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

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
- Intended Use: Pharmaceutical product used as antibiotic agent

2. HAZARDS IDENTIFICATION

Appearance: Aqueous sterile solution

Statement of Hazard: Non-hazardous in accordance with international standards for workplace safety.

Additional Hazard Information:
- 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).
- EU Indication of danger: Not classified


Note: This document has been prepared in accordance with standards for workplace safety, which require the inclusion of all known hazards of the active substance or its intermediates regardless of the potential risk. The precautionary statements and warnings 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>%</th>
</tr>
</thead>
<tbody>
<tr>
<td>Neomycin Sulfate</td>
<td>1405-10-3</td>
<td>215-773-1</td>
<td>Xn;R42/43</td>
<td>4</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>Repr.Cat.3;R63</td>
<td></td>
</tr>
<tr>
<td>Polymyxin B sulfate</td>
<td>1405-20-5</td>
<td>215-774-7</td>
<td>Xn;R22</td>
<td>&lt;1.0</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>Xn;R42/43</td>
<td></td>
</tr>
</tbody>
</table>

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

Additional Information: * Proprietary Ingredient(s) indicated as hazardous have been assessed under standards for workplace safety.

For the full text of the R phrases mentioned in this Section, see Section 16

4. 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.

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.

5. FIRE FIGHTING MEASURES

Extinguishing Media: Use carbon dioxide, dry chemical, or water spray.

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

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

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

6. ACCIDENTAL RELEASE MEASURES

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

Measures for Cleaning / Collecting: Absorb spills with non-combustible absorbent material and transfer into a labeled container for disposal.
Measures for Environmental Protections: Place waste in an appropriately labeled, sealed container for disposal. Care should be taken to avoid environmental release.

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

General Handling: Use adequate ventilation. Avoid contact with eyes, skin and clothing. When handling, use appropriate personal protective equipment (see Section 8). Wash thoroughly after handling. Releases to the environment should be avoided. Review and implement appropriate technical and procedural waste water and waste disposal measures to prevent occupational exposure or environmental releases. Potential points of process emissions of this material to the atmosphere should be controlled with dust collectors, HEPA filtration systems or other equivalent controls.

Storage Conditions: Store as directed by product packaging.

8. EXPOSURE CONTROLS / PERSONAL PROTECTION

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)

Engineering Controls: General room ventilation is adequate unless the process generates dust, mist or fumes. Local and general ventilation should be used as necessary, when handling this material in bulk.

Environmental Exposure Controls: Refer to specific Member State legislation for requirements under Community environmental legislation.

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 airborne exposures are within or exceed the Occupational Exposure Band (OEB) range, wear an appropriate respirator with a protection factor sufficient to control exposures to the bottom of the OEB range.
9. PHYSICAL AND CHEMICAL PROPERTIES

Physical State: Sterile solution  
Color: No data available.  
Molecular Formula: Mixture  
Molecular Weight: Mixture

Polymerization: Will not occur

10. STABILITY AND REACTIVITY

Chemical Stability: Stable under normal conditions of use.  
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

11. TOXICOLOGICAL INFORMATION

General Information: The information included in this section describes the potential hazards of the individual ingredients.

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

**Neomycin Sulfate**
- Rat Oral LD₅₀ 2750 mg/kg
- Mouse Oral LD₅₀ 2880 mg/kg
- Mouse Intraperitoneal LD₅₀ 116 mg/kg
- Rat Subcutaneous LD₅₀ 633 mg/kg
- Mouse Subcutaneous LD₅₀ 275 mg/kg

**Polymyxin B sulfate**
- Mouse Oral LD₅₀ 790 mg/kg
- Rat SC LD₅₀ 50 mg/kg
- Rat IV LD₅₀ 3.98 mg/kg

**Methylparaben**
- Mouse Oral LD₅₀ > 8000 mg/kg
- Rat Oral LD₅₀ 2280 mg/kg

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)

**Neomycin Sulfate**
- Skin Irritation Rabbit Moderate
- Eye Irritation Rabbit Minimal

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
11. TOXICOLOGICAL INFORMATION

<table>
<thead>
<tr>
<th>Duration</th>
<th>Species</th>
<th>Route</th>
<th>Dose</th>
<th>End Point</th>
<th>Effect(s)</th>
</tr>
</thead>
<tbody>
<tr>
<td>3 Month(s)</td>
<td>Dog</td>
<td>Subcutaneous</td>
<td>20 mg/kg/day</td>
<td>LOAEL</td>
<td>Kidney</td>
</tr>
<tr>
<td>12 Month(s)</td>
<td>Cat</td>
<td>Oral</td>
<td>12 mg/kg/day</td>
<td>NOAEL</td>
<td>Blood forming organs</td>
</tr>
<tr>
<td>3 Month(s)</td>
<td>Guinea Pig</td>
<td>Subcutaneous</td>
<td>10 mg/kg/day</td>
<td>LOAEL</td>
<td>Kidney</td>
</tr>
</tbody>
</table>

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))

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.

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 | 3 Hours | 399 mg/L |
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

EU Symbol: Not classified
EU Indication of danger: Not classified

OSHA Label:
Non-hazardous in accordance with international standards for workplace safety.

Canada - WHMIS: Classifications

WHMIS hazard class:
None required
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.

Neomycin Sulfate
- California Proposition 65: developmental toxicity initial date 10/1/92
- Inventory - United States TSCA - Sect. 8(b): Present
- Australia (AICS): Present
- EU EINECS/ELINCS List: 215-773-1

Polymyxin B sulfate
- Australia (AICS): Present
- EU EINECS/ELINCS List: 215-774-7

Water for injection
- Inventory - United States TSCA - Sect. 8(b): Present
15. REGULATORY INFORMATION

Australia (AICS): Present
REACH - Annex IV - Exemptions from the obligations of Register: Present
EU EINECS/ELINCS List 231-791-2

Methylparaben
Inventory - United States TSCA - Sect. 8(b) Present
Australia (AICS): Present
EU EINECS/ELINCS List 202-785-7

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 mentioned in Section 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.

Prepared by: Product Stewardship Hazard Communication
Pfizer Global Environment, Health, and Safety Operations

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