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

Product Identifier

Material Name: CORTISPORIN Ophthalmic Suspension Sterile
(neomycin and polymyxin B sulfates and hydrocortisone ophthalmic suspension, USP)

Trade Name: CORTISPORIN
Synonyms: Neomycin and polymyxin B sulfates and hydrocortisone ophthalmic suspension, 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

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

Pfizer Ltd
Ramsgate Road
Sandwich, Kent
CT13 9NJ
United Kingdom
+00 44 (0)1304 616161

Emergency telephone number: CHEMTREC (24 hours): 1-800-424-9300
Emergency telephone number: International CHEMTREC (24 hours): +1-703-527-3887
Contact E-Mail: pfizer-MSDS@pfizer.com

2. HAZARDS IDENTIFICATION

Classification of the Substance or Mixture

EU Classification:
EU Indication of danger: Not classified

Label Elements

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</th>
<th>EU Classification</th>
<th>GHS Classification</th>
<th>%</th>
</tr>
</thead>
</table>

PZ02103
Material Name: CORTISPORIN Ophthalmic Suspension Sterile
(neomycin and polymyxin B sulfates and hydrocortisone ophthalmic suspension, USP)
Revision date: 22-May-2015
Version: 2.0

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>Cetyl alcohol</td>
<td>36653-82-4</td>
<td>Not Listed</td>
<td>Not Listed</td>
<td>Not Listed</td>
<td>*</td>
</tr>
<tr>
<td>Glyceryl monostearate</td>
<td>31566-31-1</td>
<td>Not Listed</td>
<td>Not Listed</td>
<td>Not Listed</td>
<td>*</td>
</tr>
<tr>
<td>Hydrocortisone acetate</td>
<td>50-03-3</td>
<td>Not Listed</td>
<td>Not Listed</td>
<td>1</td>
<td></td>
</tr>
<tr>
<td>Mineral oil</td>
<td>8012-95-1</td>
<td>Not Listed</td>
<td>Not Listed</td>
<td>*</td>
<td></td>
</tr>
<tr>
<td>Neomycin Sulfate</td>
<td>1405-10-3</td>
<td>215-773-1</td>
<td>Xn;R42/43</td>
<td>Resp. Sens. 1</td>
<td>0.35</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td>(H334)</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td>Repr. Cat.3,R63</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td>Skin Sens.1(H317)</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td>Repro. 2 (H361d)</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td>Aq. Acute 2(H402)</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td>Aq. Chronic 3</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td>(H412)</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>Acute Tox.4</td>
<td>0.1</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>Xn;R42</td>
<td>(H302)</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>Xi; R43</td>
<td>Skin Sens.1</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td>(H317)</td>
<td></td>
</tr>
<tr>
<td>Propylene glycol</td>
<td>57-55-6</td>
<td>200-338-0</td>
<td>Not Listed</td>
<td>Resp Sens.1</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td>(H334)</td>
<td></td>
</tr>
<tr>
<td>Sulfuric acid</td>
<td>7664-93-9</td>
<td>231-639-5</td>
<td>C; R35</td>
<td>Skin Corr. 1A</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td>(H314)</td>
<td>**</td>
</tr>
<tr>
<td>Thimerosal</td>
<td>54-64-8</td>
<td>200-210-4</td>
<td>T+; R26/27/28;</td>
<td>Acute Tox.2</td>
<td>0.01</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>R33</td>
<td>(H300)</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>N; R50/53</td>
<td>Acute Tox. 1(H310)</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td>STOT RE 2(H373)</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td>Acute Tox.2(H330)</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td>Acute Aquatic 1(H400)</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td>Chronic Aquatic 1(H410)</td>
<td></td>
</tr>
</tbody>
</table>

Additional Information:
* Proprietary
** to adjust pH
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

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
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.

Conditions for Safe Storage, Including any Incompatibilities

Storage Conditions: Store as directed by product packaging.
Specific end use(s): Pharmaceutical drug product

8. EXPOSURE CONTROLS / PERSONAL PROTECTION

Control Parameters
8. EXPOSURE CONTROLS / PERSONAL PROTECTION

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

Cetyl alcohol
- Germany - TRGS 900 - TWAs: 20 ppm, 200 mg/m³

Glyceryl monostearate
- ACGIH Threshold Limit Value (TWA): 10 mg/m³
- Lithuania OEL - TWA: 5 mg/m³
- Sweden OEL - TWAs: 5 mg/m³

Mineral oil
- ACGIH Threshold Limit Value (TWA): 5 mg/m³
- Australia TWA: 5 mg/m³
- Belgium OEL - TWA: 5 mg/m³
- Bulgaria OEL - TWA: 5.0 mg/m³
- Czech Republic OEL - TWA: 5 mg/m³
- Denmark OEL - TWA: 1 mg/m³
- Finland OEL - TWA: 5 mg/m³
- Greece OEL - TWA: 5 mg/m³
- Lithuania OEL - TWA: 1 mg/m³
- Netherlands OEL - TWA: 5 mg/m³
- OSHA - Final PELS - TWAs:
  - 5 mg/m³
- Poland OEL - TWA: 5 mg/m³
- Portugal OEL - TWA: 5 mg/m³
- Romania OEL - TWA: 5 mg/m³
- Slovakia OEL - TWA:
  - 5 ppm
  - 1 mg/m³
  - 5 mg/m³
- Spain OEL - TWA: 5 mg/m³
- Sweden OEL - TWAs: 1 mg/m³
- Vietnam OEL - TWAs: 5 mg/m³

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

Propylene glycol
- Australia TWA: 150 ppm, 474 mg/m³, 10 mg/m³
- Ireland OEL - TWAs:
  - 150 ppm
  - 470 mg/m³
  - 10 mg/m³
- Latvia OEL - TWA: 7 mg/m³
- Lithuania OEL - TWA: 7 mg/m³

Sulfuric acid
- ACGIH Threshold Limit Value (TWA): 0.2 mg/m³
- Australia STEL: 3 mg/m³
- Australia TWA: 1 mg/m³
- Austria OEL - MAKs: 0.1 mg/m³
### Exposure Controls / Personal Protection

<table>
<thead>
<tr>
<th>Country</th>
<th>OEL - TWA</th>
</tr>
</thead>
<tbody>
<tr>
<td>Belgium</td>
<td>1 mg/m³</td>
</tr>
<tr>
<td>Bulgaria</td>
<td>0.05 mg/m³</td>
</tr>
<tr>
<td>Cyprus</td>
<td>0.05 mg/m³</td>
</tr>
<tr>
<td>Czech Republic</td>
<td>1 mg/m³</td>
</tr>
<tr>
<td></td>
<td>0.05 mg/m³</td>
</tr>
<tr>
<td>Denmark</td>
<td>0.05 mg/m³</td>
</tr>
<tr>
<td>Estonia</td>
<td>0.05 mg/m³</td>
</tr>
<tr>
<td>Finland</td>
<td>0.05 mg/m³</td>
</tr>
<tr>
<td>France</td>
<td>0.05 mg/m³</td>
</tr>
<tr>
<td>Germany</td>
<td>0.1 mg/m³</td>
</tr>
<tr>
<td>Germany (DFG)</td>
<td>0.1 mg/m³</td>
</tr>
<tr>
<td>Greece</td>
<td>0.05 mg/m³</td>
</tr>
<tr>
<td>Hungary</td>
<td>0.05 mg/m³</td>
</tr>
<tr>
<td>Ireland</td>
<td>1 mg/m³</td>
</tr>
<tr>
<td>Japan</td>
<td>1 mg/m³</td>
</tr>
<tr>
<td>Latvia</td>
<td>0.05 mg/m³</td>
</tr>
<tr>
<td>Lithuania</td>
<td>0.05 mg/m³</td>
</tr>
<tr>
<td>Luxembourg</td>
<td>0.05 mg/m³</td>
</tr>
<tr>
<td>Malta</td>
<td>0.05 mg/m³</td>
</tr>
<tr>
<td>Netherlands</td>
<td>0.05 mg/m³</td>
</tr>
<tr>
<td>OSHA</td>
<td>1 mg/m³</td>
</tr>
<tr>
<td>Poland</td>
<td>1 mg/m³</td>
</tr>
<tr>
<td></td>
<td>0.05 mg/m³</td>
</tr>
<tr>
<td>Portugal</td>
<td>0.2 mg/m³</td>
</tr>
<tr>
<td>Romania</td>
<td>0.05 mg/m³</td>
</tr>
<tr>
<td>Slovakia</td>
<td>0.1 mg/m³</td>
</tr>
<tr>
<td>Slovenia</td>
<td>0.05 mg/m³</td>
</tr>
<tr>
<td>Spain</td>
<td>0.05 mg/m³</td>
</tr>
<tr>
<td>Sweden</td>
<td>0.1 mg/m³</td>
</tr>
<tr>
<td>Switzerland</td>
<td>0.1 mg/m³</td>
</tr>
<tr>
<td>Vietnam</td>
<td>1 mg/m³</td>
</tr>
</tbody>
</table>

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.

**Hydrocortisone acetate**

- **Pfizer Occupational Exposure Band (OEB):** OEB 2 (control exposure to the range of 100μg/m³ to < 1000μg/m³)

**Polymyxin B sulfate**

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

**Exposure Controls**

**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.

**Personal Protective Equipment:** Refer to applicable national standards and regulations in the selection and use of personal protective equipment (PPE).
## 8. EXPOSURE CONTROLS / PERSONAL PROTECTION

**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:
- Suspension

### Odor:
- No data available.

### Molecular Formula:
- Mixture

### 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)

### 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:
SAFETY DATA SHEET

Material Name: CORTISPORIN Ophthalmic Suspension Sterile (neomycin and polymyxin B sulfates and hydrocortisone ophthalmic suspension, USP)
Revision date: 22-May-2015

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)

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

Hydrocortisone acetate
Mouse IP LD50 2300 mg/kg
Rat SC LD50 449mg/kg

Neomycin Sulfate
Rat Oral LD 50 2750 mg/kg
Mouse Oral LD 50 2880mg/kg
Mouse Intraperitoneal LD 50 116mg/kg
Rat Subcutaneous LD 50 633mg/kg
Mouse Subcutaneous LD 50 275mg/kg

Sulfuric acid
Rat Oral LD50 2140 mg/kg

Cetyl alcohol

PZ02103
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)**

<table>
<thead>
<tr>
<th>Material Name</th>
<th>Study Type</th>
<th>Species</th>
<th>Route</th>
<th>Endpoint</th>
<th>Target Organ</th>
</tr>
</thead>
<tbody>
<tr>
<td>Neomycin Sulfate</td>
<td>Skin Irritation</td>
<td>Rabbit</td>
<td>Moderate</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Neomycin Sulfate</td>
<td>Eye Irritation</td>
<td>Rabbit</td>
<td>Minimal</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Neomycin Sulfate</td>
<td>Skin Sensitization</td>
<td>Positive</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Sulfuric acid</td>
<td>Eye Irritation</td>
<td>Rabbit</td>
<td>Severe</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Propylene glycol</td>
<td>Skin Irritation</td>
<td>Rabbit</td>
<td>Mild</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Propylene glycol</td>
<td>Eye Irritation</td>
<td>Rabbit</td>
<td>Mild</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Mineral oil</td>
<td>Eye Irritation</td>
<td>Rabbit</td>
<td>Moderate</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Mineral oil</td>
<td>Skin Irritation</td>
<td>Rabbit</td>
<td>Mild</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Thimerosal</td>
<td>Eye Irritation</td>
<td>Rabbit</td>
<td>Mild</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

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

<table>
<thead>
<tr>
<th>Material Name</th>
<th>Duration</th>
<th>Species</th>
<th>Route</th>
<th>Dose</th>
<th>End Point</th>
<th>Target Organ</th>
</tr>
</thead>
<tbody>
<tr>
<td>Polymyxin B sulfate</td>
<td>9 Day(s)</td>
<td>Mouse</td>
<td>Subcutaneous</td>
<td>284 mg/kg</td>
<td>LOAEL</td>
<td>Skin</td>
</tr>
<tr>
<td>Neomycin Sulfate</td>
<td>6 Week(s)</td>
<td>Dog</td>
<td>Oral</td>
<td>100 mg/kg/day</td>
<td>NOAEL</td>
<td>No effects at maximum dose</td>
</tr>
</tbody>
</table>
SAFETY DATA SHEET

Material Name: CORTISPORIN Ophthalmic Suspension Sterile
(neomycin and polymyxin B sulfates and hydrocortisone ophthalmic suspension, USP)
Revision date: 22-May-2015

11. TOXICOLOGICAL INFORMATION

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.

Sulfuric acid
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)
SAFETY DATA SHEET

Material Name: CORTISPORIN Ophthalmic Suspension Sterile (neomycin and polymyxin B sulfates and hydrocortisone ophthalmic suspension, USP)
Revision date: 22-May-2015

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:
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.
## 15. REGULATORY INFORMATION

### Cetyl alcohol

<table>
<thead>
<tr>
<th>Category</th>
<th>Status</th>
</tr>
</thead>
<tbody>
<tr>
<td>CERCLA/SARA 313 Emission reporting</td>
<td>Not Listed</td>
</tr>
<tr>
<td>California Proposition 65</td>
<td>Not Listed</td>
</tr>
<tr>
<td>Inventory - United States TSCA - Sect. 8(b)</td>
<td>Present</td>
</tr>
<tr>
<td>Australia (AICS):</td>
<td>Present</td>
</tr>
<tr>
<td>EU EINECS/ELINCS List</td>
<td>253-149-0</td>
</tr>
</tbody>
</table>

### Glyceryl monostearate

<table>
<thead>
<tr>
<th>Category</th>
<th>Status</th>
</tr>
</thead>
<tbody>
<tr>
<td>CERCLA/SARA 313 Emission reporting</td>
<td>Not Listed</td>
</tr>
<tr>
<td>California Proposition 65</td>
<td>Not Listed</td>
</tr>
<tr>
<td>Inventory - United States TSCA - Sect. 8(b)</td>
<td>Present</td>
</tr>
<tr>
<td>Australia (AICS):</td>
<td>Present</td>
</tr>
<tr>
<td>EU EINECS/ELINCS List</td>
<td>250-705-4</td>
</tr>
</tbody>
</table>

### Hydrocortisone acetate

<table>
<thead>
<tr>
<th>Category</th>
<th>Status</th>
</tr>
</thead>
<tbody>
<tr>
<td>CERCLA/SARA 313 Emission reporting</td>
<td>Not Listed</td>
</tr>
<tr>
<td>California Proposition 65</td>
<td>Not Listed</td>
</tr>
<tr>
<td>Australia (AICS):</td>
<td>Present</td>
</tr>
<tr>
<td>Standard for the Uniform Scheduling for Drugs and Poisons:</td>
<td>Schedule 2</td>
</tr>
<tr>
<td>EU EINECS/ELINCS List</td>
<td>200-004-4</td>
</tr>
</tbody>
</table>

### Mineral oil

<table>
<thead>
<tr>
<th>Category</th>
<th>Status</th>
</tr>
</thead>
<tbody>
<tr>
<td>CERCLA/SARA 313 Emission reporting</td>
<td>Not Listed</td>
</tr>
<tr>
<td>California Proposition 65</td>
<td>Not Listed</td>
</tr>
<tr>
<td>Inventory - United States TSCA - Sect. 8(b)</td>
<td>Present</td>
</tr>
<tr>
<td>Australia (AICS):</td>
<td>Present</td>
</tr>
<tr>
<td>EU EINECS/ELINCS List</td>
<td>232-384-2</td>
</tr>
</tbody>
</table>

### Neomycin Sulfate

<table>
<thead>
<tr>
<th>Category</th>
<th>Status</th>
</tr>
</thead>
<tbody>
<tr>
<td>CERCLA/SARA 313 Emission reporting</td>
<td>Not Listed</td>
</tr>
<tr>
<td>California Proposition 65</td>
<td>developmental toxicity initial date 10/1/92 internal use</td>
</tr>
<tr>
<td>Inventory - United States TSCA - Sect. 8(b)</td>
<td>Present</td>
</tr>
<tr>
<td>Australia (AICS):</td>
<td>Present</td>
</tr>
<tr>
<td>EU EINECS/ELINCS List</td>
<td>215-773-1</td>
</tr>
</tbody>
</table>

### Polymyxin B sulfate

<table>
<thead>
<tr>
<th>Category</th>
<th>Status</th>
</tr>
</thead>
<tbody>
<tr>
<td>CERCLA/SARA 313 Emission reporting</td>
<td>Not Listed</td>
</tr>
<tr>
<td>California Proposition 65</td>
<td>Not Listed</td>
</tr>
<tr>
<td>Australia (AICS):</td>
<td>Present</td>
</tr>
<tr>
<td>EU EINECS/ELINCS List</td>
<td>215-774-7</td>
</tr>
</tbody>
</table>

### Polyoxymethylene stearate

<table>
<thead>
<tr>
<th>Category</th>
<th>Status</th>
</tr>
</thead>
<tbody>
<tr>
<td>CERCLA/SARA 313 Emission reporting</td>
<td>Not Listed</td>
</tr>
<tr>
<td>California Proposition 65</td>
<td>Not Listed</td>
</tr>
<tr>
<td>Inventory - United States TSCA - Sect. 8(b)</td>
<td>Present</td>
</tr>
<tr>
<td>Australia (AICS):</td>
<td>Present</td>
</tr>
<tr>
<td>EU EINECS/ELINCS List</td>
<td>Not Listed</td>
</tr>
</tbody>
</table>

### Propylene glycol
15. REGULATORY INFORMATION

CERCLA/SARA 313 Emission reporting: Not Listed
California Proposition 65: Not Listed
Inventory - United States TSCA - Sect. 8(b): Present
Australia (AICS): Present
EU EINECS/ELINCS List: 200-338-0

Sulfuric acid
CERCLA/SARA 313 Emission reporting: 1.0 %
CERCLA/SARA Hazardous Substances and their Reportable Quantities: 454 kg
CERCLA/SARA - Section 302 Extremely Hazardous TPQs: 1000 lb
CERCLA/SARA - Section 302 Extremely Hazardous Substances EPCRA RQs: Not Listed
California Proposition 65: Not Listed
Inventory - United States TSCA - Sect. 8(b): Present
Australia (AICS): Present
Standard for the Uniform Scheduling for Drugs and Poisons: Schedule 6
EU EINECS/ELINCS List: 231-639-5

Thimerosal
CERCLA/SARA 313 Emission reporting: Not Listed
California Proposition 65: Not Listed
Inventory - United States TSCA - Sect. 8(b): Present
Australia (AICS): Present
EU EINECS/ELINCS List: 200-210-4

Water for injection
CERCLA/SARA 313 Emission reporting: Not Listed
California Proposition 65: Not Listed
Inventory - United States TSCA - Sect. 8(b): Present
Australia (AICS): Present
REACH - Annex IV - Exemptions from the obligations of Register: Present
EU EINECS/ELINCS List: 231-791-2

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
SAFETY DATA SHEET

Material Name: CORTISPORIN Ophthalmic Suspension Sterile
(neomycin and polymyxin B sulfates and hydrocortisone ophthalmic suspension, USP)
Revision date: 22-May-2015

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
Reproductive toxicity-Cat.2; H361d - Suspected of damaging the unborn child
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
Hazardous to the aquatic environment, acute toxicity-Cat.1; H400 - Very toxic to aquatic life
Hazardous to the aquatic environment, chronic toxicity-Cat.1; H410 - Very toxic to aquatic life with long lasting effects
Acute toxicity, oral-Cat.4; H302 - Harmful if swallowed
Skin corrosion/irritation-Cat.1A; H314 - Causes severe skin burns and eye damage
Acute toxicity, oral-Cat.2; H300 - Fatal if swallowed
Acute toxicity, dermal-Cat.1; H310 - Fatal in contact with skin

C - Corrosive
T+ - Very toxic
N - Dangerous for the environment
Xi - Irritant
Xn - Harmful
Toxic to Reproduction: Category 3
R22 - Harmful if swallowed.
R63 - Possible risk of harm to the unborn child.
R35 - Causes severe burns.
R33 - Danger of cumulative effects.
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 2 - Hazard Identification. Updated Section 3 - Composition / Information on Ingredients. Updated Section 7 - Handling and Storage. Updated Section 11 - Toxicology Information. Updated Section 12 - Ecological Information. Updated Section 16 - Other Information.

Revision date: 22-May-2015
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