### 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

Tel.: (800) 665-6334 Fax: (518) 563-5047

# **Material Safety Data Sheet**

I - Product Identification: 1937 Code: CAS#: 81103-11-9

Product Name: Clarithromycin, USP

Empirical Formula:  $C_{38}H_{69}NO_{13}$ 

Chemical Name: 6-O-Methylerythromycin

Uses: Antibacterial

II - <u>Toxicological Information</u>:

May cause irritation to eyes, skin, mucous membranes, respiratory and gastrointestinal tract. Irritancy:

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

throbocytopenia.

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

III - Physical Data:

Physical State: Liquid Solid X 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: mp: 222 - 225°C (w.decomposition) mw: 747.95

IV - Fire and Explosion Hazards:

Flammability: May be combustible at high temperature.

Flash Point:

Extinguishing Media: Small fire: dry chemical, CO<sub>2</sub> or water spray. Large fire: dry chemical, CO<sub>2</sub>, 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.

Preserve in tight containers. Protect from light. Storage:

Shipping:

VII - First Aid Measures:

Inhalation:

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.

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

This is intended only as a guide to the appropriate precautionary handling of the product. We assume no responsibility and/or liability whatsoever for the use or misuse of this product.



### **SECTION 1: PRODUCT IDENTIFICATION**

PRODUCT NAME CLARITHROMYCIN, USP

PRODUCT CODE

SUPPLIER

MEDISCA Inc.

1937

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

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

**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

MEDISCA UK Limited

Tel.: 0800.029.4641

33 St. James's Square, London, United Kingdom SW1Y 4JS

EMERGENCY PHONE 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

**USES** Antibacteria

#### SECTION 2: HAZARDS IDENTIFICATION

GHS CLASSIFICATION Acute Toxicity - Oral (Category 4)
Sensitization - Skin (Category 1)

Acute Aquatic Toxicity (Category 3)

PICTOGRAM

SIGNAL WORD

Warning

HAZARD STATEMENT(S) Harmful if swallowed.

May cause an allergic skin reaction.

Suspected of damaging fertility or the unborn child.

Harmful to aquatic life.

ADVERSE PHYSIOCHEMICAL, HUMAN HEALTH AND ENVIRONMENTAL

**EFFECTS** 

Not Applicable.



PRECAUTIONARY STATEMENT(S) Prevention 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.

Response 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.

Storage Store locked up.

Disposal Dispose of contents and/or container in accordance with local regulations.

HMIS CLASSIFICATION Health Hazard 2 Flammability 0

Reactivity 0 Personal Protection

### **SECTION 3: COMPOSITION/INFORMATION ON INGREDIENTS**

CHEMICAL NAME 6-O-Methylerythromycin

BOTANICAL NAME

SYNONYM

Not applicable

CHEMICAL FORMULA

CAS NUMBER

ALTERNATE CAS NUMBER

C38H69NO13

81103-11-9

Not applicable

MOLECULAR WEIGHT 747.9571
COMPOSITION

NOTES

CHEMICAL NAME CAS NUMBER EC NUMBER % BY WEIGHT
CLARITHROMYCIN 81103-11-9 658-034-2 100

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.

Chemical family: Macrolide antibiotic.

Clarithromycin is a macrolide derived from erythromycin.

#### **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**

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SPECIFIC HAZARDS ARISING FROM THE CHEMICAL

Explosion hazard: Avoid generating dust; fine dust dispersed in air in sufficient concentrations and in the

presence of an ignition source is a potential dust explosion hazard.

Dust explosion properties:

Kst: 262 bar.m/s

Minimum ignition energy (MIE) - dust cloud: 1 - 3 mJ

FLAMMABLE PROPERTIES

May be combustible at high temperature

HAZARDOUS COMBUSTION PRODUCTS

Under fire conditions, hazardous fumes will be present.

SUITABLE & UNSUITABLE EXTINGUISHING MEDIA

Small fire: dry chemical, CO<sub>2</sub> or water spray. Large fire: dry chemical, CO<sub>2</sub>, alcohol resistant foam or water

spray

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.

Preserve in tight containers. Protect from light.

SPECIFIC END USE(S)

See Section 1

#### **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	-	-	- (%)
GESTIS	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/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.

NOTES USP: ELV: Industrial 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

FLAMMABILITY	May be combustible at hig	gh temperature	perature				
AUTO-IGNITION TEMPERATURE	Not available	BOILING POINT	Not available	DECOMPOSITION TEMPERATURE	(217 - 225 )°C, (422.6 - 437)°F		
EVAPORATION RATE	Not available	EXPLOSIVE LIMIT	Not available	FLASH POINT	Not available		
log P (OCTANOL-WATER)	2.69 (20°C)	LOWER FLAMMABLE/ EXPLOSIVE LIMIT(S)	Not available	MELTING/FREEZING POINT	(217 - 225)°C, (422.6 - 437)°F (decomposes)		
ODOR THRESHOLD	Not available	OXIDIZING PROPERTY	Not available	рН	8.0 - 10.0 (0.2%)		
RELATIVE DENSITY (WATER = 1)	Not available	SPECIFIC GRAVITY	Not available	UPPER FLAMMABLE/ EXPLOSIVE LIMIT(S)	Not available		
VAPOR DENSITY (AIR = 1)	Not available	VAPOR PRESSURE	< 0.0000001 kPa (25°C)	VISCOSITY	Not available		

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



#### **SECTION 10: STABILITY AND REACTIVITY**

**REACTIVITY** Not established

CHEMICAL STABILITY Stable under recommended storage conditions

INCOMPATIBLE MATERIALS Strong oxidants.

HAZARDOUS DECOMPOSITION Toxic

**PRODUCTS** 

Toxic fumes of carbon monoxide, carbon dioxide, nitrogen oxides and other gases may occur

HAZARDOUS POLYMERIZATION POSSIBLITY OF HAZARDOUS

REACTION

Will not occur 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: LC50: (mg/L/4hr): Not available

Due to lack of data the classification is not possible.

**SKIN CORROSION/IRRITATION**Due to lack of data the classification is not possible.

SERIOUS EYE DAMAGE/EYE

IRRITATION

RESPIRATORY SENSITIZATION Due to lack of data the classification is not possible.

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.

Persons sensitive to erythromycin or other macrolide antibiotics may be sensitive to this material also.

GERM CELL MUTAGENICITY

Based on available data, the classification criteria are not met.

CARCINOGENICITY OSHA CLARITHROMYCIN is not listed.

NTP CLARITHROMYCIN is not listed.

IARC CLARITHROMYCIN is not evaluated.

California This product contains the following chemical known to the State of California to cause birth

**Proposition 65** defects or other reproductive harm: CLARITHROMYCIN.

ADDITIONAL CARCINOGENICITY

INFORMATION

Due to lack of data the classification is not possible.

REPRODUCTIVE TOXICITY Based on available data, the classification criteria are not met.

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

Based on available data, the classification criteria are not met.



SIGNS AND SYMPTOMS OF EXPOSURE

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. Gastroitenstinal 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: Crustacea: Daphnia magna: (mg/L): 25.72

LC50: 96 Hr: Fish: (mg/L): Not available

EC50: 72 or 96 Hr: Algae (or other aqua plants): (mg/L): Not available

PERSISTENCE AND DEGRADABILITY

**BIOACCUMULATIVE POTENTIAL** 

Log Pow: 2.69 (20°C).

MOBILITY IN SOIL

Water Solubility: 0.342 mg/L (25°C).

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

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**

UN PROPER SHIPPING NAME Not dangerous good

UN NUMBER Not applicable
CLASS Not applicable
PACKING GROUP Not applicable

<u>AUSTRALIA</u>

HAZCHEM Not applicable

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EU

TRANSPORT IN BULK ACCORDING TO ANNEX II OF MARPOL 73/78 AND THE IBC CODE

Not listed

ENVIRONMENTAL HAZARDS
SPECIAL SHIPPING INFORMATION

Not available
Not applicable

### **SECTION 15: REGULATORY INFORMATION**

#### **UNITED STATES REGULATIONS**

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

N/L = Not Listed; X = Listed

#### **AUSTRALIAN REGULATIONS**

Chemical Name Poisons and Therap Goods Regulation		Therapeutic Goods Act	Code of Practices - Illicit Drug Precursors		
CLARITHROMYCIN, 81103-11-9	N/L	Listed as Schedule 4	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	EC 649/2012	EC 2012/118
CLARITHROMYCIN, 81103-11-9	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.

### **SECTION 16: OTHER INFORMATION**

REFERENCES Available upon request



#### ABBREVIATIONS AND ACRONYMS

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 – Instituto 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

07/2019 LAST REVISION **SUPERSEDES** 04/2019

> For a list of changes to the SDS since the last version, please communicate with MEDISCA at www.medisca.com

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.

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

SUPPLEMENTARY INFORMATION