SAFETY DATA SHEET

1. IDENTIFICATION OF THE SUBSTANCE/MIXTURE AND THE COMPANY/UNDERTAKING

Product Identifier

Material Name: NEOSPORIN G.U. Irrigant Sterile (neomycin sulfate–polymyxin B sulfate solution for irrigation)

Trade Name: NEOSPORIN

Synonyms: Neomycin sulfate–polymyxin B sulfate solution for irrigation

Chemical Family: Not applicable

Relevant Identified Uses of the Substance or Mixture and Uses Advised Against

Intended Use: Pharmaceutical product used as antibiotic agent

Details of the Supplier of the Safety Data Sheet

Pfizer Inc
Pfizer Pharmaceuticals Group
235 East 42nd Street
New York, New York 10017
1-800-879-3477

Emergency telephone number: CHEMTREC (24 hours): 1-800-424-9300
Contact E-Mail: pfizer-MSDS@pfizer.com

2. HAZARDS IDENTIFICATION

Classification of the Substance or Mixture

GHS - Classification

Respiratory Sensitization: Category 1
Skin Sensitization: Category 1
Reproductive Toxicity: Category 2

EU Classification:

EU Indication of danger: Xn - Harmful
Toxic to Reproduction: Category 3

EU Risk Phrases:

R63 - Possible risk of harm to the unborn child.
R42/43 - May cause sensitization by inhalation and skin contact.

Label Elements

Signal Word: Danger

Hazard Statements:

H317 - May cause an allergic skin reaction
H334 - May cause allergy or asthma symptoms or breathing difficulties if inhaled
H361d - Suspected of damaging the unborn child

PZ02107
Precautionary Statements:
P201 - Obtain special instructions before use
P261 - Avoid breathing dust/fume/gas/mist/vapors/spray
P281 - Use personal protective equipment as required
P304 + P341 - IF INHALED: If breathing is difficult, remove to fresh air and keep at rest in a position comfortable for breathing
P342 + P311 - If experiencing respiratory symptoms: Call a POISON CENTRE or doctor/physician
P308 + P313 - IF exposed or concerned: Get medical attention/advice
P405 - Store locked up

Other Hazards
Australian Hazard Classification (NOHSC):

Note:
This document has been prepared in accordance with standards for workplace safety, which requires the inclusion of all known hazards of the product or its ingredients regardless of the potential risk. The precautionary statements and warning included may not apply in all cases. Your needs may vary depending upon the potential for exposure in your workplace.

3. COMPOSITION / INFORMATION ON INGREDIENTS

<table>
<thead>
<tr>
<th>Ingredient</th>
<th>CAS Number</th>
<th>EU EINECS/ELINCS List</th>
<th>EU Classification</th>
<th>GHS Classification</th>
<th>%</th>
</tr>
</thead>
<tbody>
<tr>
<td>Neomycin Sulfate</td>
<td>1405-10-3</td>
<td>215-773-1</td>
<td>Xn;R42/43 Repr.Cat.3;R63</td>
<td>Resp. Sens. 1 (H334) Skin Sens.1(H317) Repro. 2 (H361d) Aq. Acute 3 (H402) Aq. Chronic 3 (H412)</td>
<td>1-5</td>
</tr>
<tr>
<td>Polymyxin B sulfate</td>
<td>1405-20-5</td>
<td>215-774-7</td>
<td>Xn;R22 Xn;R42 Xi; R43</td>
<td>Acute Tox.4 (H302) Skin Sens.1 (H317) Resp Sens.1 (H334)</td>
<td>0.1 - 1</td>
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</table>

<table>
<thead>
<tr>
<th>Ingredient</th>
<th>CAS Number</th>
<th>EU EINECS/ELINCS List</th>
<th>EU Classification</th>
<th>GHS Classification</th>
<th>%</th>
</tr>
</thead>
<tbody>
<tr>
<td>Methylparaben</td>
<td>99-76-3</td>
<td>202-785-7</td>
<td>Not Listed</td>
<td>Not Listed</td>
<td>&lt;1.0</td>
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<td>Water for injection</td>
<td>7732-18-5</td>
<td>231-791-2</td>
<td>Not Listed</td>
<td>Not Listed</td>
<td>*</td>
</tr>
</tbody>
</table>
4. FIRST AID MEASURES

Description of First Aid Measures

Eye Contact: Flush with water while holding eyelids open for at least 15 minutes. Seek medical attention immediately.

Skin Contact: If irritation occurs or persists, get medical attention. Remove clothing and wash affected skin with soap and water.

Ingestion: Never give anything by mouth to an unconscious person. Wash out mouth with water. Do not induce vomiting unless directed by medical personnel. Seek medical attention immediately.

Inhalation: Remove to fresh air and keep patient at rest. Seek medical attention immediately.

Most Important Symptoms and Effects, Both Acute and Delayed

Symptoms and Effects of Exposure: For information on potential signs and symptoms of exposure, See Section 2 - Hazards Identification and/or Section 11 - Toxicological Information.

Medical Conditions Aggravated by Exposure: None known

Indication of the Immediate Medical Attention and Special Treatment Needed

Notes to Physician: None

5. FIRE FIGHTING MEASURES

Extinguishing Media: Extinguish fires with CO2, extinguishing powder, foam, or water.

Special Hazards Arising from the Substance or Mixture

Hazardous Combustion Products: Formation of toxic gases is possible during heating or fire.

Fire / Explosion Hazards: Fine particles (such as dust and mists) may fuel fires/explosions.

Advice for Fire-Fighters

During all fire fighting activities, wear appropriate protective equipment, including self-contained breathing apparatus.

6. ACCIDENTAL RELEASE MEASURES

Personal Precautions, Protective Equipment and Emergency Procedures

Personnel involved in clean-up should wear appropriate personal protective equipment (see Section 8). Minimize exposure.

Environmental Precautions

Place waste in an appropriately labeled, sealed container for disposal. Care should be taken to avoid environmental release.

Methods and Material for Containment and Cleaning Up

Measures for Cleaning / Collecting: Absorb spills with non-combustible absorbent material and transfer into a labeled container for disposal.
Additional Consideration for Large Spills: Non-essential personnel should be evacuated from affected area. Report emergency situations immediately. Clean up operations should only be undertaken by trained personnel.

7. HANDLING AND STORAGE

Precautions for Safe Handling
Avoid breathing vapor or mist. Avoid contact with eyes, skin and clothing. When handling, use appropriate personal protective equipment (see Section 8). Wash thoroughly after handling.

Conditions for Safe Storage, Including any Incompatibilities
Storage Conditions: Store as directed by product packaging.
Specific end use(s): Pharmaceutical product used as antibiotic agent

8. EXPOSURE CONTROLS / PERSONAL PROTECTION

Control Parameters
Refer to available public information for specific member state Occupational Exposure Limits.

Neomycin Sulfate
Pfizer OEL TWA-8 Hr: 100 µg/m³, Sensitizer

The purpose of the Occupational Exposure Band (OEB) classification system is to separate substances into different Hazard categories when the available data are sufficient to do so, but inadequate to establish an Occupational Exposure Limit (OEL). The OEB given is based upon an analysis of all currently available data; as such, this value may be subject to revision when new information becomes available.

Polymyxin B sulfate
Pfizer Occupational Exposure Band (OEB): OEB 2 - Sensitizer (control exposure to the range of 100ug/m³ to < 1000ug/m³, provide additional precautions to protect from skin contact)

Exposure Controls
Engineering Controls: Engineering controls should be used as the primary means to control exposures. General room ventilation is adequate unless the process generates dust, mist or fumes. Keep airborne contamination levels below the exposure limits listed above in this section.

Personal Protective Equipment:
Refer to applicable national standards and regulations in the selection and use of personal protective equipment (PPE).

Hands: Impervious gloves are recommended if skin contact with drug product is possible and for bulk processing operations.
Eyes: Wear safety glasses or goggles if eye contact is possible.
Skin: Impervious protective clothing is recommended if skin contact with drug product is possible and for bulk processing operations.
Respiratory protection: If the applicable Occupational Exposure Limit (OEL) is exceeded, wear an appropriate respirator with a protection factor sufficient to control exposures to below the OEL.

9. PHYSICAL AND CHEMICAL PROPERTIES

<table>
<thead>
<tr>
<th>Property</th>
<th>Value</th>
<th>Property</th>
<th>Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Physical State:</td>
<td>Sterile solution</td>
<td>Color:</td>
<td>No data available.</td>
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<tr>
<td>Odor:</td>
<td>No data available</td>
<td>Odor Threshold:</td>
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</tr>
<tr>
<td>Molecular Formula:</td>
<td>Mixture</td>
<td>Molecular Weight:</td>
<td>Mixture</td>
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<tr>
<td>Solvent Solubility:</td>
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<td></td>
</tr>
<tr>
<td>Water Solubility:</td>
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<td></td>
<td></td>
</tr>
<tr>
<td>pH:</td>
<td>No data available</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
9. PHYSICAL AND CHEMICAL PROPERTIES

Melting/Freezing Point (°C): No data available
Boiling Point (°C): No data available.
Partition Coefficient: (Method, pH, Endpoint, Value)
Water for injection
No data available
Methylparaben
No data available

Neomycin Sulfate
Predicted 7.4 Log D 1.20

Polymyxin B sulfate
No data available
Decomposition Temperature (°C): No data available.

Evaporation Rate (Gram/s): No data available
Vapor Pressure (kPa): No data available
Vapor Density (g/ml): No data available
Relative Density: No data available
Viscosity: No data available

Flammability:
Autoignition Temperature (Solid) (°C): No data available
Flammability (Solids): No data available
Flash Point (Liquid) (°C): No data available
Upper Explosive Limits (Liquid) (% by Vol.): No data available
Lower Explosive Limits (Liquid) (% by Vol.): No data available
Polymerization: Will not occur

10. STABILITY AND REACTIVITY

Reactivity: No data available
Chemical Stability: Stable under normal conditions of use.
Possibility of Hazardous Reactions
Oxidizing Properties: No data available
Conditions to Avoid: Fine particles (such as dust and mists) may fuel fires/explosions.
Incompatible Materials: As a precautionary measure, keep away from strong oxidizers
Hazardous Decomposition Products: No data available

11. TOXICOLOGICAL INFORMATION

Information on Toxicological Effects
General Information: The information included in this section describes the potential hazards of the individual ingredients.
Short Term: May be harmful if swallowed. May cause allergic reaction (based on components).
Long Term: Repeat-dose studies in animals have shown a potential to cause adverse effects on developing fetus (based on components)

Acute Toxicity: (Species, Route, End Point, Dose)

Neomycin Sulfate
Rat Oral LD 50 2750 mg/kg
Mouse Oral LD 50 2880 mg/kg
SAFETY DATA SHEET

Material Name: NEOSPORIN G.U. Irrigant Sterile (neomycin sulfate–polymyxin B sulfate solution for irrigation)
Revision date: 03-Apr-2015
Version: 2.0

11. TOXICOLOGICAL INFORMATION

Acute Toxicity Comments: A greater than symbol (>) indicates that the toxicity endpoint being tested was not achievable at the highest dose used in the test.

Irritation / Sensitization: (Study Type, Species, Severity)

Skin Irritation
Rabbit Moderate

Skin Sensitization
Positive

Repeated Dose Toxicity: (Duration, Species, Route, Dose, End Point, Target Organ)

Neomycin Sulfate
6 Week(s)  Dog  Oral  100 mg/kg/day  NOAEL  No effects at maximum dose
3 Month(s) Guinea Pig  Oral  10 mg/kg/day  NOAEL  No effects at maximum dose
3 Month(s) Dog  Subcutaneous  20 mg/kg/day  LOAEL  Kidney
12 Month(s) Cat  Oral  12 mg/kg/day  NOAEL  Blood forming organs
3 Month(s) Guinea Pig  Subcutaneous  10 mg/kg/day  LOAEL  Kidney

Polymyxin B sulfate
9 Day(s)  Mouse  Subcutaneous  284 mg/kg  LOAEL  Skin

Reproduction & Developmental Toxicity: (Study Type, Species, Route, Dose, End Point, Effect(s))

Neomycin Sulfate
Reproductive & Fertility  Mouse  Oral  4000 mg/L  NOAEL  No effects at maximum dose
2 Generation Reproductive Toxicity  Rat  Oral  25 mg/kg/day  NOAEL  Fetotoxicity
Reproductive & Fertility  Rat  Oral  25 mg/kg/day  NOAEL  No effects at maximum dose
Prenatal & Postnatal Development  Rat  Subcutaneous  6 mg/kg/day  LOAEL  Developmental toxicity

Genetic Toxicity: (Study Type, Cell Type/Organism, Result)

Neomycin Sulfate
Bacterial Mutagenicity (Ames)  Salmonella, E. coli  Negative
Mammalian Cell Mutagenicity  Chinese Hamster Ovary (CHO) cells  Negative
In Vivo Cytogenetics  Mouse  Negative
In Vitro Chromosome Aberration  Human Lymphocytes  Positive

Carcinogenicity: (Duration, Species, Route, Dose, End Point, Effect(s))

PZ02107
11. TOXICOLOGICAL INFORMATION

Neomycin Sulfate
2 Year(s)  Rat  Oral  25 mg/kg/day  NOAEL  Not carcinogenic

Carcinogen Status:  None of the components of this formulation are listed as a carcinogen by IARC, NTP or OSHA.

12. ECOLOGICAL INFORMATION

Environmental Overview:  The environmental characteristics of this material have not been fully evaluated. Releases to the environment should be avoided.

Toxicity:
Aquatic Toxicity: (Species, Method, End Point, Duration, Result)

Neomycin Sulfate
*Daphnia magna* (Water Flea)  OECD  EC50  48 Hours  68 mg/L
*Salmo gairdneri* (Trout)  OECD  NOEC  96 Hours  >1000 mg/L

Bacterial Inhibition: (Inoculum, Method, End Point, Result)

Neomycin Sulfate
Activated sludge  OECD  EC50  399 mg/L

Persistence and Degradability:  No data available

Bio-accumulative Potential:
Partition Coefficient: (Method, pH, Endpoint, Value)

Neomycin Sulfate
Predicted  7.4  Log D  1.20

Mobility in Soil:  No data available

13. DISPOSAL CONSIDERATIONS

Waste Treatment Methods:  Dispose of waste in accordance with all applicable laws and regulations. Member State specific and Community specific provisions must be considered. Considering the relevant known environmental and human health hazards of the material, review and implement appropriate technical and procedural waste water and waste disposal measures to prevent occupational exposure and environmental release. It is recommended that waste minimization be practiced. The best available technology should be utilized to prevent environmental releases. This may include destructive techniques for waste and wastewater.

14. TRANSPORT INFORMATION

The following refers to all modes of transportation unless specified below.

Not regulated for transport under USDOT, EUADR, IATA, or IMDG regulations.
### 15. REGULATORY INFORMATION

Safety, Health and Environmental Regulations/Legislation Specific for the Substance or Mixture

**Canada - WHMIS: Classifications**

**WHMIS hazard class:**
- D2a very toxic materials
- D2b toxic materials

This product has been classified in accordance with the hazard criteria of the CPR and the MSDS contains all of the information required by the CPR.

<table>
<thead>
<tr>
<th>Substance</th>
<th>CERCLA/SARA 313 Emission reporting</th>
<th>California Proposition 65</th>
<th>Inventory - United States TSCA - Sect. 8(b)</th>
<th>Australia (AICS)</th>
<th>EU EINECS/ELINCS List</th>
</tr>
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<tbody>
<tr>
<td>Methylparaben</td>
<td>Not Listed</td>
<td>Not Listed</td>
<td>Present</td>
<td>Present</td>
<td>202-785-7</td>
</tr>
<tr>
<td>Neomycin Sulfate</td>
<td>Not Listed</td>
<td>developmental toxicity initial date 10/1/92 internal use</td>
<td>Present</td>
<td></td>
<td>215-773-1</td>
</tr>
<tr>
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<td>Not Listed</td>
<td>Not Listed</td>
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<td>Not Listed</td>
<td>Not Listed</td>
<td>Present</td>
<td></td>
<td>231-791-2</td>
</tr>
</tbody>
</table>
15. REGULATORY INFORMATION

Additional Information: White petrolatum is not classified as a carcinogen. Nota N applies since the full refining history is known and it can be shown that the substances from which the petroleum jelly was produced are not a carcinogen.

16. OTHER INFORMATION

Text of R phrases and GHS Classification abbreviations mentioned in Section 3

- Reproductive toxicity-Cat.2; H361d - Suspected of damaging the unborn child
- Sensitization, skin-Cat.1; H317 - May cause an allergic skin reaction
- Sensitization, respiratory-Cat.1; H334 - May cause allergy or asthma symptoms or breathing difficulties if inhaled
- Hazardous to the aquatic environment, acute toxicity-Cat.3; H402 - Harmful to aquatic life
- Hazardous to the aquatic environment, chronic toxicity-Cat.3; H412 - Harmful to aquatic life with long lasting effects
- Acute toxicity, oral-Cat.4; H302 - Harmful if swallowed

Xn - Harmful
Xi - Irritant
Toxic to Reproduction: Category 3

- R22 - Harmful if swallowed.
- R63 - Possible risk of harm to the unborn child.
- R42/43 - May cause sensitization by inhalation and skin contact.

Data Sources: Pfizer proprietary drug development information. Safety data sheets for individual ingredients.

Revision date: 03-Apr-2015

Prepared by: Product Stewardship Hazard Communication

Pfizer Inc believes that the information contained in this Material Safety Data Sheet is accurate, and while it is provided in good faith, it is without warranty of any kind, expressed or implied. If data for a hazard are not included in this document there is no known information at this time.

End of Safety Data Sheet