

Safety Data Sheet

Revision Date: 12/12/2019

Section 1: Chemical Identification

1.1 Chemical Identification

Product Name: Roxithromycin
 Alternative Name: (Z)-Roxithromycin
 Catalog Number: R-500

1.2 Relevant Uses and Uses Advised Against

Recommended use: This product is not for use in humans. It is for research purposes only.

1.3 Supplier Contact Information

Distributed by: Gold Biotechnology, Inc.
 1328 Ashby Rd.
 St. Louis, MO 63132
 Phone: (314) 890-8778
 Fax: (314) 890-0503
 Email: contactgoldbio86@goldbio.com

1.4 Emergency Contact Information

Emergency Phone: (800)248-7609 (Monday-Friday, 9:00 a.m. – 5:00 p.m. CST)

Section 2: Hazardous Information

2.1 GHS Classification

Acute Toxicity, Oral (Category 4)

2.2 GHS Label Elements, Including Precautionary statements



Warning

2.3 Hazard Statements

H302: Harmful if swallowed

2.4 Precautionary Statements

P264: Wash skin thoroughly after handling
 P270: Do not eat, drink or smoke when using this product
 P301+312: IF SWALLOWED: Call a POISON CENTER or doctor/physician if you feel unwell
 P330: Rinse mouth
 P501: Dispose of contents/container to an approved waste disposal plant

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2.8 HMIS Classification

Health Hazard:	1
Chronic Health Hazard:	*
Flammability:	0
Physical Hazards:	0

2.9 NFPA Rating

Health Hazard:	1
Fire:	0
Reactivity Hazard:	0

Section 3: Composition/Information on Ingredients

3.1 Composition

Identity:	Roxithromycin
IUPAC:	(3R,4S,5S,6R,7R,9R,10Z,11S,12R,13S,14R)-6-[(2S,3R,4S,6R)-4-(dimethylamino)-3-hydroxy-6-methyloxan-2-yl]oxy-14-ethyl-7,12,13-trihydroxy-4-[(2R,4R,5S,6S)-5-hydroxy-4-methoxy-4,6-dimethyloxan-2-yl]oxy-10-(2-methoxyethoxymethoxyimino)-3,5,7,9,11,13-hexamethyl-oxacyclotetradecan-2-one
Synonyms:	(Z)-Roxithromycin
CAS Number:	80214-83-1
Molecular Formula:	C ₄₁ H ₇₆ N ₂ O ₁₅
Molecular Weight:	837.05 g/mol

Section 4: First Aid Measures

4.1 Detailed First Aid Measures

Inhalation:	If breathed in, move person into fresh air. If not breathing, give artificial respiration. Consult a physician.
Skin:	Immediately wash skin copiously with soap and water. Take victim immediately to hospital. Consult a physician.
Eye:	Immediately rinse out with water for at least 15 minutes. Assure adequate flushing by separating the eyelids with fingers. Consult a physician.
Ingestion:	Wash out mouth with water. Drink plenty of water. Consult a physician. Never give anything by mouth to an unconscious person.
Notes to Physician:	Treat symptomatically and supportively.

4.2 Most Important Symptoms And Effects, Either Acute Or Delayed

The most important known symptoms and effects are described in the labeling (see section 2). And /or in section 11.

4.3 Indication of immediate medical attention and special treatment needed

Not available

Section 5: Fire Fighting Measures

5.1 Conditions of flammability:

Not flammable or combustible.

5.2 Suitable extinguishing media:

Use water spray, alcohol-resistant foam, dry chemical or carbon dioxide.

5.3 Specific hazards arising from the chemical

During a fire, highly toxic gases may be generated by thermal decomposition or combustion
– Carbon Oxides, Nitrogen oxides, Hydrogen Peroxide.

5.4 Specific protective actions for fire-fighters:

Wear self-contained breathing apparatus and protective clothing to prevent contact with skin and eyes.

Section 6: Accidental Release Measures

6.1 Personal precautions, protective equipment and emergency procedures:

Use personal protective equipment. Avoid breathing vapors, mist or gas. Ensure adequate ventilation.

6.2 Environmental precautions:

Do not let product enter drains.

6.3 Methods and materials for containment and cleaning up:

Soak up with absorbent material, discard.

Section 7: Handling and Storage

7.1 Precautions for safe handling:

Always wear personal protective equipment (PPE, see section 8).

7.2 Conditions for safe storage, including and incompatibilities:

Keep container tightly closed.

Store at 4°C.

Section 8: Exposure Controls / Personal Protection

8.1 Control Parameters:

Contains no substances with occupational exposure limit values.

8.2: Appropriate engineering controls:

Contains no substances with occupational exposure limit values.

8.3 Personal Protective Equipment (PPE):

Eye/Face Protection: Safety glasses with side-shields conforming to EN166. Use equipment for eye protection tested and approved under appropriate government standards such as NIOSH (US) or EN 166(EU).

Skin Protection: Handle with gloves. Gloves must be inspected prior to use. Use proper glove removal technique - without touching outer surface of glove - to avoid skin contact with this product. Dispose of contaminated gloves after use in accordance with applicable laws and good laboratory practices. Wash and dry hands. The type of protective equipment must be selected according to the concentration and amount of the dangerous substance at the specific workplace.

Respiratory Protection: Where risk assessment shows air-purifying respirators are appropriate use a full-face particle respirator type N100 (US) or type P3 (EN 143) respirator cartridges as a backup to engineering controls. If the respirator is the sole means of protection, use a full-face supplied air respirator. Use respirators and components tested and approved under appropriate government standards such as NIOSH (US) or CEN (EU).

Other Protective Clothing or Equipment: Wear appropriate protective clothing to prevent exposure.

Section 9: Physical and Chemical Properties

9.1 General chemical and physical properties

Appearance:	White Powder
Odor:	Not Available
Odor Threshold:	Not Available
pH:	Not Available
Melting Point:	111-118°C
Freezing Point:	Not Available
Boiling Point/Range:	Not Available
Flash Point:	Not Available
Evaporation Rate:	Not Available
Lower Explosion Limit:	Not Available
Upper Explosion Limit:	Not Available
Vapor Pressure:	Not Available
Vapor Density:	Not Available
Relative Density:	Not Available
Solubility:	18.9 µg/mg in Water
Partition Coefficient n-octanol/water:	Not Available
Auto-Ignition Temperature:	Not Available
Decomposition Temperature:	Not Available

Viscosity: Not Available

Section 10: Stability and Reactivity Data

10.1 Reactivity:

Not available

10.2 Chemical Stability:

Stable under recommended storage conditions.

10.3 Possibility of hazardous reactions:

Not available.

10.4 Conditions to avoid:

Incompatible materials.

10.5 Incompatible materials:

Strong oxidizing agents.

10.6 Hazardous decomposition products:

Hazardous decomposition products formed under fire conditions. – Carbon Oxides, Nitrogen oxides, Hydrogen Peroxide.

Section 11: Toxicological Information

11.1 Toxicological effects

Acute toxicity:

Roxithromycin Oral: LD₅₀ (Rat) - 830 mg/kg

Skin corrosion/irritation:

Not available.

Respiratory or skin sensitization:

Not available.

Germ cell mutagenicity:

Not available.

Carcinogenicity:

- IARC:** No component of this product present at levels greater than or equal to 0.1% is identified as probable, possible or confirmed human carcinogen by IARC.
- ACGIH:** No component of this product present at levels greater than or equal to 0.1% is identified as probable, possible or confirmed human carcinogen by ACGIH.
- NTP:** No component of this product present at levels greater than or equal to 0.1% is identified as probable, possible or confirmed human carcinogen by NTP.

OSHA: No component of this product present at levels greater than or equal to 0.1% is identified as a carcinogen or potential carcinogen by OSHA.

Reproductive toxicity:

Not available.

STOT-single exposure:

Not available.

STOT-repeated exposure:

Not available.

Aspiration hazard:

Not available.

Likely routes of exposure:

Respiratory organs, mouth, skin, and eyes.

Symptoms of exposure:

To the best of our knowledge, the chemical, physical, and toxicological properties have not been thoroughly investigated.

Section 12: Ecological Information

12.1 Toxicity:

Not available.

12.2 Persistence and degradability:

Inherent biodegradability.

12.3 Bioaccumulative potential:

Does not bioaccumulate.

12.4 Mobility in soil:

Not available.

12.5 Other adverse effects:

None.

Section 13 Disposal Considerations

Dispose of product in accordance with local rules and regulations.

Section 14: Transport Information

14.1 US Department of Transportation (DOT)

This material is considered to be non-hazardous for transport.

14.2 International Maritime Dangerous Goods (IMDG):

This material is considered to be non-hazardous for transport.

14.2 International Air Transportation Association (IATA)

This material is considered to be non-hazardous for transport.

Section 15: Regulatory Information

SARA 302 Components:

SARA 302: No chemicals in this material are subject to the reporting requirements of SARA Title III, Section 302.

SARA 313 Components:

SARA 313: This material does not contain any chemical components with known CAS numbers that exceed the threshold (De Minimis) reporting levels established by SARA Title III, Section 313.

SARA 311/312 Hazards:

No SARA Hazards.

Massachusetts Right To Know Components:

Roxithromycin

CAS - No.

80214-83-1

Pennsylvania Right To Know Components:

Roxithromycin

CAS - No.

80214-83-1

New Jersey Right To Know Components:

Roxithromycin

CAS - No.

80214-83-1

California Prop. 65 Components:

This product does not contain any chemical known to the State of California to cause cancer, birth, or any other reproductive defects.

Section 16: Other Information

While Gold Biotechnology, Inc. believes the information contained herein to be true and accurate, it has relied on information provided by others. Gold Biotechnology, INC. makes no warranties, express or implied, as to the accuracy or adequacy of the information contained herein or with respect to the results to be obtained from the use of the product. Gold Biotechnology, Inc. disclaims all liability with respect to the use of this product, including without limitation, liability for injury to the user or third-party persons.

Preparation Information

Gold Biotechnology
Content/Marketing Department
(800) 248-7609
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