


**SECTION 1: PRODUCT IDENTIFICATION**

<b>PRODUCT NAME</b>	<b>GENTAMICIN SULFATE, USP</b>
<b>PRODUCT CODE</b>	<b>0632</b>
<b>SUPPLIER</b>	<b>MEDISCA Inc.</b> Tel.: 1.800.932.1039   Fax.: 1.855.850.5855 626 Tom Miller Road, Plattsburgh, NY, 12901 <b>MEDISCA Pharmaceutique Inc.</b> Tel.: 1.800.665.6334   Fax.: 514.338.1693 4509 Rue Dobrin, St. Laurent, QC, H4R 2L8 <b>MEDISCA Australia PTY LTD</b> Tel.: 1.300.786.392   Fax.: 61.2.9700.9047 Unit 7, Heritage Business Park 5-9 Ricketty Street, Mascot, NSW 2020
<b>EMERGENCY PHONE</b>	CHEMTREC Day or Night Within USA and Canada: 1-800-424-9300 NSW Poisons Information Centre: 131 126 National Chemical Emergency Centre 44(0)1235239670
<b>RECOMMENDED USES</b>	Pharmaceutical Manufacturing
<b>RESTRICTIONS ON USE</b>	Not applicable

**SECTION 2: HAZARDS IDENTIFICATION**

<b>GHS CLASSIFICATION</b>	Acute Toxicity - Oral (Category 5) Toxic to Reproduction (Category 1B) Sensitization - Skin (Category 1) Eye Irritation (Category 2B)
<b>PICTOGRAM</b>	
<b>SIGNAL WORD</b>	Danger
<b>HAZARD STATEMENT(S)</b>	May be harmful if swallowed. May damage fertility or the unborn child. May cause an allergic skin reaction. Causes eye irritation.
<b>ADVERSE PHYSIOCHEMICAL, HUMAN HEALTH AND ENVIRONMENTAL EFFECTS</b>	Repeated exposure may cause skin dryness or cracking.

<b>PRECAUTIONARY STATEMENT(S)</b>	<b>Prevention</b>	Obtain, read and follow all special instructions before use. Do not handle until all safety precautions have been read and understood. Wear protective gloves, protective clothing, eye and face protection and hearing protection. Avoid breathing dust, fume, gas, mist, vapors, spray. Contaminated work clothing should not be allowed out of the workplace. Wash hands thoroughly after handling. Do not touch eyes.		
	<b>Response</b>	IF SWALLOWED: Get medical help. IF EXPOSED OR CONCERNED: Get medical advice. IF ON SKIN: Wash with plenty of water. If skin irritation or rash occurs: Get medical help advice/attention. Take off contaminated clothing and wash it before reuse. IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing. If eye irritation persists, get medical help.		
	<b>Storage</b>	Store locked up.		
	<b>Disposal</b>	Dispose of contents and/or container in accordance with local regulations.		
<b>HMIS CLASSIFICATION</b>	<b>Health Hazard</b>	1	<b>Flammability</b>	0
	<b>Reactivity</b>	0	<b>Personal Protection</b>	E

## SECTION 3: COMPOSITION/INFORMATION ON INGREDIENTS

<b>CHEMICAL NAME</b>	Sulfate salt of 4, 6-(glycoside)-2-deoxystreptamine
<b>BOTANICAL NAME</b>	Not applicable
<b>SYNONYM</b>	Gentamicin C complex sulfate
<b>CHEMICAL FORMULA</b>	C <sub>21</sub> H <sub>43</sub> N <sub>5</sub> O <sub>7</sub> · H <sub>2</sub> SO <sub>4</sub>
<b>CHEMICAL FAMILY</b>	Aminoglycoside
<b>CAS NUMBER</b>	1405-41-0
<b>ALTERNATE CAS NUMBER</b>	Not applicable
<b>MOLECULAR WEIGHT</b>	575.67

CHEMICAL NAME	CAS NUMBER	EC NUMBER	% BY WEIGHT
GENTAMICIN SULFATE	1405-41-0	215-778-9	100

There are no additional ingredients present which, within the current knowledge of the supplier and in the concentrations applicable, are classified as health hazards and hence require reporting in this section.

<b>NOTES</b>	<p>Composition: A natural complex antibiotic substance with four components:</p> <ul style="list-style-type: none"> <li>• Sulfate of Gentamicin C1</li> <li>• Gentamicin C2</li> <li>• Gentamicin C1a</li> <li>• Gentamicin C2a</li> </ul>
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## SECTION 4: FIRST-AID MEASURES

<b>IN CASE OF EYE CONTACT</b>	Flush with copious amounts of water for 15 minutes, separating eyelids with fingers. If irritation persists seek medical aid.
<b>IN CASE OF SKIN CONTACT</b>	Wash with soap & water for 15 minutes. If irritation persists seek medical aid.
<b>IF SWALLOWED</b>	Call a physician. Wash out mouth with water. Do not induce vomiting without medical advice.

IF INHALED	Remove to fresh air. If not breathing, give artificial respiration. If breathing is difficult, give oxygen. Call a physician.
MEDICAL ATTENTION AND SPECIAL TREATMENT	Get emergency medical help.
SYMPTOMS CAUSED BY EXPOSURE	Not expected to present a significant hazard under anticipated conditions of normal use.

## SECTION 5: FIREFIGHTING MEASURES

SPECIFIC HAZARDS ARISING FROM THE CHEMICAL	Not applicable
FLAMMABLE PROPERTIES	May be combustible at high temperature.
HAZARDOUS COMBUSTION PRODUCTS	Under fire conditions, hazardous fumes will be present.
SUITABLE & UNSUITABLE EXTINGUISHING MEDIA	<b>Small fire:</b> dry chemical, CO <sub>2</sub> or water spray. <b>Large fire:</b> dry chemical, CO <sub>2</sub> , alcohol resistant foam or water spray. Do not get water inside containers.
PROTECTIVE EQUIPMENT AND PRECAUTIONS FOR FIREFIGHTERS	Wear self-contained breathing apparatus and protective clothing to prevent contact with skin and eyes.

## SECTION 6: ACCIDENTAL RELEASE MEASURES

PERSONAL PRECAUTIONS	Wear respiratory protection. Avoid dust formation. Avoid breathing vapours, mist or gas. Ensure adequate ventilation. Evacuate personnel to safe areas. Avoid breathing dust.
METHODS & MATERIAL FOR CONTAINMENT	On land, sweep or shovel into suitable containers. Minimize generation of dust.
CLEANUP PROCEDURE	Do not touch damaged containers or spilled material unless wearing appropriate protective clothing. Wear respirator, chemical safety goggles, rubber boots and heavy rubber gloves. Stop leak if you can do it without risk. Prevent entry into waterways, sewers, basements or confined areas. Shut off all sources of ignition. Evacuate the area. If necessary, employ water fog to disperse the vapors. Absorb the matter with compatible vermiculite or other absorbing material. Place in a suitable container and retain for disposal. Ventilate and clean the affected area. Do not flush into sewerage system or to drains.
REFERENCE TO OTHER SECTIONS	See Section 7 for information on safe handling. See Section 8 for information on personal protection equipment. See Section 13 for disposal information.

## SECTION 7: HANDLING AND STORAGE

PRECAUTIONS FOR SAFE HANDLING	Do not inhale. Avoid contact with eyes, skin and clothing. Avoid prolonged or repeated exposure. Wash thoroughly after handling. Store away from incompatible materials, in a well-ventilated area. Eliminate all sources of ignition. Store in accordance with local regulations. Do not store in unlabeled containers. Containers that have been opened must be carefully resealed and kept upright to prevent leakage. Use appropriate containment to avoid environmental contamination.
CONDITIONS FOR SAFE STORAGE	Store away from incompatible materials, in a well-ventilated area. Eliminate all sources of ignition. Store in accordance with local regulations. Do not store in unlabeled containers. Containers that have been opened must be carefully resealed and kept upright to prevent leakage. Use appropriate containment to avoid environmental contamination.

**STORAGE CONDITIONS**

Store in original container, tightly sealed, protected from direct sunlight and moisture.

Short term excursions, temperature excursions as experienced during shipping and warehousing, up to 40°C are acceptable.

## SECTION 8: EXPOSURE CONTROLS/ PERSONAL PROTECTION

Chemical Name: GENTAMICIN SULFATE CAS #: 1405-41-0

	Country	Limit value-8 hours		Limit value-Short Term		IDLH	REL	Advisory	Notes
		ppm	mg/m <sup>3</sup>	ppm	mg/m <sup>3</sup>				
OSHA	USA	N/L	N/L	N/L	N/L	N/L	N/L	N/A	N/A
ACGIH	USA	N/L	N/L	N/L	N/L	N/L	N/L	N/A	N/A
NIOSH	USA	N/L	N/L	N/L	N/L	N/L	N/L	N/A	N/A
WEEL	USA	N/L	N/L	N/L	N/L	N/L	N/L	N/A	N/A
HSIS	Australia	N/L	N/L	N/L	N/L	N/L	N/L	N/A	N/A
HSE	UK	N/L	N/L	N/L	N/L	N/L	N/L	N/A	N/A
GESTIS	Add Country	N/L	N/L	N/L	N/L	N/L	N/L	N/A	N/A

N/L = Not listed ; N/A = Not Available

PELs are 8-hour TWAs = Limit value - Eight hours

Ceiling or Short-Term TWA = STEL = Limit value - Short term

**EXPOSURE GUIDELINES**

Consult local authorities for provincial or state exposure limits. Particulates not otherwise regulated, respirable fraction: 5 mg/m<sup>3</sup>

**PERSONAL PROTECTIVE EQUIPMENT**

**Eyes:** Wear appropriate protective eyeglasses or chemical safety goggles as described by WHMIS or OSHA's eye and face protection regulations in 29 CFR 1910.133 or European Standard EN166. **Skin:** Wear appropriate gloves to prevent skin exposure. **Clothing:** Wear appropriate protective clothing to minimize contact with skin. **Respirators:** Follow WHMIS or OSHA respirator regulations found in 29 CFR 1910.134 or European Standard EN 149. Use a NIOSH/MSHA or European Standard EN 149 approved respirator if exposure limits are exceeded or if irritation or other symptoms are experienced. **Thermal Hazards:** For products representing a thermal hazard, appropriate Personal Protective Equipment should be used.

**SPECIFIC ENGINEERING CONTROLS**

Adequate mechanical ventilation. Fumehood, eye wash station, and safety shower.

**BIOLOGICAL MONITORING**

Not available

**CONTROL BANDING**

Not available

## SECTION 9: PHYSICAL AND CHEMICAL PROPERTIES

**PHYSICAL STATE**

Solid

**DESCRIPTION**

White to buff, hygroscopic powder.

**SOLUBILITY**

Freely soluble in water; insoluble in alcohol, in acetone, in chloroform, in ether, and in benzene.

**ODOR**

Odorless

**FLAMMABILITY**

May be combustible at high temperature

<b>AUTO-IGNITION TEMPERATURE</b>	Not available	<b>BOILING POINT</b>	Not available	<b>DECOMPOSITION TEMPERATURE</b>	Not available
<b>EVAPORATION RATE</b>	Not available	<b>EXPLOSIVE LIMIT</b>	Not available	<b>FLASH POINT</b>	Not available
<b>log P (OCTANOL-WATER)</b>	Not available	<b>LOWER FLAMMABLE/EXPLOSIVE LIMIT(S)</b>	Not available	<b>MELTING/FREEZING POINT</b>	(218 - 237)°C, (424.4-458.6)°F
<b>PARTICLE CHARACTERISTICS</b>	Not available	<b>OXIDIZING PROPERTY</b>	Not available	<b>pH</b>	3.5 -5.5 (4%)
<b>RELATIVE DENSITY (WATER = 1)</b>	Not available	<b>SPECIFIC GRAVITY</b>	Not available	<b>UPPER FLAMMABLE/EXPLOSIVE LIMIT(S)</b>	Not available
<b>VAPOR DENSITY (AIR = 1)</b>	Not available	<b>VAPOR PRESSURE</b>	Not available	<b>VISCOSITY</b>	Not available

The physical data presented above are typical values and should not be construed as a specification.

## SECTION 10: STABILITY AND REACTIVITY

<b>REACTIVITY</b>	Not established.
<b>CHEMICAL STABILITY</b>	Stable under recommended storage conditions.
<b>INCOMPATIBLE MATERIALS</b>	Strong oxidants.
<b>HAZARDOUS DECOMPOSITION PRODUCTS</b>	Toxic fumes of carbon monoxide, carbon dioxide, nitrogen oxides and other gases may occur.
<b>HAZARDOUS POLYMERIZATION</b>	Will not occur.
<b>POSSIBILITY OF HAZARDOUS REACTION</b>	Not established.
<b>CONDITIONS TO AVOID</b>	Moisture, sunlight and extreme temperatures.

## SECTION 11: TOXICOLOGICAL INFORMATION

<b>ACUTE TOXICITY</b>	Oral: Rat: LD50: (mg/kg): > 5000 Dermal: Rabbit LD50: (mg/kg): Not available Inhalation: Rat: LC50: (mg/L/4hr): Not available
<b>SKIN CORROSION/IRRITATION</b>	Based on available data, the classification criteria are not met. Skin irritation; Result: Irritant.; Species: Rabbit; Severity: Slight
<b>SERIOUS EYE DAMAGE/EYE IRRITATION</b>	Causes eye irritation. Result: Irritant; Species: Rabbit; Organ: Eye; Severity: Slight
<b>RESPIRATORY SENSITIZATION</b>	Due to lack of data the classification is not possible.
<b>SKIN SENSITIZATION</b>	May cause an allergic skin reaction. Contact dermatitis has been reported in literature following the therapeutic use of aminoglycosides.

<b>GERM CELL MUTAGENICITY</b>	Due to lack of data the classification is not possible. Data from germ cell mutagenicity tests were not found.								
<b>CARCINOGENICITY</b>	<table border="0"> <tr> <td><b>OSHA</b></td> <td>GENTAMICIN SULFATE is not listed.</td> </tr> <tr> <td><b>NTP</b></td> <td>GENTAMICIN SULFATE is not listed.</td> </tr> <tr> <td><b>IARC</b></td> <td>GENTAMICIN SULFATE is not evaluated.</td> </tr> <tr> <td><b>California Proposition</b></td> <td>This product does not contain any chemicals known to the State of California to cause cancer, birth defects, or any other reproductive harm.</td> </tr> </table>	<b>OSHA</b>	GENTAMICIN SULFATE is not listed.	<b>NTP</b>	GENTAMICIN SULFATE is not listed.	<b>IARC</b>	GENTAMICIN SULFATE is not evaluated.	<b>California Proposition</b>	This product does not contain any chemicals known to the State of California to cause cancer, birth defects, or any other reproductive harm.
<b>OSHA</b>	GENTAMICIN SULFATE is not listed.								
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<b>IARC</b>	GENTAMICIN SULFATE is not evaluated.								
<b>California Proposition</b>	This product does not contain any chemicals known to the State of California to cause cancer, birth defects, or any other reproductive harm.								
<b>ADDITIONAL CARCINOGENICITY INFORMATION</b>	Based on available data, the classification criteria are not met.								
<b>REPRODUCTIVE TOXICITY</b>	<p>May damage fertility or the unborn child. Aminoglycosides have been reported to cause kidney toxicity and deafness in the fetus when given to mothers during pregnancy.</p> <p>10 mg/kg/day; Result: Fetotoxicity; Species: Mouse 4 mg/kg/day; Result: Transient abnormalities in fetus; Species: Guinea pig 50 mg/kg/day; Result: Fetotoxicity; Species: Rat 75 mg/kg/day; Result: Reduced birth weights and other adverse effects in offspring; Species: Rat</p> <p>Suspected toxic for reproduction: The Toolbox profiler DART scheme v.1.0 gives an alert for toxicity to reproduction; CAESAR developmental toxicity model in VEGA (Q)SAR platform predicts that the chemical is Toxicant (good reliability); Developmental/Reproductive Toxicity library (PG) in VEGA (Q)SAR platform predicts that the chemical is Toxicant (moderate reliability).</p>								
<b>SPECIFIC TARGET ORGAN TOXICITY - SINGLE EXPOSURE</b>	Due to lack of data the classification is not possible.								
<b>SPECIFIC TARGET ORGAN TOXICITY - REPEATED EXPOSURE</b>	Due to lack of data the classification is not possible.								
<b>ASPIRATION HAZARDS</b>	Based on available data, the classification criteria are not met.								
<b>SIGNS AND SYMPTOMS OF EXPOSURE</b>	<p>ROUTES OF EXPOSURE: Oral, Dermal, Inhalation, Eye contact</p> <p>EARLY ONSET SYMPTOMS RELATED TO EXPOSURE: Not available</p> <p>DELAYED HEALTH EFFECT FROM EXPOSURE: Not available</p> <p>Symptoms related to the physical, chemical, and toxicological characteristics: Aminoglycosides: Hearing problems. Clumsiness. Dizziness. Change in frequency or amount of urination. Thirst. Loss of appetite. Numbness or tingling of skin. Gastrointestinal disturbances.</p>								
<b>POTENTIAL HEALTH EFFECTS</b>	<table border="0"> <tr> <td><b>Inhalation</b></td> <td>May be harmful if inhaled. May cause respiratory tract irritation.</td> </tr> <tr> <td><b>Ingestion</b></td> <td>Harmful if swallowed.</td> </tr> <tr> <td><b>Skin</b></td> <td>May be harmful if absorbed through skin. May cause skin irritation, allergic reaction.</td> </tr> <tr> <td><b>Eyes</b></td> <td>Causes eye irritation.</td> </tr> </table>	<b>Inhalation</b>	May be harmful if inhaled. May cause respiratory tract irritation.	<b>Ingestion</b>	Harmful if swallowed.	<b>Skin</b>	May be harmful if absorbed through skin. May cause skin irritation, allergic reaction.	<b>Eyes</b>	Causes eye irritation.
<b>Inhalation</b>	May be harmful if inhaled. May cause respiratory tract irritation.								
<b>Ingestion</b>	Harmful if swallowed.								
<b>Skin</b>	May be harmful if absorbed through skin. May cause skin irritation, allergic reaction.								
<b>Eyes</b>	Causes eye irritation.								

## SECTION 12: ECOLOGICAL INFORMATION

<b>ECOTOXICITY</b>	<p>EC50: 48 Hr: Crustacea: (mg/L): Not available LC50: 96 Hr: Fish: (mg/L): Not available EC50: 72 or 96 Hr: Algae (or other aqua plants): (mg/L): Not available</p>
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<b>PERSISTENCE AND DEGRADABILITY</b>	Not available
<b>BIOACCUMULATIVE POTENTIAL</b>	Not available
<b>MOBILITY IN SOIL</b>	Freely soluble in water (>1 mg/L)
<b>OTHER ADVERSE EFFECTS</b>	Suspected hazardous to the aquatic environment: Fish toxicity classification (SarPy/IRFMN) model in VEGA (Q)SAR platform predicts that the chemical is Toxic-3 (between 10 and 100 mg/l) (moderate reliability).  This product is not intended to be released into the environment.

## SECTION 13: DISPOSAL CONSIDERATIONS

<b>DISPOSAL METHODS</b>	Dispose of in accordance with federal / local laws and regulations. Avoid release into the environment.
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## SECTION 14: TRANSPORT INFORMATION

<b>UN PROPER SHIPPING NAME</b>	Not dangerous good
<b>UN NUMBER</b>	Not applicable
<b>CLASS</b>	Not applicable
<b>PACKING GROUP</b>	Not applicable

### AUSTRALIA

<b>HAZCHEM</b>	Not applicable
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### EU

<b>TRANSPORT IN BULK ACCORDING TO ANNEX II OF MARPOL 73/78 AND THE IBC CODE</b>	Not listed
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<b>ENVIRONMENTAL HAZARDS</b>	Not available
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<b>SPECIAL SHIPPING INFORMATION</b>	Not applicable
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## SECTION 15: REGULATORY INFORMATION

### UNITED STATES REGULATIONS

Chemical Name & CAS	CERCLA 40 CFR Part 302.4	SARA (Title III) 40 CFR	EPA 40 CFR Part 355		Pennsylvania	Right-to-know		California Prop 65
			Appendix A	Appendix B		New Jersey	Massachusetts	
GENTAMICIN SULFATE 1405-41-0	N/L	N/L	N/L	N/L	N/L	N/L	N/L	N/L

N/L = Not Listed; X = Listed

### AUSTRALIAN REGULATIONS

Chemical Name & CAS	Poisons and Therapeutic Goods	Therapeutic Goods Act	Code of Practices - Illicit Drug	Poisons Standard	Work Health and Safety Regulations	Inventory of Industrial Chemicals
GENTAMICIN SULFATE 1405-41-0	N/L	N/L	N/L	N/L	N/L	N/L

N/L = Not Listed

**EU REGULATIONS**

Chemical Name & CAS	REACH ANNEX XVII	REACH ANNEX XIV	EC 1005/2009	EC 850/2004	EC 1107/2009	PIC - Prior Informed Consent Regulation	EC 2012/18
GENTAMICIN SULFATE 1405-41-0	N/L	N/L	N/L	N/L	N/L	N/L	N/L

N/L = Not Listed; X = Listed

Any EU regulation not listed above is not applicable to this product.

SUBJECT TO INTERNATIONAL AGREEMENT                      Not applicable

**SECTION 16: OTHER INFORMATION**
**REFERENCES**
**ABBREVIATIONS AND ACRONYMS**

Available upon request

**ACGIH** - American Conference of Governmental Industrial Hygienists; **AIHA WEEL** – American Industrial Hygiene Association Workplace Environment Exposure Levels; **CAESAR** – Computer Assisted Evaluation of industrial chemical Substances According to Regulations; **CAS** – Chemical Abstract Service; **CERCLA** – Comprehensive Environmental Response, Compensation, and Liability Act; **EC50** – Effective Concentration, 50%; **EPA** – Environmental Protection Agency; **GHS** – Global Harmonized System; **HMIS** – Hazardous Materials Information System; **HSE** – Health and Safety Executive; **HSIS** – Hazardous Substances Information System; **IARC** – International Agency for Research on Cancer; **IDLH** - Immediately Dangerous to Life or Health; **IRFMN** – Ready Biodegradability Model; **ISS** – Istituto Superiore Sanità; **LC50** – Lethal Concentration, 50%; **LD50** – Lethal Dose, 50%; **MSHA** - Mine Safety and Health Administration; **NIOSH** – National Institute for Occupational Safety and Health; **NTP** – National Toxicology Program; **OSHA PEL** – Occupational Safety & Health Administration Permissible Exposure Limits; **QSAR** – Quantitative Structure-activity relationship; **REL** - Recommended Exposure Limit; **SARA** – Superfund Amendments and Reauthorization Act; **STEL** – Short Term Exposure Limit; **TLV** – Threshold Limit Value; **TWA** – Time Weighted Average; **WHMIS** – Workplace Hazardous Materials Information System

**LAST REVISION**

03/2023

**SUPERSEDES**

05/2021

For a list of changes to the SDS since the last version, please communicate with MEDISCA at [www.medisca.com](http://www.medisca.com)



# SAFETY DATA SHEET

## DISCLAIMER

This document was created in accordance with OSHA, Safe Work Australia and WHMIS regulations. The above information is believed to be correct but does not purport to be all inclusive and shall be used only as a guide. The information in this document is based on the present state of our knowledge and is applicable to the product with regard to appropriate safety precautions. It does not represent any guarantee of the properties of the product. MEDISCA® shall not be held liable for any damage resulting from handling or from contact with the above product. Recipients of the product must take responsibility for observing existing laws and regulations.

## SUPPLEMENTARY INFORMATION

For all country specific requirements not outlined on this Safety Data Sheet, please request Supplementary Page to this Safety Data Sheet.