

SAFETY DATA SHEETS

This SDS packet was issued with item:

078588340

The safety data sheets (SDS) in this packet apply to one or more components included in the items listed below. Items listed below may require one or more SDS. Please refer to invoice for specific item number(s).

078588399



Material Safety Data Sheet

I - Product Identification:

Product Name: Clarithromycin, USP
Empirical Formula: C₃₈H₆₉NO₁₃
Chemical Name: 6-O-Methylerythromycin
Uses: Antibacterial

Code: 1937
CAS#: 81103-11-9

II - Toxicological Information:

Irritancy: May cause irritation to eyes, skin, mucous membranes, respiratory and gastrointestinal tract.
Adverse Effects: May be harmful if swallowed, inhaled, or absorbed through skin. May cause frequent gastrointestinal disturbances. Taste disturbances, stomatitis, glossitis, tooth discoloration, and headache have occurred. There have been reports of transient CNS effects such as anxiety, dizziness, insomnia, hallucinations, and confusion; convulsions have also occurred. Other adverse effects include hypoglycaemia, leucopenia, and thrombocytopenia.

Toxicity Data: Oral: Rat: LD50: 1270 mg/kg Mouse: LD50: 1230 mg/kg

III - Physical Data:

Physical State: Liquid ☐ Solid ☒ Gas ☐
Description: White to off-white, crystalline powder.
Solubility: Soluble in acetone; slightly soluble in dehydrated alcohol, in methanol, and in acetonitrile, and in phosphate buffer at pH values of 2 to 5; practically insoluble in water.
Other Physical Properties: mw: 747.95 mp: 222 - 225°C (w.decomposition)

IV - Fire and Explosion Hazards:

Flammability: May be combustible at high temperature.
Flash Point: N/A
Extinguishing Media: Small fire: dry chemical, CO₂ or water spray. Large fire: dry chemical, CO₂, alcohol resistant foam or water spray. Do not get water inside containers.
Fire Fighting: Wear self-contained breathing apparatus and protective clothing to prevent contact with skin and eyes.

V - Reactivity Data:

Stability: Stable
Incompatibilities: Strong oxidizing agents
Hazardous Decomp. Products: Toxic fumes of carbon monoxide, carbon dioxide, nitrogen oxide.
Hazardous Polymerization: Will not occur.

VI - Preventive Measures:

Preventive Measures: Do not inhale dust. Avoid contact with eyes, skin and clothing. Avoid prolonged or repeated exposure. Wash thoroughly after handling.

Personal Protective Equipment: Eyes: Wear appropriate protective eyeglasses or chemical safety goggles as described by WHIMIS 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 WHIMIS 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.

Specific Engineering Controls: Adequate mechanical ventilation. Fumehood, eye wash station, and safety shower.

Spills & Leaks: 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.

Waste Disposal: Dispose of in accordance with federal / local laws and regulations.

Storage: Preserve in tight containers. Protect from light.

Shipping: N/A

VII - First Aid Measures:

Eyes: Flush with copious amounts of water for 15 minutes, separating eyelids with fingers. If irritation persists seek medical aid.

Skin: Wash with soap & water for 15 minutes. If irritation persists seek medical aid.

Ingestion: Call a physician. Wash out mouth with water. Do not induce vomiting without medical advice.

Inhalation: Remove to fresh air. If not breathing, give artificial respiration. If breathing is difficult, give oxygen. Call a physician.

NOTE: If victim is unconscious, never induce vomiting nor give liquids. Place victim in a stable side position and keep warm.

Ecological Data: N/A


Hazardous Ingredients: N/A

References: Available on request

SECTION 1: PRODUCT IDENTIFICATION

PRODUCT NAME	CLARITHROMYCIN, USP
PRODUCT CODE	1937
SUPPLIER	<p>MEDISCA Inc. Tel.: 1.800.932.1039 Fax.: 1.855.850.5855 661 Route 3, Unit C, Plattsburgh, NY, 12901 3955 W. Mesa Vista Ave., Unit A-10, Las Vegas, NV, 89118 6641 N. Belt Line Road, Suite 130, Irving, TX, 75063</p> <p>MEDISCA Pharmaceutique Inc. Tel.: 1.800.665.6334 Fax.: 514.338.1693 4509 Rue Dobrin, St. Laurent, QC, H4R 2L8 21300 Gordon Way, Unit 153/158, Richmond, BC V6W 1M2</p> <p>MEDISCA Australia PTY LTD Tel.: 1.300.786.392 Fax.: 61.2.9700.9047 Unit 7, Heritage Business Park 5-9 Ricketty Street, Mascot, NSW 2020</p>
EMERGENCY PHONE	CHEMTREC Day or Night Within USA and Canada: 1-800-424-9300 NSW Poisons Information Centre: 131 126
USES	Antibacterial

SECTION 2: HAZARDS IDENTIFICATION

GHS CLASSIFICATION	<p>Acute Toxicity - Oral (Category 4) Sensitization - Skin (Category 1) Toxic to Reproduction (Category 2) Acute Aquatic Toxicity (Category 3)</p>
PICTOGRAM	
SIGNAL WORD	Warning
HAZARD STATEMENT(S)	<p>Harmful if swallowed. May cause an allergic skin reaction. Suspected of damaging fertility or the unborn child. Harmful to aquatic life.</p>
AUSTRALIA-ONLY HAZARDS	Not Applicable.
PRECAUTIONARY STATEMENT(S)	<p>Prevention</p> <p>Wash thoroughly after handling. Do not eat, drink or smoke when using this product. Avoid breathing dust, fume, gas, mist, vapors, spray. Contaminated work clothing must not be allowed out of the workplace. Obtain special instructions before use. Do not handle until all safety precautions have been read and understood. Wear protective gloves, protective clothing, eye protection, face protection. Avoid release to the environment.</p> <p>Response</p> <p>IF SWALLOWED: Immediately call a poison center or medical professional. Rinse mouth. IF ON SKIN: Wash with plenty of water. If skin irritation or rash occurs: Get medical advice/attention. Wash contaminated clothing before reuse. IF EXPOSED OR CONCERNED: Get medical advice/attention.</p> <p>Storage</p> <p>Store locked up.</p>

HMIS CLASSIFICATION	Disposal	Dispose of contents and/or container in accordance with local regulations.		
	Health Hazard	2	Flammability	0
	Reactivity	0	Personal Protection	E

SECTION 3: COMPOSITION/INFORMATION ON INGREDIENTS

CHEMICAL NAME	6-O-Methylerythromycin								
BOTANICAL NAME	Not applicable								
SYNONYM	Not applicable								
CHEMICAL FORMULA	C ₃₈ H ₆₉ NO ₁₃								
CAS NUMBER	81103-11-9								
ALTERNATE CAS NUMBER	Not applicable								
MOLECULAR WEIGHT	747.95								
COMPOSITION	<table><tr><th>CHEMICAL NAME</th><th>CAS NUMBER</th><th>% BY WEIGHT</th></tr><tr><td>CLARITHROMYCIN</td><td>81103-11-9</td><td>100</td></tr></table>			CHEMICAL NAME	CAS NUMBER	% BY WEIGHT	CLARITHROMYCIN	81103-11-9	100
CHEMICAL NAME	CAS NUMBER	% BY WEIGHT							
CLARITHROMYCIN	81103-11-9	100							
NOTES	<p>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.</p> <p>Chemical family: Macrolide antibiotic.</p> <p>Clarithromycin is a macrolide derived from erythromycin.</p>								

SECTION 4: FIRST-AID MEASURES

IN CASE OF EYE CONTACT	Flush with copious amounts of water for 15 minutes, separating eyelids with fingers. If irritation persists seek medical aid.
IN CASE OF SKIN CONTACT	Wash with soap & water for 15 minutes. If irritation persists seek medical aid.
IF SWALLOWED	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
SYMPTOMS AND EFFECTS	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.
EXTINGUISHING MEDIA	Small fire: dry chemical, CO ₂ or water spray. Large fire: dry chemical, CO ₂ , 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.

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.

STORAGE CONDITIONS

Store in original container, tightly sealed, protected from direct sunlight, in a dry and well-ventilated area, away from incompatible materials. Store in accordance with local regulations. Eliminate all ignition sources. Separate from oxidizing materials. Containers that have been opened must be carefully resealed and kept upright to prevent leakage. Do not store in unlabelled containers. Use appropriate containment to avoid environmental contamination. Recommended storage temperature: 15° - 30°C. Preserve in tight containers. Protect from light.

SECTION 8: EXPOSURE CONTROLS/ PERSONAL PROTECTION

Chemical Name: CLARITHROMYCIN CAS #: 81103-11-9

	TWA	Ceiling	STEL	REL	IDLH	Remarks
OSHA PEL	N/L	N/L	-	-	-	-
ACGIH TLV	N/L	N/L	N/L	-	-	-
NIOSH	N/L	N/L	N/L	N/L	N/L	-
AIHA WEEL	N/L	N/L	N/L	-	-	-
Safe Work Australia HSIS	N/L	N/L	N/L	-	-	-
HSE	N/L	N/L	N/L	-	-	-

N/L = Not Listed

EXPOSURE GUIDELINES

Consult local authorities for provincial or state exposure limits. Particulates not otherwise regulated, respirable fraction: 5 mg/m³.

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.

SPECIFIC ENGINEERING CONTROLS

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

NOTES

USP TWA: 1 mg/m³

SECTION 9: PHYSICAL AND CHEMICAL PROPERTIES

PHYSICAL STATE	Solid				
DESCRIPTION	White to off-white, crystalline powder.				
SOLUBILITY	Soluble in acetone; slightly soluble in dehydrated alcohol, in methanol, and in acetonitrile, and in phosphate buffer at pH values of 2 to 5; practically insoluble in water.				
ODOR	Odorless				
FLAMMABILITY	May be combustible at high temperature				
ODOR THRESHOLD	Not available	pH	8.0 - 10.0	MELTING POINT	(217 - 225)°C, (422.6 - 437)°F (decomposes)
BOILING POINT	(217 - 225)°C, (422.6 - 437)°F (decomposes)	FREEZING POINT	Not available	FLASH POINT	Not available
SPECIFIC GRAVITY	Not available	EVAPORATION RATE	Not available	EXPLOSIVE LIMIT	Not available
UPPER FLAMMABLE/ EXPLOSIVE LIMIT(S)	Not available	LOWER FLAMMABLE/ EXPLOSIVE LIMIT(S)	Not available	VAPOR PRESSURE	< 0.0000001 kPa (25°C)
VAPOR DENSITY (AIR = 1)	Not available	RELATIVE DENSITY (WATER = 1)	Not available	log P (OCTANOL-WATER)	2.69 (20°C)
AUTO-IGNITION TEMPERATURE	Not available	DECOMPOSITION TEMPERATURE	(217 - 225)°C, (422.6 - 437)°F	VISCOSITY	Not available

SECTION 10: STABILITY AND REACTIVITY

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

SECTION 11: TOXICOLOGICAL INFORMATION

ACUTE TOXICITY	Oral: Rat: LD50: (mg/kg): 1270 Dermal: Rabbit: LD50: (mg/kg): Not available Inhalation: Rat: LD50: (mg/L/4hr): Not available
-----------------------	--

SKIN CORROSION/IRRITATION	Due to lack of data the classification is not possible.
SERIOUS EYE DAMAGE/EYE IRRITATION	Due to lack of data the classification is not possible.
RESPIRATORY OR SKIN SENSITIZATION	In addition to skin rashes and other hypersensitivity reactions which occasionally occur in patients receiving macrolides, leukocytoclastic vasculitis, Henoch-Schönlein purpura, and toxic epidermal necrolysis have been reported in patients receiving clarithromycin. Cross sensitivity: Persons sensitive to erythromycin or other macrolide antibiotics may be sensitive to this material also.
GERM CELL MUTAGENICITY	Mammalian microsome bacterial induced mutation: Negative. Mouse dominant lethal assay: Negative. Mouse lymphoma assay: Negative. Mouse micronucleus test: Negative. Rat hepatocyte DNA synthesis assay: Negative. S. typhimurium Ames assay: Negative.
CARCINOGENICITY	OSHA CLARITHROMYCIN is not listed. NTP CLARITHROMYCIN is not listed. IARC CLARITHROMYCIN is not evaluated. California Proposition 65 This product contains the following chemical known to the State of California to cause birth defects or other reproductive harm: CLARITHROMYCIN. Not available
ADDITIONAL CARCINOGENICITY INFORMATION	
REPRODUCTIVE TOXICITY	Teratogen. Reproductivity study: Rat: 150 mg/kg/day: Caused increased incidence of cardiovascular abnormalities. Reproductivity study: Mouse: 500 mg/kg/day: Increased incidence of cleft palate. Reproductivity study: Rabbit: < 125 mg/kg: No teratogenicity or fetotoxicity; offspring were normal. It should not be used during pregnancy if possible as high doses have been associated with embryotoxicity in animal studies
SPECIFIC TARGET ORGAN TOXICITY - SINGLE EXPOSURE	Due to lack of data the classification is not possible.
SPECIFIC TARGET ORGAN TOXICITY - REPEATED EXPOSURE	Due to lack of data the classification is not possible.
ASPIRATION HAZARDS	Due to lack of data the classification is not possible.
SIGNS AND SYMPTOMS OF EXPOSURE	Not expected to present a significant hazard under anticipated conditions of normal use. Symptoms related to the physical, chemical, and toxicological characteristics: Fever. Chills. Painful or difficult urination. Diarrhea. Nausea. Vomiting. Abdominal pain. Headache. Blisters. Fast heartbeat. Irregular heartbeat. Chest pain. Bleeding or bruising. Delayed and immediate effects of exposure: Gastrointestinal disturbances. Cross sensitivity: Persons sensitive to erythromycin or other macrolide antibiotics may be sensitive to this material also. Medical conditions aggravated by exposure: Impaired liver function. Impaired kidney function.
POTENTIAL HEALTH EFFECTS	Inhalation May be harmful if inhaled. May cause respiratory tract irritation. Ingestion Harmful if swallowed. Gastrointestinal disturbances. Skin May be harmful if absorbed through skin. May cause skin irritation. May cause an allergic skin reaction. Eyes May cause eye irritation.

SECTION 12: ECOLOGICAL INFORMATION

TOXICITY	EC50: 48 Hr: Daphnia magna: (mg/L): 25.72 LC50: 96 Hr: Fish: (mg/L): Not available IC50: 72 Hr: Algae: (mg/L): Not available
-----------------	--

PERSISTENCE AND DEGRADABILITY

Half-life elimination in humans: 2 - 3h.

BIOACCUMULATIVE POTENTIAL

Log Pow: 2.69 (20°C).

MOBILITY IN SOIL

Water Solubility: 0.342 mg/L (25°C).

 Henry's Law Constant: 1.73E-29 atm-m³/mole (25°C).

OTHER ADVERSE EFFECTS

Not available

This product is not intended to be released into the environment

SECTION 13: DISPOSAL CONSIDERATIONS

WASTE DISPOSAL

Dispose of in accordance with federal / local laws and regulations. Avoid release into the environment.

SECTION 14: TRANSPORT INFORMATION

UNITED STATES & CANADA
UN PROPER SHIPPING NAME

Not dangerous good

UN NUMBER

Not applicable

CLASS

Not applicable

PACKING GROUP

Not applicable

AUSTRALIA
UN PROPER SHIPPING NAME

Not dangerous good

UN NUMBER

Not applicable

CLASS

Not applicable

PACKING GROUP

Not applicable

HAZCHEM

Not applicable

ENVIRONMENTAL HAZARDS

Not available

SPECIAL SHIPPING INFORMATION

Not applicable

SECTION 15: REGULATORY INFORMATION

Chemical Name & CAS	CERCLA 40 CFR Part 302.4	SARA (Title III) 40 CFR Part 372.65	EPA 40 CFR Part 355		Right-to-know			California Prop 65
			Appendix A	Appendix B	Pennsylvania	New Jersey	Massachusetts	
CLARITHROMYCIN 81103-11-9	N/L	N/L	N/L	N/L	N/L	N/L	N/L	X

N/L = Not Listed; X = Listed

AUSTRALIAN REGULATIONS

Chemical Name & CAS	Poisons and Therapeutic Goods Regulation	Therapeutic Goods Act	Code of Practices - Illicit Drug Precursors
CLARITHROMYCIN 81103-11-9	Not Listed	Listed as Schedule 4	Not Listed

SECTION 16: OTHER INFORMATION

REFERENCES

Available upon request

ABBREVIATIONS AND ACRONYMS

CAS – Chemical Abstract Service; **GHS** – Global Harmonized System; **OSHA PEL** – Occupational Safety & Health Administration Permissible Exposure Limits; **TWA** – Time Weighted Average; **HSIS** – Hazardous Substances Information System; **STEL** – Short Term Exposure Limit; **AIHA WEEL** – American Industrial Hygiene Association Workplace Environment Exposure Levels; **LD50** – Lethal Dose, 50%; **IARC** – International Agency for Research on Cancer; **NTP** – National Toxicology Program; **WHMIS** – Workplace Hazardous Materials Information System; **SARA** – Superfund Amendments and Reauthorization Act; **EPA** – Environmental Protection Agency; **CERCLA** – Comprehensive Environmental Response, Compensation, and Liability Act; **HMIS** – Hazardous Materials Information System; **NIOSH** – National Institute for Occupational Safety and Health; **MSHA** – Mine Safety and Health Administration; **ACGIH** – American Conference of Governmental Industrial Hygienists; **IDHL** – Immediately Dangerous to Health or Life; **TLV** – Threshold Limit Value; **HSE** – Health and Safety Executive; **REL** – Recommended Exposure Limit

LAST REVISION

01/2016

SUPERSEDES

04/2012

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.