

Dactinomycin for Injection

Section 1: Chemical Product and Company Identification

Product Name: Dactinomycin for Injection

Chemical Name(s): 2-Amino- 4,6-dimethyl- 3-oxo- 3H-phenoxazine- 1,9-dicarboxylic acid bis- [(5,12-diisopropyl- 9,13,16-trimethyl- 4,7,11,14,17-pentaoxo- hexadecahydro- 10-oxa- 3a,6,13,16-tetraaza-cyclopentacyclohexadecen- 8-yl)- amide] and Mannitol

Synonym: Dactinomycin for Injection

CAS Number: 69-65-8, 50-76-0

RTECS #: N/A

Trade Name: Cosmegen for Injection

Chemical Formula: C₄₃H₅₃NO₁₄

Contact Information:

X-GEN Pharmaceuticals, Inc.

PO Box 445, Big Flats, NY 14814

Technical Assistance: 607-562-2700

Online Assistance: www.x-gen.us

Emergency phone number:

National Poison Control

1-800-222-1222



Health	3
Fire	2
Reactivity	0
Personal Protection	E

**For information regarding recommended uses and restrictions on usage refer to the product package insert.

Section 2: Hazard Identification

Hazard pictograms (GHS-US):

OSHA HCS 2012 • Acute Toxicity Oral 3

Label elements

OSHA HCS 2012

DANGER



Hazard Overview: Toxic if swallowed. Contact Poison. Avoid contact with skin, mucous membranes, or eyes. Do not inhale the dust or vapor.

Prevention: Wash thoroughly after handling. Do not eat, drink or smoke when using this product.

Response

- IF SWALLOWED: immediately call a POISON CENTER/doctor. Specific treatment see supplemental first aid information. Rinse mouth.

Storage/Disposal

- Store at controlled room temperature of 20-25° C (68-77° F) according to Package Labeling instructions. Protect from heat, light and moisture. Storage consistent with chemotherapeutic pharmaceutical agents, such as secondary containment to minimize risk of spill or breakage, is appropriate. Dispose of content and/or container in accordance with local, regional, national, and/or international regulations.

Other Hazards

OSHA HCS 2012

Section 3: Composition and Information on Ingredients

Substances

- Material does not meet the criteria of a substance

Composition					
Chemical Name	Identifiers	%	LD50/LC50	Classifications According to Regulation/Directive	Comments
Dactinomycin	CAS:50-76-0	2.5%	No Data Available	OSHA HCS 2012: Acute Tox. 2 (Orl)	No Data Available
Mannitol, D-	CAS:69-65-8	97.5%	Ingestion/Oral-Rat LD50 • 13500 mg/kg	OSHA HCS 2012: Not Classified	No Data Available

Section 4: First Aid Measures

Description of first aid measures

Inhalation • Move victim to fresh air. Administer oxygen if breathing is difficult. Give artificial respiration if victim is not breathing.

Skin • In case of contact with substance, immediately flush skin with running water for at least 20 minutes.

Eye • In case of contact with substance, immediately flush eyes with running water for at least 20 minutes.

Ingestion • Obtain medical attention immediately if ingested.

Most important symptoms and effects, both acute and delayed

- Refer to Section 11 - Toxicological Information.

Indication of any immediate medical attention and special treatment needed

- Notes to Physician**
- All treatments should be based on observed signs and symptoms of distress in the patient. Consideration should be given to the possibility that overexposure to materials other than this product may have occurred.

Section 5: Fire Fighting Measures

Extinguishing Media

Suitable Extinguishing Media

- In case of fire use media as appropriate for surrounding fire.

Unsuitable Extinguishing Media

- No data available

Special hazards arising from the substance or mixture

Unusual Fire and Explosion Hazards

- This product is not flammable

Hazardous Combustion

- When involved in a fire, the products of combustion or thermal decomposition can include irritating fumes and toxic gases (e.g., carbon oxides, nitrogen oxides and hydrogen chloride)

Advice for Firefighters

- No special procedures are necessary. Firefighters should follow normal fire response procedures consistent with surrounding materials.

Section 6: Accidental Release Measures

Personal precautions, protective equipment and emergency procedures

Personal Precautions

- Do not walk through spilled material. For small releases of this compound (1 vial), wear latex or butyl rubber gloves and safety glasses. In case of a large spill, trained personnel using pre-planned procedures should respond to large or uncontrolled releases. Proper protective equipment should be used, including light-weight glove underneath with heavy neoprene-type gloves as an over-glove, full body gown, and a Powered-Air Purifying Respirator (PAPR) equipped with a High Efficiency Particulate (HEPA) filter or Self- Contained Breathing Apparatus (SCBA).

Emergency Procedures • In case of a large spill, clear the affected area and protect people. Stay upwind. Eliminate all ignition sources.

Environmental precautions

- Avoid run off to waterways and sewers.

Methods and material for containment and cleaning up

Containment/Clean-up Measures • Stop leak if you can do it without risk.
For small releases of this compound (1 vial), wipe up spilled material with damp sponge or polypad. Place in a cytotoxic compound bag and hold for waste disposal. The spill areas then should be cleaned (three times) using a detergent solution followed by a clean water rinse.
In case of a large spill, clean-up or vacuum spilled solid (an explosion-proof HEPA vacuum should be used). Decontaminate the area of the spill thoroughly using a 5% trisodium phosphate (TSP) solution. A contact time with the TSP solution of 30 minutes is recommended. Place neutralized spill residue in an appropriate container and seal. Place all other spill residue in an appropriate cytotoxic compound container and seal.

Section 7: Handling and Storage

Precautions for safe handling

Handling • Employees must be trained to properly use this product. Handle this material following standard medical practices and following the recommendations presented on the Package Labeling. As with all chemicals, avoid getting this material on you or in you. Conduct all open manipulations in a Class II Biological Safety Cabinet and use adequate personal protective equipment to minimize all exposure to this material in powdered and reconstituted form. Wear appropriate personal protective equipment, avoid direct contact. Do not eat, drink, smoke, or apply cosmetics while handling this product. Wash thoroughly with soap and water after handling and before eating, drinking, or using tobacco.

Conditions for safe storage, including any incompatibilities

Storage • Store at controlled room temperature of 15-30°F (59-86°C) according to Package Labeling instructions. Store in secondary containment to minimize risk of spill or breakage, and to protect the environment.
Store in a cool, dry place away from light, heat and moisture. Storage consistent with chemotherapeutic pharmaceutical agents is appropriate.

Section 8: Exposure Controls / Personal Protection

Control parameters

- Exposure Limits/Guidelines**
- No applicable exposure limits available for product or components.

Exposure controls

- Engineering Measures/Controls**
- No open handling of powder or solutions of this product should occur. Admixtures or manipulations of this drug should be carried out in a cytotoxic drug safety cabinet or Class I or II Biological Safety Cabinet. The cabinet should be regularly cleaned following the manufacturer's recommendations and those of the NSF. HEPA filters in the safety cabinet should be changed per recommendations of the manufacturer or the NSF. The safety cabinet should be tested and certified as recommended by the National Sanitation Foundation in Standard Number 49. If appropriate, refer to Australian National Code of Practice for the Control of Workplace Hazardous Substances [NOHSC: 2007 (1994)] for further information.

Personal Protective Equipment

- Respiratory**
- A respirator is not required for routine conditions of use with a Biological Safety Cabinet, or glove box. If respiratory protection is needed, such as in a spill or other situation where the material may be airborne, use only protection authorized in the U.S. Federal OSHA Respiratory Protection Standard (29 CFR 1910.134) and equivalent U.S. State standards, Canadian CSA Standard Z94.4-93, the European Standard EN 529:2005 and Respiratory Protection Standards of EU member states, or the Australian Standard 1716-Respiratory Protective Devices and Australian Standard 1715-Selection, Use, and Maintenance of Respiratory Protective Devices. Oxygen levels below 19.5% are considered IDLH by OSHA. In such atmospheres, use of a full-facepiece pressure/demand SCBA or a full facepiece, supplied air respirator with auxiliary self-contained air supply is required under U.S. Federal OSHA's Respiratory Protection Standard (1910.134-1998) or the regulations of various U.S. States, Canada, Australia, New Zealand, Mexico, or EU Member States.
- Eye/Face**
- Prevent all eye contact with the use of safety glasses or chemical splash goggles.

Skin/Body

- Double glove, using butyl or nitrile-type rubber gloves or other appropriate gloves. Check gloves for leaks. Gloves should cover the gown cuff. Because all gloves are to some extent permeable and their permeability increases with time, they should be changed regularly (hourly is preferable) or immediately if they are torn or punctured. During patient administration, use of lightweight cotton gown or other medical attire is recommended to prevent all skin contact. For operations involving open material, additional protective clothing such as sleeve covers, shoe covers and body suits may be necessary. Additional protective clothing would be necessary for spill clean-up or other operations involving open material, such as sleeve covers, shoe covers and body suits.

Environmental Exposure Controls

- Controls should be engineered to prevent release to the environment, including procedures to prevent spills, atmospheric release and release to waterways. Follow best practice for site management and disposal of waste.

Section 9:	Physical and Chemical Properties
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Information on Physical and Chemical Properties

Material Description			
Physical Form	Solid	Appearance/Description	Yellow to orange lyophilized powder with no odor.
Color	Yellow to orange.	Odor	Odorless
Odor Threshold	No data available		
General Properties			
Boiling Point	No data available	Melting Point/Freezing Point	No data available
Decomposition Temperature	No data available	pH	No data available
Specific Gravity/Relative Density	No data available	Water Solubility	Soluble 100 %
Viscosity	No data available		
Volatility			
Vapor Pressure	No data available	Vapor Density	No data available
Evaporation Rate	No data available		
Flammability			
Flash Point	No data available	UEL	No data available
LEL	No data available	Autoignition	No data available
Flammability (solid, gas)	No data available		
Environmental			
Octanol/Water Partition coefficient	No data available		

Section 10: Stability and Reactivity

Reactivity

- No dangerous reaction known under conditions of normal use.

Chemical stability

- Stable under normal temperatures and pressures.

Possibility of hazardous reactions

- Hazardous polymerization will not occur.

Conditions to avoid

- Avoid heat, light, moisture and contact with incompatible chemicals.

Incompatible materials

- Incompatible chemicals such as acids, caustics.

Hazardous decomposition products

- If exposed to extremely high temperatures, the products of thermal decomposition may include irritating fumes and toxic gases.

Section 11: Toxicological Information

Information on toxicological effects

Components		
Dactinomycin (2.5%)	50-76-0	Acute Toxicity: Ingestion/Oral-Rat LD50 • 7200 µg/kg; <i>Gastrointestinal:Hypermotility, diarrhea; Blood:Other changes;</i> Reproductive: Ingestion/Oral-Mouse TDLo • 20 mg/kg (8-12D preg); <i>Reproductive Effects:Effects on Newborn:Live birth index; Reproductive Effects:Effects on Newborn:Viability index (e.g., # alive at day 4 per # born alive);</i> Intraperitoneal-Mouse TDLo • 150 µg/kg (8D preg); <i>Reproductive Effects:Specific Developmental Abnormalities:Eye, ear; Reproductive Effects:Specific Developmental Abnormalities:Craniofacial (including nose and tongue)</i>
Mannitol, D- (97.5%)	69-65-8	Acute Toxicity: Ingestion/Oral-Rat LD50 • 13500 mg/kg

GHS Properties	Classification
Acute toxicity	OSHA HCS 2012•Acute Toxicity - Oral 3 - ATEmix (oral) = 288 mg/kg
Skin corrosion/Irritation	OSHA HCS 2012•No data available
Serious eye damage/Irritation	OSHA HCS 2012•No data available

Skin sensitization	OSHA HCS 2012•No data available
Respiratory sensitization	OSHA HCS 2012•No data available
Aspiration Hazard	OSHA HCS 2012•No data available
Carcinogenicity	OSHA HCS 2012•No data available
Germ Cell Mutagenicity	OSHA HCS 2012•No data available
Toxicity for Reproduction	OSHA HCS 2012•No data available
STOT-SE	OSHA HCS 2012•No data available
STOT-RE	OSHA HCS 2012•No data available

Potential Health Effects

Inhalation

Acute (Immediate) • May cause irritation.
 Chronic (Delayed) • No data available

Skin

Acute (Immediate) • May cause irritation.
 Chronic (Delayed) • No data available

Eye

Acute (Immediate) • May cause irritation.
 Chronic (Delayed) • No data available

Ingestion

Acute (Immediate) • Toxic if swallowed.

Section 12: Ecological Information

Toxicity

Non-mandatory section - information about this substance not compiled for this reason.

Persistence and degradability

Non-mandatory section - information about this substance not compiled for this reason.

Bioaccumulative potential

Non-mandatory section - information about this substance not compiled for this reason.

Mobility in Soil

Non-mandatory section - information about this substance not compiled for this reason.

Other adverse effects

Non-mandatory section - information about this substance not compiled for this reason.

Section 13: Disposal Considerations

Waste treatment methods

- Product waste** • Dispose of content and/or container in accordance with local, regional, national, and/or international regulations.
- Packaging waste** • Dispose of content and/or container in accordance with local, regional, national, and/or international regulations.

Section 14: Transport Information

	UN number	UN proper shipping name	Transport hazard class(es)	Packing group	Environmental hazards
DOT	Not Applicable	Not Regulated	Not Applicable	Not Applicable	No Data Available
TDG	Not Applicable	Not Regulated	Not Applicable	Not Applicable	No Data Available

Special precautions for user • None specified.

Transport in bulk according to Annex II of MARPOL 73/78 and the IBC Code • No data available

Section 15: Regulatory Information

Safety, health and environmental regulations/legislation specific for the substance or mixture

SARA Hazard Classifications Acute

Inventor

Component	CAS	Canada DSL	Canada NDSL	TS CA
Dactinomycin	50-76-0	No	No	No
Mannitol, D-	69-65-8	Yes	No	Yes

Canada

Labor

Canada - WHMIS 1988 - Classifications of Substances

•Mannitol, D-	69-65-8	Uncontrolled product according to WHMIS classification criteria
•Dactinomycin	50-76-0	Not Listed

Canada - WHMIS 1988 - Ingredient Disclosure List

•Mannitol, D-	69-65-8	Not Listed
•Dactinomycin	50-76-0	Not Listed

Environment

Canada - CEPA - Priority Substances List

•Mannitol, D-	69-65-8	Not Listed
•Dactinomycin	50-76-0	Not Listed

United States

Labor

U.S. - OSHA - Process Safety Management - Highly Hazardous Chemicals

•Mannitol, D-	69-65-8	Not Listed
•Dactinomycin	50-76-0	Not Listed

U.S. - OSHA - Specifically Regulated Chemicals

•Mannitol, D-	69-65-8	Not Listed
•Dactinomycin	50-76-0	Not Listed

Environment

U.S. - CAA (Clean Air Act) - 1990 Hazardous Air Pollutants

•Mannitol, D-	69-65-8	Not Listed
•Dactinomycin	50-76-0	Not Listed

U.S. - CERCLA/SARA - Hazardous Substances and their Reportable Quantities

•Mannitol, D-	69-65-8	Not Listed
•Dactinomycin	50-76-0	Not Listed

U.S. - CERCLA/SARA - Radionuclides and Their Reportable Quantities

•Mannitol, D-	69-65-8	Not Listed
•Dactinomycin	50-76-0	Not Listed

U.S. - CERCLA/SARA - Section 302 Extremely Hazardous Substances EPCRA RQs

•Mannitol, D-	69-65-8	Not Listed
•Dactinomycin	50-76-0	Not Listed

U.S. - CERCLA/SARA - Section 302 Extremely Hazardous Substances TPQs

•Mannitol, D-	69-65-8	Not Listed
•Dactinomycin	50-76-0	Not Listed

U.S. - CERCLA/SARA - Section 313 - Emission Reporting

•Mannitol, D-	69-65-8	Not Listed
•Dactinomycin	50-76-0	Not Listed

U.S. - CERCLA/SARA - Section 313 - PBT Chemical Listing

•Mannitol, D-	69-65-8	Not Listed
•Dactinomycin	50-76-0	Not Listed

United States - California

Environment

U.S. - California - Proposition 65 - Carcinogens List

•Mannitol, D-	69-65-8	Not Listed
•Dactinomycin	50-76-0	carcinogen, 10/1/1989

U.S. - California - Proposition 65 - Developmental Toxicity

•Mannitol, D-	69-65-8	Not Listed
•Dactinomycin	50-76-0	developmental toxicity, 10/1/1992
U.S. - California - Proposition 65 - Maximum Allowable Dose Levels (MADL)		
•Mannitol, D-	69-65-8	Not Listed
•Dactinomycin	50-76-0	Not Listed
U.S. - California - Proposition 65 - No Significant Risk Levels (NSRL)		
•Mannitol, D-	69-65-8	Not Listed
•Dactinomycin	50-76-0	0.00008 µg/day NSRL
U.S. - California - Proposition 65 - Reproductive Toxicity - Female		
•Mannitol, D-	69-65-8	Not Listed
•Dactinomycin	50-76-0	Not Listed
U.S. - California - Proposition 65 - Reproductive Toxicity - Male		
•Mannitol, D-	69-65-8	Not Listed
•Dactinomycin	50-76-0	Not Listed

Other Information

- **WARNING:** This product contains a chemical known to the State of California to cause cancer, birth defects or other reproductive harm.

Section 16: Other Information

References: Not Available

Created: 22 July 2019

Last Updated: N/A

Prepared & Approved by: X-Gen Pharmaceuticals, Inc., Safety Committee

The above information is believed to be accurate and represents the best information currently available to us. The use of this product should be through or under the direction of a physician. This SDS does not address therapeutic use of this material. X-GEN Pharmaceuticals, Inc. makes no warranties, express or implied with respect to such information, and we assume no liability resulting from its use. Users should make their own investigations to determine the suitability of the information. In no event should X-GEN Pharmaceuticals be liable for any claim, loss, or damage of any third party, even if X-GEN Pharmaceuticals has been advised of the possibility of such damages to occur.