

# SAFETY DATA SHEET



## Gentamicin (8%) Injection Formulation



Version 4.1      Revision Date: 30.09.2023      SDS Number: 1845023-00013      Date of last issue: 04.04.2023  
Date of first issue: 25.07.2017

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### Section 1: Identification

Product name : Gentamicin (8%) Injection Formulation

#### Manufacturer or supplier's details

Company : Organon & Co.

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

Telephone : +1-551-430-6000

Emergency telephone number : +1-215-631-6999

E-mail address : EHSSTEWARD@organon.com

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

Recommended use : Pharmaceutical

Restrictions on use : Not applicable

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### Section 2: Hazard identification

#### GHS Classification

Respiratory sensitisation : Category 1

Skin sensitisation : Category 1

Reproductive toxicity : Category 1

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

Hazardous to the aquatic environment - acute hazard : Category 1

Hazardous to the aquatic environment - chronic hazard : Category 2

#### GHS label elements

Hazard pictograms :



Signal word : Danger

Hazard statements : H317 May cause an allergic skin reaction.

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H334 May cause allergy or asthma symptoms or breathing difficulties if inhaled.  
 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.  
 P260 Do not breathe mist or vapours.  
 P272 Contaminated work clothing should not be allowed out of the workplace.  
 P273 Avoid release to the environment.  
 P280 Wear protective gloves/ protective clothing/ eye protection/ face protection.  
 P284 Wear respiratory protection.

**Response:**

P302 + P352 IF ON SKIN: Wash with plenty of water.  
 P304 + P340 IF INHALED: Remove person to fresh air and keep comfortable for breathing.  
 P308 + P313 IF exposed or concerned: Get medical advice/ attention.  
 P333 + P313 If skin irritation or rash occurs: Get medical advice/ attention.  
 P342 + P311 If experiencing respiratory symptoms: Call a POISON CENTER/ doctor.  
 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.

**Section 3: Composition/information on ingredients**

Substance / Mixture : Mixture

**Components**

Chemical name	CAS-No.	Concentration (% w/w)
Gentamicin	1403-66-3	8
Benzyl alcohol	100-51-6	1.5
Sodium metabisulphite	7681-57-4	0.32

**Section 4: First-aid measures**

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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 cause an allergic skin reaction. May cause allergy or asthma symptoms or breathing difficulties if inhaled. 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, and use the recommended personal protective equipment when the potential for exposure exists (see section 8).
Notes to physician	:	Treat symptomatically and supportively.

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**Section 5: Fire-fighting 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.
Hazchem Code	:	3Z

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**Section 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.

**Section 7: Handling and storage**

- 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.
- 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

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- engineering controls, proper personal protective equipment, appropriate degowning and decontamination procedures, industrial hygiene monitoring, medical surveillance and the use of administrative controls.
- Conditions for safe storage : Keep in properly labelled containers.  
Store locked up.  
Keep tightly closed.
- Materials to avoid : Store in accordance with the particular national regulations.  
Do not store with the following product types:  
Strong oxidizing agents

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**Section 8: Exposure controls/personal protection**
**Components with workplace control parameters**

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
Further information: OTO				
Sodium metabisulphite	7681-57-4	WES-TWA	5 mg/m <sup>3</sup>	NZ OEL
Further information: Skin sensitiser, Respiratory sensitiser				
		TWA	5 mg/m <sup>3</sup>	ACGIH

- 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 : Chemical-resistant gloves
- Material
- 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.

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**Section 9: Physical and chemical properties**

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Appearance : liquid

Colour : colourless

Odour : No data available

Odour Threshold : No data available

pH : No data available

Melting point/freezing point : No data available

Initial boiling point and boiling range : No data available

Flash point : > 93.3 °C

Evaporation rate : No data available

Flammability (solid, gas) : Not applicable

Flammability (liquids) : Not applicable

Upper explosion limit / Upper flammability limit : No data available

Lower explosion limit / Lower flammability limit : No data available

Vapour pressure : No data available

Relative vapour density : No data available

Relative density : No data available

Density : No data available

Solubility(ies)  
Water solubility : No data available

Partition coefficient: n-octanol/water : No data available

Auto-ignition temperature : No data available

Decomposition temperature : No data available

Viscosity  
Viscosity, kinematic : No data available

Explosive properties : Not explosive

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Oxidizing properties	:	The substance or mixture is not classified as oxidizing.
Molecular weight	:	No data available
Particle size	:	No data available

**Section 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. Can react with strong oxidizing agents.
Conditions to avoid	:	None known.
Incompatible materials	:	Oxidizing agents
Hazardous decomposition products	:	No hazardous decomposition products are known.

**Section 11: Toxicological information**

Exposure routes	:	Inhalation Skin contact Ingestion Eye contact
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**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
Acute dermal toxicity	:	Acute toxicity estimate: > 2,000 mg/kg 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

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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

Acute dermal toxicity : Acute toxicity estimate: 1,100 mg/kg  
Method: Expert judgement  
Remarks: Based on national or regional regulation.

**Sodium metabisulphite:**

Acute oral toxicity : LD50 (Rat): 1,540 mg/kg  
Method: OECD Test Guideline 401

Acute inhalation toxicity : LC50 (Rat): > 5.5 mg/l  
Exposure time: 4 h  
Test atmosphere: dust/mist  
Remarks: Based on data from similar materials

Acute dermal toxicity : LD50 (Rat): > 2,000 mg/kg  
Method: OECD Test Guideline 402  
Remarks: Based on data from similar materials

**Skin corrosion/irritation**

Not classified based on available information.

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

Species : Rabbit  
Result : Mild skin irritation

**Benzyl alcohol:**

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



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**Sodium metabisulphite:**

Result : Skin irritation  
Remarks : Based on national or regional regulation.

**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

**Sodium metabisulphite:**

Species : Rabbit  
Result : Irreversible effects on the eye  
Method : OECD Test Guideline 405

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

May cause an allergic skin reaction.

**Respiratory sensitisation**

May cause allergy or asthma symptoms or breathing difficulties if inhaled.

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

Remarks : No data available

**Benzyl alcohol:**

Assessment : Probability or evidence of skin sensitisation in humans  
Remarks : Based on national or regional regulation.

**Sodium metabisulphite:**

Assessment : Probability or evidence of skin sensitisation in humans  
Remarks : Based on national or regional regulation.

Assessment : May cause sensitisation by inhalation.  
Remarks : Based on national or regional regulation.

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**Chronic toxicity****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

Test Type: Chromosome aberration test in vitro  
Result: equivocal

Genotoxicity in vivo : Test Type: Mammalian erythrocyte micronucleus test (in vivo cytogenetic assay)  
Species: Mouse  
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

**Sodium metabisulphite:**

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

Test Type: In vitro mammalian cell gene mutation test  
Method: OECD Test Guideline 476  
Result: negative

Genotoxicity in vivo : Test Type: Mammalian erythrocyte micronucleus test (in vivo cytogenetic assay)  
Species: Mouse  
Application Route: Subcutaneous  
Method: OECD Test Guideline 474  
Result: negative  
Remarks: Based on data from similar materials

**Carcinogenicity**

Not classified based on available information.

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**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

**Sodium metabisulphite:**

Species : Mouse  
 Application Route : Ingestion  
 Exposure time : 24 Months  
 Result : negative  
 Remarks : Based on data from similar materials

**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  
 Developmental Toxicity: LOAEL: 10 mg/kg body weight  
 Result: foetal mortality, No malformations were observed.

Test Type: Embryo-foetal development  
 Species: Rat  
 Application Route: Intraperitoneal  
 Developmental Toxicity: LOAEL: 50 mg/kg body weight

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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  
Species: Rat  
Application Route: Ingestion  
Result: negative  
Remarks: Based on data from similar materials

Effects on foetal development : Test Type: Embryo-foetal development  
Species: Mouse  
Application Route: Ingestion  
Result: negative

**Sodium metabisulphite:**

Effects on fertility : Test Type: Three-generation study  
Species: Rat  
Application Route: Ingestion  
Result: negative

Effects on foetal development : Test Type: Embryo-foetal development  
Species: Rabbit  
Application Route: Ingestion  
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

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Exposure time : 12 Months  
 Target Organs : Kidney  
 Symptoms : Vomiting, Salivation

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

**Sodium metabisulphite:**

Species : Rat  
 NOAEL : 110 mg/kg  
 LOAEL : 220 mg/kg  
 Application Route : Ingestion  
 Exposure time : 104 Weeks

**Aspiration toxicity**

Not classified based on available information.

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**Experience with human exposure****Components:****Gentamicin:**

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

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**Section 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

LC50 (Americamysis): 30 mg/l  
 Exposure time: 96 h  
 Method: US-EPA OPPTS 850.1035

Toxicity to algae/aquatic plants : EC50 (Pseudokirchneriella subcapitata (green algae)): 10 µg/l  
 Exposure time: 72 h  
 Method: OECD Test Guideline 201

NOEC (Pseudokirchneriella subcapitata (green algae)): 1.5 µg/l  
 Exposure time: 72 h  
 Method: OECD Test Guideline 201

EC50 (Anabaena flos-aquae (cyanobacterium)): 4.7 µg/l  
 Exposure time: 72 h  
 Method: OECD Test Guideline 201

NOEC (Anabaena flos-aquae (cyanobacterium)): 1.6 µg/l  
 Exposure time: 72 h  
 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  
 Exposure time: 3 h  
 Test Type: Respiration inhibition  
 Method: OECD Test Guideline 209

**Benzyl alcohol:**

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Toxicity to fish : LC50 (Pimephales promelas (fathead minnow)): 460 mg/l  
Exposure time: 96 h

Toxicity to daphnia and other aquatic invertebrates : EC50 (Daphnia magna (Water flea)): 230 mg/l  
Exposure time: 48 h  
Method: OECD Test Guideline 202

Toxicity to algae/aquatic plants : EC50 (Pseudokirchneriella subcapitata (green algae)): 770 mg/l  
Exposure time: 72 h  
Method: OECD Test Guideline 201

NOEC (Pseudokirchneriella subcapitata (green algae)): 310 mg/l  
Exposure time: 72 h  
Method: OECD Test Guideline 201

Toxicity to daphnia and other aquatic invertebrates (Chronic toxicity) : NOEC (Daphnia magna (Water flea)): 51 mg/l  
Exposure time: 21 d  
Method: OECD Test Guideline 211

### **Sodium metabisulphite:**

Toxicity to fish : LC50 (Oncorhynchus mykiss (rainbow trout)): 178 mg/l  
Exposure time: 96 h

Toxicity to daphnia and other aquatic invertebrates : EC50 (Daphnia magna (Water flea)): 89 mg/l  
Exposure time: 48 h

Toxicity to algae/aquatic plants : ErC50 (Desmodesmus subspicatus (green algae)): 43.8 mg/l  
Exposure time: 72 h

EC10 (Desmodesmus subspicatus (green algae)): 33.3 mg/l  
Exposure time: 72 h

Toxicity to fish (Chronic toxicity) : NOEC (Danio rerio (zebra fish)): >= 316 mg/l  
Exposure time: 34 d  
Method: OECD Test Guideline 210  
Remarks: Based on data from similar materials

Toxicity to daphnia and other aquatic invertebrates (Chronic toxicity) : NOEC (Daphnia magna (Water flea)): >= 10 mg/l  
Exposure time: 21 d

Toxicity to microorganisms : EC10 (Pseudomonas putida): 30.8 mg/l  
Exposure time: 17 h

### **Persistence and degradability**

#### **Components:**

##### **Gentamicin:**

Biodegradability : Result: rapidly degradable

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Biodegradation: 100 %  
 Exposure time: 28 d  
 Method: OECD Test Guideline 314

**Benzy alcohol:**

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

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

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

**Benzy alcohol:**

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

**Mobility in soil**

No data available

**Other adverse effects**

No data available

**Section 13: Disposal considerations****Disposal methods**

Waste from residues : Do not dispose of waste into sewer.  
 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.

**Section 14: Transport information****International Regulations****UNRTDG**

UN number : UN 3082  
 Proper shipping name : ENVIRONMENTALLY HAZARDOUS SUBSTANCE, LIQUID, N.O.S.  
 (Gentamicin)  
 Class : 9  
 Packing group : III  
 Labels : 9  
 Environmentally hazardous : yes

**IATA-DGR**

UN/ID No. : UN 3082



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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****NZS 5433**

UN number : UN 3082  
Proper shipping name : ENVIRONMENTALLY HAZARDOUS SUBSTANCE, LIQUID,  
N.O.S.  
(Gentamicin)  
Class : 9  
Packing group : III  
Labels : 9  
Hazchem Code : 3Z  
Marine pollutant : no

**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.

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**Section 15: Regulatory information****Safety, health and environmental regulations/legislation specific for the substance or mixture****HSNO Approval Number**

HSR100425 Pharmaceutical Active Ingredients Group Standard

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**HSW Controls**

Certified handler certificate not required.  
 Tracking hazardous substance not required.  
 Refer to the Health and Safety at Work (Hazardous Substances) Regulations 2017, for further information.

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

AICS	:	not determined
DSL	:	not determined
IECSC	:	not determined

**Section 16: Other information**

Revision Date : 30.09.2023

**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/>

Date format : dd.mm.yyyy

**Full text of other abbreviations**

ACGIH	:	USA. ACGIH Threshold Limit Values (TLV)
NZ OEL	:	New Zealand. Workplace Exposure Standards for Atmospheric Contaminants
ACGIH / TWA	:	8-hour, time-weighted average
NZ OEL / WES-TWA	:	Workplace Exposure Standard - Time Weighted average

AllC - 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; KECI - 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: 04.04.2023
4.1	30.09.2023	1845023-00013	Date of first issue: 25.07.2017

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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; TECL - Thailand Existing Chemicals Inventory; 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.

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