SAFETY DATA SHEET

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

Product Identifier

Material Name: NEOSPORIN Ophthalmic Solution Sterile (neomycin and polymyxin B sulfates and gramicidin ophthalmic solution, USP)

Trade Name: NEOSPORIN
Synonyms: Neomycin and polymyxin B sulfates and gramicidin ophthalmic solution, USP
Chemical Family: Not applicable

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

Intended Use: Pharmaceutical product used as antibiotic agent

2. HAZARDS IDENTIFICATION

Classification of the Substance or Mixture

GHS - Classification

Respiratory Sensitization: Category 1
Skin Sensitization: Category 1

EU Classification:

EU Indication of danger: Irritant

EU Risk Phrases:

R42/43 - May cause sensitization by inhalation and skin contact.

Label Elements

Signal Word: Danger
Hazard Statements:
H334 - May cause allergy or asthma symptoms or breathing difficulties if inhaled
H317 - May cause an allergic skin reaction
Precautionary Statements:

- P261 - Avoid breathing dust/fume/gas/mist/vapors/spray
- P285 - In case of inadequate ventilation wear respiratory protection
- 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
- P302+ P352 - IF ON SKIN: Wash with plenty of soap and water
- P333 + P313 - If skin irritation or rash occurs: Get medical advice/attention

Other Hazards

No data available

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>Hazardous 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>Alcohol</td>
<td>64-17-5</td>
<td>200-578-6</td>
<td>F; R11</td>
<td>Flam. Liq. 2 (H225)</td>
<td>0.1 - 1</td>
</tr>
<tr>
<td>Gramicidin</td>
<td>1405-97-6</td>
<td>215-790-4</td>
<td>Not Listed</td>
<td>Not Listed</td>
<td>&lt;0.01</td>
</tr>
<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>&lt;0.01</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>
</tr>
<tr>
<td>Propylene glycol</td>
<td>57-55-6</td>
<td>200-338-0</td>
<td>Not Listed</td>
<td>Not Listed</td>
<td>*</td>
</tr>
</tbody>
</table>

Material Name: NEOSPORIN Ophthalmic Solution Sterile (neomycin and polymyxin B sulfates and gramicidin ophthalmic solution, USP)
Revision date: 03-Apr-2015

PZ02104
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>Thimerosal</td>
<td>54-64-8</td>
<td>200-210-4</td>
<td>T+; R26/27/28; R33 N; R50/53</td>
<td>Acute Tox. 2 (H300) Acute Tox. 1(H310) STOT RE 2 (H373) Acute Tox. 2 (H330) Acute Aquatic 1 (H400) Chronic Aquatic 1 (H410)</td>
<td>0.01 - 0.1</td>
</tr>
<tr>
<td>Polyethylene-polypropylene block copolymer</td>
<td>106392-12-5</td>
<td>Not Listed</td>
<td>Not Listed</td>
<td>Not Listed</td>
<td>*</td>
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<tr>
<td>Sodium chloride</td>
<td>7647-14-5</td>
<td>231-598-3</td>
<td>Not Listed</td>
<td>Not Listed</td>
<td>*</td>
</tr>
<tr>
<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>

Additional Information: * Proprietary
In ingredient(s) indicated as hazardous have been assessed under standards for workplace safety. In accordance with 29 CFR 1910.1200, the exact percentage composition of this mixture has been withheld as a trade secret.

For the full text of the R phrases and CLP/GHS abbreviations mentioned in this Section, see Section 16

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
SAFETY DATA SHEET

Material Name: NEOSPORIN Ophthalmic Solution Sterile
(neomycin and polymyxin B sulfates and gramicidin ophthalmic solution, USP)
Revision date: 03-Apr-2015

6. ACCIDENTAL RELEASE MEASURES

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.

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.

Alcohol

ACGIH Threshold Limit Value (STEL) 1000 ppm
Australia TWA 1000 ppm 1880 mg/m³
Austria OEL - MAKs 1000 ppm 1900 mg/m³
Belgium OEL - TWA 1000 ppm 1907 mg/m³
Bulgaria OEL - TWA 1000.0 mg/m³
Czech Republic OEL - TWA 1000 mg/m³
Denmark OEL - TWA 1000 ppm 1900 mg/m³
Estonia OEL - TWA 500 ppm 1000 mg/m³
Finland OEL - TWA 1000 ppm 1900 mg/m³

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## 8. EXPOSURE CONTROLS / PERSONAL PROTECTION

<table>
<thead>
<tr>
<th>Material</th>
<th>Country/OEL</th>
<th>TWA</th>
<th>1000 ppm</th>
<th>1900 mg/m³</th>
</tr>
</thead>
<tbody>
<tr>
<td>Neomycin Sulfate</td>
<td>France OEL</td>
<td>TWA</td>
<td>1000 ppm</td>
<td>1900 mg/m³</td>
</tr>
<tr>
<td></td>
<td>Germany - TRGS 900 - TWAs</td>
<td>500 ppm</td>
<td>960 mg/m³</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Germany (DFG) - MAK</td>
<td>500 ppm</td>
<td>960 mg/m³</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Greece OEL - TWA</td>
<td>1000 ppm</td>
<td>1900 mg/m³</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Hungary OEL - TWA</td>
<td>1900 mg/m³</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>Latvia OEL - TWA</td>
<td>1000 mg/m³</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>Lithuania OEL - TWA</td>
<td>500 ppm</td>
<td>1000 mg/m³</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Netherlands OEL - TWA</td>
<td>260 mg/m³</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>OSHA - Final PELS - TWAs:</td>
<td>1000 ppm</td>
<td>1900 mg/m³</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Poland OEL - TWA</td>
<td>1900 mg/m³</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>Portugal OEL - TWA</td>
<td>1000 ppm</td>
<td></td>
<td></td>
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<tr>
<td></td>
<td>Romania OEL - TWA</td>
<td>1000 ppm</td>
<td>1900 mg/m³</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Russia OEL - TWA</td>
<td>1000 mg/m³</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>Slovakia OEL - TWA</td>
<td>500 ppm</td>
<td>960 mg/m³</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Slovenia OEL - TWA</td>
<td>1000 ppm</td>
<td>1900 mg/m³</td>
<td></td>
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<tr>
<td></td>
<td>Spain OEL - TWA</td>
<td>1000 ppm</td>
<td>1910 mg/m³</td>
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<td></td>
<td>Sweden OEL - TWAs</td>
<td>500 ppm</td>
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<td></td>
<td>Switzerland OEL -TWAs</td>
<td>500 ppm</td>
<td>960 mg/m³</td>
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</tr>
<tr>
<td></td>
<td>Vietnam OEL - TWAs</td>
<td>1000 mg/m³</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Sodium chloride</td>
<td>Latvia OEL - TWA</td>
<td>5 mg/m³</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>Lithuania OEL - TWA</td>
<td>5 mg/m³</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Neomycin Sulfate</td>
<td>Pfizer OEL TWA-8 Hr:</td>
<td>100 µg/m³, Sensitizer</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Propylene glycol</td>
<td>Australia TWA</td>
<td>150 ppm</td>
<td>474 mg/m³</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>10 mg/m³</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>Ireland OEL - TWAs</td>
<td>150 ppm</td>
<td>470 mg/m³</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>10 mg/m³</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>Latvia OEL - TWA</td>
<td>7 mg/m³</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>Lithuania OEL - TWA</td>
<td>7 mg/m³</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
SAFETY DATA SHEET

Material Name: NEOSPORIN Ophthalmic Solution Sterile (neomycin and polymyxin B sulfates and gramicidin ophthalmic solution, USP)
Revision date: 03-Apr-2015
Version: 2.0

8. EXPOSURE CONTROLS / PERSONAL PROTECTION

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.

**Gramicidin**

| Pfizer Occupational Exposure Band (OEB): | Default (control exposure to the range of 1ug/m³ to <10ug/m³) |

**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>Physical State:</th>
<th>Sterile solution</th>
</tr>
</thead>
<tbody>
<tr>
<td>Odor:</td>
<td>No data available.</td>
</tr>
<tr>
<td>Molecular Formula:</td>
<td>Mixture</td>
</tr>
</tbody>
</table>

| Solvent Solubility: | No data available |
| Water Solubility: | No data available |
| pH: | No data available. |
| Melting/Freezing Point (°C): | No data available |
| Boiling Point (°C): | No data available. |
| Partition Coefficient: (Method, pH, Endpoint, Value) | No data available |
| Water for injection | No data available |
| Propylene glycol | No data available |
| Polyoxyethylene-polyoxypropylene block copolymer | No data available |
| Sodium chloride | No data available |
| Alcohol | No data available |

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9. PHYSICAL AND CHEMICAL PROPERTIES

Gramicidin
No data available

Neomycin Sulfate
Predicted 7.4  Log D 1.20

Polymyxin B sulfate
No data available

Thimerosal
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)

Propylene glycol
Rat  Oral  LD 50  22,000 mg/kg
Mouse  Oral  LD 50  24,900 mg/kg
Rabbit  Dermal  LD 50  20,800 mg/kg
11. TOXICOLOGICAL INFORMATION

Polyoxyethylene-polyoxypropylene block copolymer
Rat Para-periosteal LD50 > 320 mg/kg
Mouse Para-periosteal LD50 129mg/kg
Rat Oral LD50 9380mg/kg

Sodium chloride
Rat Oral LD50 3000 mg/kg
Mouse Oral LD50 4000 mg/kg

Alcohol
Rat Inhalation LC50 20,000mg/L

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

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

Thimerosal
Rat Oral LD50 75 mg/kg
Mouse Oral LD50 91 mg/kg
Rat Subcutaneous LD50 98mg/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)

Propylene glycol
Skin Irritation Rabbit Mild
Eye Irritation Rabbit Mild

Polyoxyethylene-polyoxypropylene block copolymer
Eye Irritation Rabbit Mild
Skin Irritation Rabbit Mild

Sodium chloride
Eye Irritation Rabbit Moderate
Skin Irritation Rabbit Mild
11. TOXICOLOGICAL INFORMATION

Alcohol
Eye Irritation Rabbit Severe

Neomycin Sulfate
Skin Irritation Rabbit Moderate
Eye Irritation Rabbit Minimal
Skin Sensitization Positive

Thimerosal
Eye Irritation Rabbit Mild

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))

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

Carcinogen Status:
None of the components present in this material at concentrations equal to or greater than 0.1% are listed by IARC, NTP, OSHA, or ACGIH as a carcinogen.
11. TOXICOLOGICAL INFORMATION

Alcohol
IARC: Group 1 (Carcinogenic to Humans)

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. This product contains trace quantities of mercury and may qualify as a RCRA Hazardous Waste. Status should be confirmed using the EPA Toxicity Characteristic Leaching Procedure (TCLP).

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.

Alcohol

CERCLA/SARA 313 Emission reporting  Not Listed
California Proposition 65  carcinogen initial date 4/29/11 in alcoholic beverages
developmental toxicity initial date 10/1/87 in alcoholic beverages
Inventory - United States TSCA - Sect. 8(b)  Present
Australia (AICS):  Present
EU EINECS/ELINCS List  200-578-6

Gramicidin

CERCLA/SARA 313 Emission reporting  Not Listed
California Proposition 65  Not Listed
Australia (AICS):  Present
Standard for the Uniform Scheduling for Drugs and Poisons:  Schedule 4
EU EINECS/ELINCS List  215-790-4

Polyoxyethylene-polyoxypropylene block copolymer

CERCLA/SARA 313 Emission reporting  Not Listed
California Proposition 65  Not Listed
Australia (AICS):  Present
EU EINECS/ELINCS List  Not Listed

Sodium chloride

CERCLA/SARA 313 Emission reporting  Not Listed
California Proposition 65  Not Listed
Inventory - United States TSCA - Sect. 8(b)  Present
Australia (AICS):  Present
15. REGULATORY INFORMATION

<table>
<thead>
<tr>
<th>Substance</th>
<th>EU EINECS/ELINCS List</th>
<th>Additional Information</th>
</tr>
</thead>
<tbody>
<tr>
<td>Neomycin Sulfate</td>
<td>231-598-3</td>
<td>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.</td>
</tr>
<tr>
<td>Polymyxin B sulfate</td>
<td>215-774-7</td>
<td></td>
</tr>
<tr>
<td>Propylene glycol</td>
<td>200-338-0</td>
<td></td>
</tr>
<tr>
<td>Thimerosal</td>
<td>200-210-4</td>
<td></td>
</tr>
<tr>
<td>Water for injection</td>
<td>231-791-2</td>
<td></td>
</tr>
</tbody>
</table>

16. OTHER INFORMATION

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

Material Name: NEOSPORIN Ophthalmic Solution Sterile
(neomycin and polymyxin B sulfates and gramicidin ophthalmic solution, USP)
Revision date: 03-Apr-2015

Xn - Harmful
Xi - Irritant
Toxic to Reproduction: Category 3
F - Highly flammable
N - Dangerous for the environment
T+ - Very toxic

R22 - Harmful if swallowed.
R63 - Possible risk of harm to the unborn child.
R33 - Danger of cumulative effects.
R11 - Highly flammable.
R42/43 - May cause sensitization by inhalation and skin contact.
R50/53 - Very toxic to aquatic organisms, may cause long-term adverse effects in the aquatic environment.
R26/27/28 - Very toxic by inhalation, in contact with skin and if swallowed.

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

Reasons for Revision: Updated Section 1 - Identification of the Substance/Preparation and the Company/Undertaking. Updated Section 2 - Hazard Identification. Updated Section 3 - Composition / Information on Ingredients. Updated Section 11 - Toxicology Information. Updated Section 15 - Regulatory Information. Updated Section 16 - Other Information.

Revision date: 03-Apr-2015
Prepared by: Product Stewardship Hazard Communication
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End of Safety Data Sheet

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