



Dactinomycin for Injection

Getwell Pharmaceuticals
474, Udyog Vihar, Phase-V, Gurgaon - 122 016, Haryana, INDIA

Section I - IDENTITY

Common/Trade Name: Dactinomycin for Injection, USP (0.5 mg/vial as lyophilized powder) **Chemical Names:** Dactinomycin, C(62) H(86) N(12) O(16)

Synonyms: Dactinoget, Tinowel

Manufacturer's Name: GETWELL PHARMACEUTICALS
Address: 474, UDYOG VIHAR, PHASE-V,
GURGAON - 122 016, HARYANA, INDIA

Telephone Number for Info.: + 91 124 4014 403 / 04

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Section II - HAZARDOUS INGREDIENTS/COMPOSITION INFORMATION

<u>Component</u>	<u>%</u>	<u>CAS#</u>	<u>OSHA PEL</u>	<u>ACGIH TLV</u>	<u>Other Limits Recommended</u>
Dactinomycin	2.4%	50-76-0	NONE	NONE	< 1 mcg/m ³ (OTR)
Mannitol	97.6 %	69-65-8	NONE	NONE	NONE

Dactinomycin is a sterile parenteral injectable drug presented as a powder cake. It must be reconstituted with Sterile Water for Injection prior to administration.

Section III - HEALTH HAZARD DATA

Routes of Entry: Product may be absorbed via inhalation, ingestion, or skin contact.

Health Hazard (Acute & Chronic): Dactinomycin is a cytotoxic/genotoxic antibiotic and anticancer drug. Irritation of exposed tissue is possible. Chronic effects due to occupational exposure are not anticipated. Patients receiving this compound via injection experience effects on the following systems: blood forming, lymphatic, cardiovascular, and gastrointestinal systems. Allergic reactions are possible.

Carcinogenicity: NTP? NO **IARC Monographs?** Group 3 Not classified to humans

OSHA Regulated? NO

Signs & Symptoms of Exposure: Dactinomycin is a suspect cancer agent and may cause fetotoxic, teratogenic and reproductive health effects upon excessive exposure. Also, fever, nausea, vomiting, headache, chills, bruising, bleeding, severe abdominal pain, drowsiness, diarrhea, and rash.

Medical Conditions Generally Aggravated by Exposure: May affect those with liver disorders.

BVL Hazard Category: 4

Section IV - FIRST AID MEASURES

Eye Exposure: Flush eyes with large volumes of water for 15 or more minutes.

Skin Exposure: Wash skin with cool, soapy water.

Ingestion: If ingestion occurs, flush mouth with water and seek medical attention immediately. If person is conscious, induce vomiting; never induce vomiting on an unconscious person.

Inhalation: If difficulty breathing, administer oxygen. Seek attention of a physician immediately. Do not administer mouth to mouth. Overdose should be treated symptomatically and blood chemistry monitored closely.

Section V - FIRE AND EXPLOSION HAZARD DATA

Flash Point (Method Used): 241 deg C **LEL:** NA **UEL:** NA

Flammable Limits: Not Applicable

Extinguishing Media: Use water or a multi-purpose ABC extinguisher.

Special Fire Fighting Procedures: As with all fires, evacuate personnel to a safe area. Fire fighters must wear self-contained breathing apparatus to avoid inhalation of smoke. Product is not expected to present a fire hazard concern.

Unusual Fire/Explosion Hazards: NONE

Section VI - ACCIDENTAL RELEASE INFORMATION

Release to Land: Wet Dactinomycin with water to prevent dusting and absorb with proper absorbents. Prevent contact with sewers and waterways. Use a 1% bleach solution to effectively degrade and remove from non-porous surfaces.

Release to Air: If dust is generated, reduce exposures by ventilating and prevent the generation of dust. Wear respiratory protection.

Release to Water: Refer to local water authority; drain disposal is not recommended. Refer to local, state, and federal guidelines.

Section VII - PRECAUTIONS FOR SAFE HANDLING AND USE

Steps to be taken in case material is released or spilled: See Section VI above.

Wear all necessary protective equipment including nitrile or latex gloves, protective clothing, safety glasses, and air-purifying respirator with HEPA (P100) cartridges. Large spills require the use of SCBA.

Waste Disposal Method: Dactinomycin is not a RCRA listed hazardous waste

Precautions to be taken in handling and storing: Store at 15° - 30°C.

Other Precautions: Follow OSHA guidelines on the safe handling of cytotoxic products (see Section XVI).

Section VIII - CONTROL MEASURES AND PERSONAL PROTECTIVE EQUIPMENT

Respiratory Protection: Under normal use, respirators are not required. If dust generation is likely, an air-purifying respirator with HEPA (P100) cartridges must be worn. For large spill emergencies, SCBA may be required. Personnel wearing respirators should be fit tested and approved for respirator use under the OSHA Respiratory Protection Standard, 29 CFR 1910.134.

Ventilation: Use with adequate ventilation such as in a Class II Type B biological safety cabinet.

Protective Gloves: Nitrile or latex

Eye Protection: Safety glasses or goggles

Other Protective Clothing or Equipment: Lab coat

Work/Hygienic Practices: Wash hands following use. No eating, drinking, or smoking when handling this product.

Section IX - PHYSICAL/CHEMICAL CHARACTERISTICS

Physical State:	Solid	Specific Gravity:	1.418
Appearance and Odor:	Red powder with no odor	Melting Point:	252 °C
Boiling Point:	Not Applicable	Evaporation Rate:	Not Applicable
Vapor Pressure:	Not Applicable	Solubility in Water:	Soluble in Methanol
Vapor Density:	Not Applicable	pH:	Not Supplied

Section X - STABILITY AND REACTIVITY DATA

Stability: Stable

Incompatibility (Materials to Avoid): Oxidizers. Light

Hazardous Decomposition or Byproducts: Decomposition products of this compound may include potentially hazardous byproducts of nitrogen oxides, carbon monoxide and sulfur dioxide.

Hazardous Polymerization: Will not occur.

Conditions to Avoid: Avoid contact with oxidizers.

Section XI - TOXICOLOGICAL INFORMATION

For active ingredient Dactinomycin: RTECS # AU1575000

LD₅₀ oral, rat = 7200 ug/kg

LD₅₀ oral, mouse = 13 mg/kg, 20 mg/kg

LD₅₀ subcutaneous, rat = 800 ug/kg

LD₅₀ intraperitoneal, mouse = 0.5 mg/kg, 750 ug/kg

LD₅₀ intraperitoneal, rat = 100 ug/kg

LD₅₀ subcutaneous, mouse = 500 ug/kg, 0.5 mg/kg

LD

⁵⁰ intravenous, rat = 460 ug / kg

Microsomal mutagenicity assay = N/D

Cytogenic analysis system test (human, fibroblast) = 100 mcg/L

Additional reproductive health and toxicity data is available from the National Institute for Occupational Safety and Health (NIOSH) Registry of Toxic Effects of Chemical Substances (RTECS).

Section XII - ENVIRONMENTAL IMPACT INFORMATION

Information is currently not available on the environmental impact of Dactinomycin. Handle in a manner that prevents spills or releases to the environment.

Section XIII - DISPOSAL INFORMATION

Dactinomycin is not an EPA listed hazardous waste.

Dispose of according to local, state, and federal guidelines for RCRA Hazardous Wastes.

Section XIV - TRANSPORTATION INFORMATION

Dactinomycin is a not listed as a DOT hazardous material according to 49 CFR 172.101

Dactinomycin is not a Marine Pollutant.

Section XV - REGULATORY INFORMATION

SARA 313 listed?: Not Listed

CERCLA listed?: Not Listed

RCRA listed?: Not Listed

Dactinomycin is listed on California's Proposition 65 List as Code 1

Listed on the Florida Toxic substance list as a "Toxic Substance in the State of Florida" Listed on Massachusetts Hazardous substance as codes 1*E*C*

Listed on the Pennsylvania Hazardous Substance List as Code S

New York List of Hazardous Substances: Classified as an acutely hazardous substance Reportable Quantity to Air: 1

Reportable Quantity to Land: 1

Section XVI - OTHER DATA

1. Hospital personnel preparing or administering toxic parenteral agents should wear disposable latex gloves, safety glasses, a closed-front gown with cuffs, and respiratory protection. Preparation of all toxic or potent agents should be done in a Class II laminar flow hood or biological safety cabinet with exhaust air discharged external to the room environment. All needles, syringes, vials, and other equipment or disposable clothing that have contacted this agent should be segregated for incineration.
2. Persons administering this drug to patients must be careful to avoid needle sticks to syringes and other sharps used in the administration. All needle sticks must be reported to your company Management.
3. Use of this product should be through or under the direction of a physician. This MSDS does not address therapeutic use of this material.
4. GP Hazard Category Definitions (internal hazard ranking used by Getwell Pharmaceuticals): 1 = Low Toxicity
2= Moderate Toxicity
3A/3B = Potent or Toxic 4
= Highly Potent or Toxic
5 = Extremely Potent or Toxic
5. OEL=Occupational Exposure Limit. An internal limit set by Getwell Pharmaceuticals for the recommended limit of employee exposure to airborne dusts or aerosols that should not be exceeded over an eight-hour time-weighted average.
6. Dactinomycin is considered a Hazardous Drug as described in the NIOSH Alert: Preventing Occupational Exposures to Antineoplastic and Other Hazardous Drugs in Health Care Settings . Employees who prepare or administer hazardous drugs or who work in areas where these drugs are used should follow specific handling guidelines in order to prevent exposure to these agents in the air or on work surfaces, clothing, or equipment.
7. **The Following Guidance Information is excerpted from the NIOSH Alert:**

Elements of a Hazardous Drug Handling Program include:

- Establishment and implementation of written policies and protocols to ensure the safe handling of oncolytic and/or potent drugs, including receipt of product.
- Training and education of employees on the recognition, evaluation and control of Hazardous Drugs
- Effective Planning and design of the workplace
- Use of best practice control measures and specialized equipment such as ventilated cabinets or isolators designed for worker protection
- Wearing recommended personal protective equipment
- An integrated health surveillance program that: includes the assessment and counseling of prospective employees before they commence any work involving oncolytic and/or potent drugs and related waste

8. **Published guidance on the handling and transport of cytotoxic drugs:**

NIOSH Alert – Preventing occupational exposures to antineoplastic and other hazardous drugs in health care settings

<http://www.cdc.gov/niosh/docs/2004-165/>

National Study Commission on Cytotoxic Exposure: Recommendation for handling Cytotoxic Agents:

<http://www.nih.gov/od/ors/ds/pubs/cyto/index.html>

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