toxicity                             | : | LD50 (Rat): 8,000 - 10,000 mg/kg             |
|   |   | LD50 (Mouse): 10,000 mg/kg                   |
|   |   |  |
| Acute inhalation toxicity                       | : | LC50 (Rat): > 0.2 mg/l                       |
|   |   | Exposure time: 4 h                           |
|   |   | Test atmosphere: dust/mist                   |
|   |   | Remarks: No mortality observed at this dose. |
| Acute toxicity (other routes of administration) | : | LD50 (Rat): 67 - 96 mg/kg                    |
|   |   | Application Route: Intravenous               |
|   |   | LD50 (Rat): 371 - 384 mg/kg                  |
|   |   | Application Route: Intramuscular             |
|   |   | LDLo (Monkey): 30 mg/kg                      |
|   |   | Application Route: Intravenous               |

**Benzyl alcohol:**

|                           |   |                                 |
|---------------------------|---|---------------------------------|
| Acute oral toxicity       | : | LD50 (Rat): 1,620 mg/kg         |
| Acute inhalation toxicity | : | LC50 (Rat): > 4.178 mg/l        |
|                           |   | Exposure time: 4 h              |
|                           |   | Test atmosphere: dust/mist      |
|                           |   | Method: OECD Test Guideline 403 |

**Skin corrosion/irritation**

Not classified based on available information.

**Components:****Gentamicin:**

|         |   |                      |
|---------|---|----------------------|
| Species | : | Rabbit               |
| Result  | : | Mild skin irritation |

**Benzyl alcohol:**

## Gentamicin (8%) Injection Formulation

|         |                |               |                                 |
|---------|----------------|---------------|---------------------------------|
| Version | Revision Date: | SDS Number:   | Date of last issue: 2020/03/23  |
| 3.0     | 2020/10/10     | 1845019-00008 | Date of first issue: 2017/07/25 |

---

|         |                           |
|---------|---------------------------|
| Species | : Rabbit                  |
| Method  | : OECD Test Guideline 404 |
| Result  | : No skin irritation      |

**Serious eye damage/eye irritation**

Not classified based on available information.

**Components:****Gentamicin:**

|         |                       |
|---------|-----------------------|
| Species | : Rabbit              |
| Result  | : Mild eye irritation |

**Benzyl alcohol:**

|         |  |
|---------|--|
| Species | : Rabbit                                       |
| Result  | : Irritation to eyes, reversing within 21 days |
| Method  | : OECD Test Guideline 405                      |

**Respiratory or skin sensitisation****Skin sensitisation**

Not classified based on available information.

**Respiratory sensitisation**

Not classified based on available information.

**Components:****Gentamicin:**

|         |                     |
|---------|---------------------|
| Remarks | : No data available |
|---------|---------------------|

**Benzyl alcohol:**

|                 |                           |
|-----------------|---------------------------|
| Test Type       | : Maximisation Test       |
| Exposure routes | : Skin contact            |
| Species         | : Guinea pig              |
| Method          | : OECD Test Guideline 406 |
| Result          | : negative                |

**Germ cell mutagenicity**

Not classified based on available information.

**Components:****Gentamicin:**

|                       |  |
|-----------------------|--|
| Genotoxicity in vitro | : Test Type: In vitro mammalian cell gene mutation test                          |
|                       | Result: negative   |
| Genotoxicity in vivo  | : Test Type: Chromosome aberration test in vitro                                 |
|                       | Result: equivocal  |
| Genotoxicity in vivo  | : Test Type: Mammalian erythrocyte micronucleus test (in vivo cytogenetic assay) |
|                       | Species: Mouse   |



## Gentamicin (8%) Injection Formulation

|         |                |               |                                 |
|---------|----------------|---------------|---------------------------------|
| Version | Revision Date: | SDS Number:   | Date of last issue: 2020/03/23  |
| 3.0     | 2020/10/10     | 1845019-00008 | Date of first issue: 2017/07/25 |

Application Route: Intravenous injection

Result: negative

**Benzyl alcohol:**

Genotoxicity in vitro : Test Type: Bacterial reverse mutation assay (AMES)  
Result: negative

Genotoxicity in vivo : Test Type: Mammalian erythrocyte micronucleus test (in vivo cytogenetic assay)  
Species: Mouse  
Application Route: Intraperitoneal injection  
Result: negative

**Carcinogenicity**

Not classified based on available information.

**Components:****Gentamicin:**

Carcinogenicity - Assessment : No data available

**Benzyl alcohol:**

Species : Mouse  
Application Route : Ingestion  
Exposure time : 103 weeks  
Method : OECD Test Guideline 451  
Result : negative

**Reproductive toxicity**

May damage the unborn child.

**Components:****Gentamicin:**

Effects on fertility : Test Type: Two-generation reproduction toxicity study  
Species: Rat  
Fertility: NOAEL: 20 mg/kg body weight  
Result: No significant adverse effects were reported

Effects on foetal development : Test Type: Embryo-foetal development  
Species: Rabbit  
Developmental Toxicity: NOAEL: 3.6 mg/kg body weight  
Result: No embryo-foetal toxicity

Test Type: Embryo-foetal development  
Species: Rat  
Application Route: Intraperitoneal  
Developmental Toxicity: LOAEL: 75 mg/kg body weight  
Result: Embryo-foetal toxicity

Test Type: Embryo-foetal development  
Species: Mouse  
Application Route: Intraperitoneal

## Gentamicin (8%) Injection Formulation

|         |                |               |                                 |
|---------|----------------|---------------|---------------------------------|
| Version | Revision Date: | SDS Number:   | Date of last issue: 2020/03/23  |
| 3.0     | 2020/10/10     | 1845019-00008 | Date of first issue: 2017/07/25 |

|                                    |  |
|------------------------------------|--|
|                                    | Developmental Toxicity: LOAEL: 10 mg/kg body weight<br>Result: foetal mortality, No malformations were observed.   |
|                                    | Test Type: Embryo-foetal development<br>Species: Rat<br>Application Route: Intraperitoneal<br>Developmental Toxicity: LOAEL: 50 mg/kg body weight<br>Result: foetal mortality, No malformations were observed. |
| Reproductive toxicity - Assessment | : Positive evidence of adverse effects on development from human epidemiological studies.  |

**Benzyl alcohol:**

|                               |   |
|-------------------------------|---|
| Effects on fertility          | : Test Type: Fertility/early embryonic development<br>Species: Rat<br>Application Route: Ingestion<br>Result: negative<br>Remarks: Based on data from similar materials |
| Effects on foetal development | : Test Type: Embryo-foetal development<br>Species: Mouse<br>Application Route: Ingestion<br>Result: negative  |

**STOT - single exposure**

Not classified based on available information.

**STOT - repeated exposure**

May cause damage to organs (Kidney, inner ear) through prolonged or repeated exposure if swallowed.

**Components:****Gentamicin:**

|               |   |
|---------------|---|
| Target Organs | : Kidney, inner ear   |
| Assessment    | : Causes damage to organs through prolonged or repeated exposure. |

**Repeated dose toxicity****Components:****Gentamicin:**

|                   |                        |
|-------------------|------------------------|
| Species           | : Dog                  |
| LOAEL             | : 3 mg/kg              |
| Application Route | : Intramuscular        |
| Exposure time     | : 12 Months            |
| Target Organs     | : Kidney               |
| Symptoms          | : Vomiting, Salivation |

|                   |                |
|-------------------|----------------|
| Species           | : Monkey       |
| LOAEL             | : 50 mg/kg     |
| Application Route | : Subcutaneous |
| Exposure time     | : 3 Weeks      |

# SAFETY DATA SHEET



## Gentamicin (8%) Injection Formulation



Version 3.0      Revision Date: 2020/10/10      SDS Number: 1845019-00008      Date of last issue: 2020/03/23  
Date of first issue: 2017/07/25

---

|| Target Organs : Kidney, inner ear  
|| Species : Monkey  
|| LOAEL : 6 mg/kg  
|| Application Route : Intramuscular  
|| Exposure time : 3 Weeks  
|| Target Organs : Blood, Kidney, inner ear, Liver

|| Species : Rat  
|| NOAEL : 5 mg/kg  
|| LOAEL : 10 mg/kg  
|| Application Route : Intramuscular  
|| Exposure time : 52 Weeks  
|| Target Organs : Kidney, Blood

|| Species : Rat  
|| NOAEL : 12.5 mg/kg  
|| LOAEL : 50 mg/kg  
|| Application Route : Intramuscular  
|| Exposure time : 13 Weeks  
|| Target Organs : Kidney

### **Benzyl alcohol:**

|| Species : Rat  
|| NOAEL : 1.072 mg/l  
|| Application Route : inhalation (dust/mist/fume)  
|| Exposure time : 28 Days  
|| Method : OECD Test Guideline 412

### **Aspiration toxicity**

Not classified based on available information.

### **Experience with human exposure**

### **Components:**

#### **Gentamicin:**

|| Ingestion : Target Organs: Kidney  
|| Target Organs: inner ear  
|| Symptoms: Dizziness, Vertigo, hearing loss, tinnitus, fetal deafness

---

## 12. ECOLOGICAL INFORMATION

### **Ecotoxicity**

#### **Components:**

#### **Gentamicin:**

|| Toxicity to daphnia and other aquatic invertebrates : EC50 (Daphnia magna (Water flea)): 86 mg/l  
|| Exposure time: 48 h  
|| Method: OECD Test Guideline 202

## Gentamicin (8%) Injection Formulation

Version 3.0      Revision Date: 2020/10/10      SDS Number: 1845019-00008      Date of last issue: 2020/03/23  
 Date of first issue: 2017/07/25

|                                     |   |  |
|-------------------------------------|---|--|
|                                     |   | LC50 (Americamysis): 30 mg/l<br>Exposure time: 96 h<br>Method: US-EPA OPPTS 850.1035                                     |
| Toxicity to algae/aquatic plants    | : | EC50 (Pseudokirchneriella subcapitata (green algae)): 10 µg/l<br>Exposure time: 72 h<br>Method: OECD Test Guideline 201  |
|                                     |   | NOEC (Pseudokirchneriella subcapitata (green algae)): 1.5 µg/l<br>Exposure time: 72 h<br>Method: OECD Test Guideline 201 |
|                                     |   | EC50 (Anabaena flos-aquae (cyanobacterium)): 4.7 µg/l<br>Exposure time: 72 h<br>Method: OECD Test Guideline 201          |
|                                     |   | NOEC (Anabaena flos-aquae (cyanobacterium)): 1.6 µg/l<br>Exposure time: 72 h<br>Method: OECD Test Guideline 201          |
| M-Factor (Acute aquatic toxicity)   | : | 100  |
| M-Factor (Chronic aquatic toxicity) | : | 1  |
| Toxicity to microorganisms          | : | EC50: 288.7 mg/l<br>Exposure time: 3 h<br>Test Type: Respiration inhibition<br>Method: OECD Test Guideline 209           |

**Benzyl alcohol:**

|  |   |  |
|--|---|--|
| Toxicity to fish   | : | LC50 (Pimephales promelas (fathead minnow)): 460 mg/l<br>Exposure time: 96 h   |
| Toxicity to daphnia and other aquatic invertebrates                    | : | EC50 (Daphnia magna (Water flea)): 230 mg/l<br>Exposure time: 48 h<br>Method: OECD Test Guideline 202                    |
| Toxicity to algae/aquatic plants                                       | : | EC50 (Pseudokirchneriella subcapitata (green algae)): 770 mg/l<br>Exposure time: 72 h<br>Method: OECD Test Guideline 201 |
|  |   | NOEC (Pseudokirchneriella subcapitata (green algae)): 310 mg/l<br>Exposure time: 72 h<br>Method: OECD Test Guideline 201 |
| Toxicity to daphnia and other aquatic invertebrates (Chronic toxicity) | : | NOEC (Daphnia magna (Water flea)): 51 mg/l<br>Exposure time: 21 d<br>Method: OECD Test Guideline 211                     |

## Gentamicin (8%) Injection Formulation

Version 3.0      Revision Date: 2020/10/10      SDS Number: 1845019-00008      Date of last issue: 2020/03/23  
 Date of first issue: 2017/07/25

---

**Persistence and degradability****Components:****Gentamicin:**

Biodegradability : Result: rapidly degradable  
 Biodegradation: 100 %  
 Exposure time: 28 d  
 Method: OECD Test Guideline 314

**Benzyl alcohol:**

Biodegradability : Result: Readily biodegradable.  
 Biodegradation: 92 - 96 %  
 Exposure time: 14 d

**Bioaccumulative potential****Components:****Gentamicin:**

Partition coefficient: n-octanol/water : log Pow: < -2

**Benzyl alcohol:**

Partition coefficient: n-octanol/water : log Pow: 1.05

**Mobility in soil**

No data available

**Hazardous to the ozone layer**

Not applicable

**Other adverse effects**

No data available

---

**13. DISPOSAL CONSIDERATIONS****Disposal methods**

Waste from residues : Dispose of in accordance with local regulations.  
 Contaminated packaging : Empty containers should be taken to an approved waste handling site for recycling or disposal.  
 If not otherwise specified: Dispose of as unused product.

---

**14. TRANSPORT INFORMATION****International Regulations****UNRTDG**

UN number : UN 3082  
 Proper shipping name : ENVIRONMENTALLY HAZARDOUS SUBSTANCE, LIQUID, N.O.S. (Gentamicin)  
 Class : 9

# SAFETY DATA SHEET



## Gentamicin (8%) Injection Formulation



Version 3.0      Revision Date: 2020/10/10      SDS Number: 1845019-00008      Date of last issue: 2020/03/23  
Date of first issue: 2017/07/25

---

Packing group : III  
Labels : 9

### IATA-DGR

UN/ID No. : UN 3082  
Proper shipping name : Environmentally hazardous substance, liquid, n.o.s.  
(Gentamicin)  
Class : 9  
Packing group : III  
Labels : Miscellaneous  
Packing instruction (cargo aircraft) : 964  
Packing instruction (passenger aircraft) : 964  
Environmentally hazardous : yes

### IMDG-Code

UN number : UN 3082  
Proper shipping name : ENVIRONMENTALLY HAZARDOUS SUBSTANCE, LIQUID,  
N.O.S.  
(Gentamicin)  
Class : 9  
Packing group : III  
Labels : 9  
EmS Code : F-A, S-F  
Marine pollutant : yes

### Transport in bulk according to Annex II of MARPOL 73/78 and the IBC Code

Not applicable for product as supplied.

### National Regulations

Refer to section 15 for specific national regulation.

### Special precautions for user

The transport classification(s) provided herein are for informational purposes only, and solely based upon the properties of the unpackaged material as it is described within this Safety Data Sheet. Transportation classifications may vary by mode of transportation, package sizes, and variations in regional or country regulations.

---

## 15. REGULATORY INFORMATION

### Related Regulations

#### Fire Service Law

Designated Flammable Substances, Flammable liquid, (2 cubic metre)

#### Chemical Substance Control Law

Not applicable for Specified Chemical Substance, Monitoring Chemical Substance and Priority Assessment Chemical Substance.

#### Industrial Safety and Health Law

#### Harmful Substances Prohibited from Manufacture

Not applicable

#### Harmful Substances Required Permission for Manufacture

Not applicable

**Gentamicin (8%) Injection Formulation**

Version      Revision Date:      SDS Number:      Date of last issue: 2020/03/23  
3.0          2020/10/10          1845019-00008      Date of first issue: 2017/07/25

---

**Substances Prevented From Impairment of Health**

Not applicable

**Circular concerning Information on Chemicals having Mutagenicity - Annex 2: Information on Existing Chemicals having Mutagenicity**

Not applicable

**Circular concerning Information on Chemicals having Mutagenicity - Annex 1: Information on Notified Substances having Mutagenicity**

Not applicable

**Substances Subject to be Notified Names**

Not applicable

**Substances Subject to be Indicated Names**

Not applicable

**Ordinance on Prevention of Hazards Due to Specified Chemical Substances**

Not applicable

**Ordinance on Prevention of Lead Poisoning**

Not applicable

**Ordinance on Prevention of Tetraalkyl Lead Poisoning**

Not applicable

**Ordinance on Prevention of Organic Solvent Poisoning**

Not applicable

**Enforcement Order of the Industrial Safety and Health Law - Attached table 1 (Dangerous Substances)**

Not applicable

**Poisonous and Deleterious Substances Control Law**

Not applicable

**Act on Confirmation, etc. of Release Amounts of Specific Chemical Substances in the Environment and Promotion of Improvements to the Management Thereof**

Not applicable

**High Pressure Gas Safety Act**

Not applicable

**Explosive Control Law**

Not applicable

**Vessel Safety Law**

Miscellaneous dangerous substances and articles (Article 2 and 3 of rules on shipping and storage of dangerous goods and its Attached Table 1)

**Aviation Law**

Miscellaneous dangerous substances and articles (Article 194 of The Enforcement Rules of Aviation Law and its Attached Table 1)

**Marine Pollution and Sea Disaster Prevention etc Law**

Bulk transportation                      : Noxious liquid substance(Category Z)

Pack transportation                      : Classified as marine pollutant

## Gentamicin (8%) Injection Formulation

|         |                |               |                                 |
|---------|----------------|---------------|---------------------------------|
| Version | Revision Date: | SDS Number:   | Date of last issue: 2020/03/23  |
| 3.0     | 2020/10/10     | 1845019-00008 | Date of first issue: 2017/07/25 |

---

**Narcotics and Psychotropics Control Act**

Narcotic or Psychotropic Raw Material (Export / Import Permission)  
Not applicable

Specific Narcotic or Psychotropic Raw Material (Export / Import permission)  
Not applicable

**Waste Disposal and Public Cleansing Law**

Industrial waste

**The components of this product are reported in the following inventories:**

AICS : not determined

DSL : not determined

IECSC : not determined

---

**16. OTHER INFORMATION****Further information**

Sources of key data used to compile the Safety Data Sheet : Internal technical data, data from raw material SDSs, OECD eChem Portal search results and European Chemicals Agency, <http://echa.europa.eu/>

Items where changes have been made to the previous version are highlighted in the body of this document by two vertical lines.

Date format : yyyy/mm/dd

**Full text of other abbreviations**

JP OEL JSOH : Japan. The Japan Society for Occupational Health. Recommendation of Occupational Exposure Limits

JP OEL JSOH / OEL-C : Occupational Exposure Limit-Ceiling

AIIC - Australian Inventory of Industrial Chemicals; ANTT - National Agency for Transport by Land of Brazil; ASTM - American Society for the Testing of Materials; bw - Body weight; CMR - Carcinogen, Mutagen or Reproductive Toxicant; DIN - Standard of the German Institute for Standardisation; DSL - Domestic Substances List (Canada); ECx - Concentration associated with x% response; ELx - Loading rate associated with x% response; EmS - Emergency Schedule; ENCS - Existing and New Chemical Substances (Japan); ErCx - Concentration associated with x% growth rate response; ERG - Emergency Response Guide; GHS - Globally Harmonized System; GLP - Good Laboratory Practice; IARC - International Agency for Research on Cancer; IATA - International Air Transport Association; IBC - International Code for the Construction and Equipment of Ships carrying Dangerous Chemicals in Bulk; IC50 - Half maximal inhibitory concentration; ICAO - International Civil Aviation Organization; IECSC - Inventory of Existing Chemical Substances in China; IMDG - International Maritime Dangerous Goods; IMO - International Maritime Organization; ISHL - Industrial Safety and Health Law (Japan); ISO - International Organisation for Standardization; KECl - Korea Existing Chemicals Inventory; LC50 - Lethal Concentration to 50 % of a test population; LD50 - Lethal Dose to 50% of a test population (Median Lethal Dose); MARPOL - International Convention for the Prevention of Pollution from Ships; n.o.s. - Not Otherwise Specified; Nch - Chilean Norm; NO(A)EC - No Observed (Adverse) Effect Concentration; NO(A)EL - No Observed (Adverse) Effect Level; NOELR - No Observable Effect Loading Rate; NOM - Official Mexican Norm; NTP - National Toxicology Program; NZIoC - New



# SAFETY DATA SHEET



## Gentamicin (8%) Injection Formulation



|         |                |               |                                 |
|---------|----------------|---------------|---------------------------------|
| Version | Revision Date: | SDS Number:   | Date of last issue: 2020/03/23  |
| 3.0     | 2020/10/10     | 1845019-00008 | Date of first issue: 2017/07/25 |

---

Zealand Inventory of Chemicals; OECD - Organization for Economic Co-operation and Development; OPPTS - Office of Chemical Safety and Pollution Prevention; PBT - Persistent, Bioaccumulative and Toxic substance; PICCS - Philippines Inventory of Chemicals and Chemical Substances; (Q)SAR - (Quantitative) Structure Activity Relationship; REACH - Regulation (EC) No 1907/2006 of the European Parliament and of the Council concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals; SADT - Self-Accelerating Decomposition Temperature; SDS - Safety Data Sheet; TCSI - Taiwan Chemical Substance Inventory; TDG - Transportation of Dangerous Goods; TSCA - Toxic Substances Control Act (United States); UN - United Nations; UNRTDG - United Nations Recommendations on the Transport of Dangerous Goods; vPvB - Very Persistent and Very Bioaccumulative; WHMIS - Workplace Hazardous Materials Information System

The information provided in this Safety Data Sheet is correct to the best of our knowledge, information and belief at the date of its publication. The information is designed only as a guidance for safe handling, use, processing, storage, transportation, disposal and release and shall not be considered a warranty or quality specification of any type. The information provided relates only to the specific material identified at the top of this SDS and may not be valid when the SDS material is used in combination with any other materials or in any process, unless specified in the text. Material users should review the information and recommendations in the specific context of their intended manner of handling, use, processing and storage, including an assessment of the appropriateness of the SDS material in the user's end product, if applicable.

JP / EN