



Gamrozyne (Gamithromycin Injection)

Safety Data Sheet

according to Federal Register / Vol. 77, No. 58 / Monday, March 26, 2012 / Rules and Regulations

Issue date: 09/10/2025

Version: 2.0

SECTION 1: Identification

1.1. Identification

Product form : Mixture
Product name : Gamrozyne (Gamithromycin Injection)

1.2. Recommended use and restrictions on use

No additional information available

1.3. Supplier

Bimeda - MTC Animal Health Inc.
420 Beaverdale Road
Cambridge ON, N3C 2W4 - Canada
T +1 519-654-8000

1.4. Emergency telephone number

Emergency number : 1-519-654-8055, 1-800-424-9300 CHEMTREC (US); +1-703-527-3887 CHEMTREC (International & Maritime)

SECTION 2: Hazard(s) identification

2.1. Classification of the substance or mixture

GHS-US classification

Not classified

2.2. GHS Label elements, including precautionary statements

GHS US labelling

No labelling applicable

2.3. Other hazards which do not result in classification

No additional information available

2.4. Unknown acute toxicity (GHS US)

Not applicable

SECTION 3: Composition/information on ingredients

3.1. Substances

Not applicable

3.2. Mixtures

Contains no hazardous ingredients at levels requiring disclosure by the OSHA Hazard Communication Standard (29 CFR 1910.1200)

SECTION 4: First-aid measures

4.1. Description of first aid measures

First-aid measures general : If exposed or concerned, get medical attention/advice. Show this safety data sheet to the doctor in attendance. Wash contaminated clothing before re-use. Never give anything to an unconscious person.

First-aid measures after inhalation : IF INHALED: Remove to fresh air and keep at rest in a comfortable position for breathing.

First-aid measures after skin contact : IF ON SKIN (or clothing): Remove affected clothing and wash all exposed skin with water for at least 15 minutes. If irritation develops or persists, get medical attention.

First-aid measures after eye contact : IF IN EYES: Immediately flush with plenty of water for at least 15 minutes. Remove contact lenses if present and easy to do so. Continue rinsing if pain, blinking, or irritation develops or persists, get medical attention. Continue rinsing.

First-aid measures after ingestion : IF SWALLOWED: rinse mouth thoroughly. Do not induce vomiting without advice from poison control center. Get medical attention if you feel unwell.

4.2. Most important symptoms and effects (acute and delayed)

Symptoms/effects : Not expected to present a significant hazard under anticipated conditions of normal use.

Symptoms/effects after inhalation : May cause respiratory irritation.

Symptoms/effects after skin contact : May cause skin irritation. People with known hypersensitivity (allergy) to similar antibiotics (macrolide class) should avoid contact with Gamithromycin.

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Symptoms/effects after eye contact : Direct contact with eyes is likely to be irritating.

Symptoms/effects after ingestion : May cause gastrointestinal irritation.

4.3. Immediate medical attention and special treatment, if necessary

No additional information available

SECTION 5: Fire-fighting measures

5.1. Suitable (and unsuitable) extinguishing media

Suitable extinguishing media : Carbon dioxide (CO2). Dry chemical. Foam. Water spray.

5.2. Specific hazards arising from the chemical

Fire hazard : Product is not flammable.

Explosion hazard : Product is not explosive.

Reactivity : No data available.

5.3. Special protective equipment and precautions for fire-fighters

Firefighting instructions : Exercise caution when fighting any chemical fire. Do not dispose of fire-fighting water in the environment. Prevent human exposure to fire, fumes, smoke and products of combustion.

Protection during firefighting : Do not enter fire area without proper protective equipment, including respiratory protection.

SECTION 6: Accidental release measures

6.1. Personal precautions, protective equipment and emergency procedures

General measures : Evacuate area. Keep upwind. Ventilate area. Keep away from heat, hot surfaces, sparks, open flames and other ignition sources. No smoking. Spill should be handled by trained clean-up crews properly equipped with respiratory equipment and full chemical protective gear (see Section 8).

6.1.1. For non-emergency personnel

Protective equipment : Wear Protective equipment as described in Section 8.

Emergency procedures : Evacuate unnecessary personnel.

6.1.2. For emergency responders

Protective equipment : Wear suitable protective clothing, gloves and eye or face protection. For further information refer to section 8: "Exposure controls/personal protection".

6.2. Environmental precautions

Prevent entry to sewers and public waters. Avoid release to the environment. Notify authorities if product enters sewers or public waters.

6.3. Methods and material for containment and cleaning up

For containment : Contain any spills with dikes or absorbents to prevent migration and entry into sewers or streams. Absorb spilled material with sand or earth. Collect spillage.

Methods for cleaning up : Place in a suitable container for disposal in accordance with the waste regulations (see Section 13). Clean up spills immediately and dispose of waste safely.

6.4. Reference to other sections

See Sections 8 and 13.

SECTION 7: Handling and storage

7.1. Precautions for safe handling

Precautions for safe handling : Do not handle until all safety precautions have been read and understood. Avoid contact with skin and eyes. Avoid breathing mist or vapor. Avoid accidental injection.

Hygiene measures : Wash hands and other exposed areas with mild soap and water before eating, drinking or smoking and when leaving work.

7.2. Conditions for safe storage, including any incompatibilities

Storage conditions : Store in an indoor area, away from high temperature, and direct sunlight. Do not freeze.

SECTION 8: Exposure controls/personal protection

8.1. Control parameters

Not applicable

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8.2. Appropriate engineering controls

Appropriate engineering controls : Provide adequate general and local exhaust ventilation. Use process enclosures, local exhaust ventilation, or other engineering controls to control airborne levels below recommended exposure limits. Use explosion-proof equipment with flammable materials. Ensure adequate ventilation, especially in confined areas.

8.3. Individual protection measures/Personal protective equipment

Personal protective equipment symbol(s):



Personal protective equipment:

Gloves. Safety glasses. Wear labcoat with full coverage clothing.

Hand protection:

Use gloves chemically resistant to this material when prolonged or repeated contact could occur. Gloves should be classified under Standard EN 374 or ASTM F1296. Suggested glove materials are: Neoprene, Nitrile/butadiene rubber, Polyethylene, Ethyl vinyl alcohol laminate, PVC or vinyl. Suitable gloves for this specific application can be recommended by the glove supplier.

Eye protection:

Wear eye protection, including chemical splash goggles and a face shield when possibility exists for eye contact due to spraying liquid or airborne particles.

Skin and body protection:

Wear long sleeves, and chemically impervious PPE/coveralls to minimize bodily exposure.

Respiratory protection:

Where vapor, mist, or dust exceed PELs or other applicable OELs, use NIOSH-approved respiratory protective equipment.

SECTION 9: Physical and chemical properties

9.1. Information on basic physical and chemical properties

Physical state	: Liquid
Color	: Clear
Odor	: Odorless
Odor threshold	: No data available
pH	: No data available
Melting point	: No data available
Freezing point	: No data available
Boiling point	: No data available
Flash point	: No data available
Relative evaporation rate (butylacetate=1)	: No data available
Flammability (solid, gas)	: No data available
Vapor pressure	: No data available
Relative vapor density at 20 °C	: No data available
Relative density	: 1.22 at 25 °C (77 °F)
Solubility	: No data available
Partition coefficient n-octanol/water (Log Pow)	: No data available
Auto-ignition temperature	: No data available
Decomposition temperature	: No data available
Viscosity, kinematic	: No data available
Viscosity, dynamic	: No data available
Explosive limits	: No data available
Explosive properties	: No data available
Oxidising properties	: No data available

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9.2. Other information

No additional information available

SECTION 10: Stability and reactivity

10.1. Reactivity

No data available.

10.2. Chemical stability

Stable under normal conditions of use.

10.3. Possibility of hazardous reactions

No data available.

10.4. Conditions to avoid

Keep away from heat, sparks and flame.

10.5. Incompatible materials

Strong oxidizing agents.

10.6. Hazardous decomposition products

Thermal decomposition may produce: Carbon oxides (COx). Nitrogen oxides (NOx).

SECTION 11: Toxicological information

11.1. Information on toxicological effects

Acute toxicity (oral)	: Not classified
Acute toxicity (dermal)	: Not classified
Acute toxicity (inhalation)	: Not classified
Skin corrosion/irritation	: Not classified
Serious eye damage/irritation	: Not classified
Respiratory or skin sensitisation	: Not classified
Germ cell mutagenicity	: Not classified
Carcinogenicity	: Not classified
Reproductive toxicity	: Not classified
STOT-single exposure	: Not classified
STOT-repeated exposure	: Not classified
Aspiration hazard	: Not classified
Viscosity, kinematic	: No data available
Symptoms/effects	: Not expected to present a significant hazard under anticipated conditions of normal use.
Symptoms/effects after inhalation	: May cause respiratory irritation.
Symptoms/effects after skin contact	: May cause skin irritation. People with known hypersensitivity (allergy) to similar antibiotics (macrolide class) should avoid contact with Gamithromycin.
Symptoms/effects after eye contact	: Direct contact with eyes is likely to be irritating.
Symptoms/effects after ingestion	: May cause gastrointestinal irritation.

SECTION 12: Ecological information

12.1. Toxicity

No additional information available

12.2. Persistence and degradability

No additional information available

12.3. Bioaccumulative potential

No additional information available

12.4. Mobility in soil

No additional information available

12.5. Other adverse effects

No additional information available

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SECTION 13: Disposal considerations

13.1. Disposal methods

- Waste treatment methods : Do not discharge to public wastewater systems without permit of pollution control authorities. No discharge to surface waters is allowed without an NPDES permit.
- Product/Packaging disposal recommendations : Dispose in a safe manner in accordance with local/national regulations. Do not allow the product to be released into the environment.

SECTION 14: Transport information

Department of Transportation (DOT)

In accordance with DOT

Not regulated for transport

Transport by sea (IMDG)

Not regulated for transport

Air transport (IATA)

Not regulated for transport

SECTION 15: Regulatory information

15.1. US Federal regulations

Gamithromycin 15% w/v injection

All chemical substances in this product are listed as "Active" in the EPA (Environmental Protection Agency) "TSCA Inventory Notification (Active-Inactive) Requirements Rule" ("the Final Rule") of Feb. 2019, as amended Feb. 2021, or are otherwise exempt or regulated by other agencies such as FDA or FIFRA.

SARA Section 311/312 Hazard Classes

None

15.2. International regulations

No additional information available

15.3. US State regulations

This product does not contain any substances known to the state of California to cause cancer and/or reproductive harm.

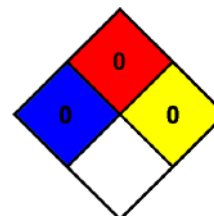
SECTION 16: Other information

Other information : Author: EMA.

NFPA health hazard : 0 - Materials that, under emergency conditions, would offer no hazard beyond that of ordinary combustible materials.

NFPA fire hazard : 0 - Materials that will not burn under typical fire conditions, including intrinsically noncombustible materials such as concrete, stone, and sand.

NFPA reactivity : 0 - Material that in themselves are normally stable, even under fire conditions.



HMIS Hazard Rating

Health : 0
Flammability : 0
Physical : 0

Indication of changes:

Revision 1.0: New SDS Created.

This information is based on our current knowledge and is intended to describe the product for the purposes of health, safety and environmental requirements only. It should not therefore be construed as guaranteeing any specific property of the product.