

Safety Data Sheet

Neomycin and Polymyxin B Sulfates Solution for Irrigation, USP

Section 1: Chemical Product and Company Identification

Product Name: Neomycin and Polymyxin B Sulfates Solution for Irrigation, USP

Chemical Name(s): mixture of Neomycin Sulfate and Polymyxin B Sulfate

Synonym:

CAS Number: 1405-10-3

RTECS #: QP4375000

Trade Name: Neosporin

Chemical Formula: $C_{23}H_{46}N_6O_{13} \cdot 3H_2SO_4 / C_{43}H_{82}N_{16}O_{12}H_2O_4S$



Health	2
Fire	0
Reactivity	0
Personal Protection	E

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

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

Section 2: Hazard Identification

Hazard pictograms (GHS-US):



Potential Acute Health Effects: Ingestion, skin contact, eye contact and inhalation may cause irritation and allergic reactions. Seek medical attention if irritation persists.

Potential Chronic Health Effects: Possible hyper sensitization to antibiotics including cross reaction to Kanamycin, Paromycin, streptomycin and possibly gentamicin.

Carcinogenic Effects: Not available

Mutagenic Effects: Not available

Teratogenic Effects: Aminoglycosides such as this product can cause fetal harm when administered to a pregnant woman, as they cross the placenta and there have been several reports of total irreversible, bilateral congenital deafness in children whose mothers received a related aminoglycoside during

pregnancy. Although serious side effects to the fetus or newborns have not been reported in the treatment of pregnant women with other aminoglycosides, the potential for harm exists.

Developmental Toxicity: Not available.

Adverse effects: Mild irritation and possible allergic reactions. May cause adverse symptoms on the ears and kidneys.

Section 3: Composition and Information on Ingredients

Principle Components:

<u>Name</u>	<u>CAS #</u>	<u>% by Weight</u>
Neomycin Sulfate	1405-10-3	4%
Polymyxin B Sulfate	1405-20-5	<1.0%

Section 4: First Aid Measures

General: Remove from exposure. Remove contaminated clothing. For treatment advice, seek guidance from an occupational health physician or other licensed health-care provider familiar with workplace chemical exposure. If person is not breathing give artificial respiration. If breathing is difficult give oxygen. Persons developing serious hypersensitivity (anaphylactic) reactions must receive immediate medical attention. Obtain medical attention

Inhalation: If mists or sprays from this product are inhaled, remove to fresh air. If necessary, use artificial respiration to support vital functions. Seek medical attention immediately.

Skin contact: If the product contaminates the skin, and adverse effect occurs, begin decontamination with running water. Minimum flushing is for 20 minutes. Do not interrupt flushing. Remove exposed or contaminated clothing, taking care not to contaminate eyes. Seek medical attention immediately.

Eye contact: If this product enters the eyes, open eyes while under gently running water. Use sufficient force to open eyelids. Minimum flushing is for 20 minutes. Do not interrupt flushing. Seek medical attention immediately.

Ingestion: If this product is swallowed, call physician or poison control center for most current information. If professional advice is not available, do not induce vomiting. Rinse mouth with water immediately. Drink large quantities of water. If milk is available, drink milk after drinking water. Seek medical attention immediately.

Notes to physician: Seek product package insert for complete information.

Overdose Treatment: Not available

Section 5: Fire Fighting Measures

Flammability of the product: Not flammable.

Combustion Products: At extremely high temperatures this product will decompose to produce irritating vapors and toxic gases. These products are carbon oxides (CO, CO₂), nitrogen oxides (NO, NO₂...), Sulfur Oxides (SO₂, SO₃...).

Unusual Fire and Explosion Hazards: This material is assumed to be combustible.

Extinguishing Media and Instruction: Water spray, dry chemical, carbon dioxide or foam as appropriate for surrounding fire and materials.

Protective equipment & precautions for firefighters: As with all fires, evacuate personnel to a safe area. Firefighters should wear self-contained breathing apparatus and protective clothing.

Special remarks on fire hazard: Not available

Special remarks on explosion hazard: Not available

Section 6: Accidental Release Measures

Release to land:

Small spill: Use appropriate tools to put the spilled solid in a convenient waste disposal container. Contain spill with an inert absorbent material such as soil, sand or oil dry. Finish cleaning by flushing spill area with soap and water to remove trace residue, and dispose of according to local, state, and federal regulations.

Large Spill: Use a shovel to put the material into a convenient waste disposal container. Sweep up or vacuum. Finish cleaning by spreading water on the contaminated surface and clean surface thoroughly to remove residual contamination. Collect in suitable container for disposal. For proper waste disposal, see section 13 of the SDS.

Release to air: Not available

Release to water: Prevent material from entering sewer or confined spaces, waterways, soil or public waters. Do not flush to sewer. For spills on water: contain, minimize dispersion, and collect.

Protective equipment: Keep unnecessary personnel away. Minimum Personal Protective Equipment should be: rubber gloves, rubber boots, face shield and Tyvek suit as well as a self-contained breathing apparatus.

Section 7: Handling and Storage

Handling: As a general rule, when handling Neomycin and Polymyxin B Sulfate Solution for Irrigation, USP, avoid all contact and inhalation of mists and/or vapors associated with the material.

Keep locked up. Keep away from heat, sources of ignition. Empty containers pose a fire risk, evaporate the residue under a fume hood. Ground all equipment containing material. Use only in accordance with directions.

Storage: Keep container tightly closed (see USP CRT storage conditions) and stored at 25°C (77°F). Protect from light. Product should be stored in secondary containers or in a diked area, as appropriate. Store away from incompatibles.

Incompatibilities: Strong oxidizers, acids, caustics and other chemicals that can affect performance.

Section 8: Exposure Controls / Personal Protection

Engineering controls: Use process enclosures, local exhaust ventilation, or other engineering controls to for adequate ventilation keep airborne levels below recommended exposure limits. If user operations generates fumes or mist, use ventilation to keep exposure to airborne contaminants below the exposure limit.

Personal protection: Safety glasses. Lab coat. Gloves. Respirator as necessary. Be sure to use an approved/ certified respirator or equivalent. **In case of large spill:** Splash goggles. Full suit. Respirator. Boots. Gloves. A self-contained breathing apparatus should be used to avoid inhalation of the product. Suggested protective clothing might not be sufficient; consult a specialist BEFORE handling this product.

Respiratory protection: A respirator is not required for routine conditions of use with adequate engineering controls. A full-face Air-Purifying Respirator with high-efficiency particulate filter or a Supplied-Air Respirator must be worn during operations where engineering controls are not sufficient, large spill cleanup, or when processing generates airborne aerosols. If fumes or mist is generated, use a disposable mask (N95). Personnel wearing respirators should be fit tested and approved for respirator use, under OSHA Respiratory Protection Standard 29 CFR 1910.134.

Exposure limit: Not available

Section 9: Physical and Chemical Properties

Physical appearance: Liquid

Color: clear, yellow

Molecular Weight: Mixture

Taste: Not available

Odor: Odorless

Odor Threshold: Not available

pH: 4.5 to 6.0

Melting Point: Not available

Freezing Point: Similar to water

Boiling Point: Similar to water

Flash Point: Not available

Evaporation rate: Not available

Flammability: Not available
Upper Flammable Limit: Not available
Lower Flammable Limit: Not available
Vapor Pressure: Not available
Vapor Density: Not available
Relative density: Not available

Partition Coefficient: Not available
Auto-Ignition Temperature: Not available
Decomposition Temperature: Not available
Viscosity: Not available
Dispersion Properties: Not available
Solubility: Completely soluble in water

Section 10: Stability and Reactivity

Reactivity: Not available

Chemical stability: The product is stable when properly stored

Possibility of hazardous reaction: Not available

Conditions to avoid: Avoid exposure to light, heat, and moisture.

Incompatible materials: Strong oxidizing agents and acids

Hazardous decomposition products: If exposed to extremely high temperatures, thermal decomposition may generate irritating fumes and toxic gases, such as carbon, nitrogen, and sulfur oxides

Corrosivity: Non-corrosive in presence of glass.

Polymerization: Will not occur.

Section 11: Toxicological Information

Routes of exposure: Inhalation, eye contact, skin contact, ingestion.

Symptoms:

Short term: Coughing, sneezing, and runny nose due to inhalation. Skin contact may cause mild irritation or dermatitis. Eye contact may cause transient irritation. Ingestion may cause nausea, vomiting and inflammation of the small intestine and the colon. **Long term:** May cause damage to kidneys and hearing.

Reproductive toxicity: No long-term animal studies have been performed with Neomycin Sulfate to evaluate impairment of fertility. It is not known whether Neomycin is excreted in human milk, but it has been shown to be excreted in cow milk following a single intramuscular injection. Other aminoglycosides have been shown to be excreted in human milk. Because many drugs are excreted in human milk, and because the potential for serious reactions in nursing infants, nursing mothers should be advised of these effects and the appropriate action should be taken to prevent exposure.

FDA Pregnancy Category: D

Toxicity to animals:

Oral Mouse (Neomycin Sulfate): LD50: >8 gm/kg

Oral Mouse (Polymyxin B Sulfate): LD50: 790 mg(base)/kg

Measures of toxicity: Not available

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

Section 12: Ecological Information

Ecotoxicity: All releases to terrestrial, atmospheric and aquatic environments should be avoided. No specific data is available for this product.

Bioaccumulation potential: Not available

Products of biodegradation: Not available

Toxicity of the products of biodegradation: Not available

Section 13: Disposal Information

Waste classification: Not available

Waste from residues/unused products: Wear proper protective equipment when handling waste materials. Dispose of waste in accordance with all applicable federal, state and local laws.

Waste Disposal: Dispose of waste in accordance with all applicable federal, state and local laws.

Section 14: Transport Information

DOT Classification: This product is not classified as dangerous goods, per U.S. DOT regulations, under 49 CFR 172.101

UN Number: Not available

UN Shipping name: Not available

Transport hazard class: Not available

Packing Group: Not available

Environmental hazard: Not available

Transport in bulk: Not available

Special precautions needed with transport: Not available

Section 15: Regulatory Information

Federal and State Regulations: This product is regulated under Food and Drug Administration standards; it is not subject to requirements under TSCA.

Other Regulations: California Proposition 65: Warning! This product contains a compound known to the State of California to cause developmental harm.

Other Classifications:

WHMIS (Canada): Not controlled under WHMIS (Canada).

DSCL (EEC): This material is not classified according to the EU regulations.

HMIS (U.S.A.):

Health Hazard: 2

Fire Hazard: 0

Reactivity: 0

Personal Protection: E

National Fire Protection Association (U.S.A.):

Health: 2

Flammability: 0

Reactivity: 0

Protective Equipment: Gloves, lab coat, safety glasses and respirator. Be sure to use an approved/certified respirator or equivalent.

Section 16: Other Information

References: Not available

Created: 1/30/2015

Last Updated: 3/27/2015

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.