SAFETY DATA SHEET

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

Product Identifier

Material Name: CORTISPORIN Ointment (neomycin and polymyxin B sulfates, bacitracin zinc, and hydrocortisone ointment, USP)

Trade Name: CORTISPORIN

Synonyms: Neomycin and polymyxin B sulfates, bacitracin zinc, and hydrocortisone ointment, 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

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

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

Emergency telephone number: International CHEMTREC (24 hours): +1-703-527-3887

2. HAZARDS IDENTIFICATION

Classification of the Substance or Mixture

GHS - Classification: Not classified as hazardous

Label Elements

Signal Word: Not Classified

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

Other Hazards

Note: No data available

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

Hazardous

PZ01690
SAFETY DATA SHEET

Material Name: CORTISPORIN Ointment (neomycin and polymyxin B sulfates, bacitracin zinc, and hydrocortisone ointment, USP)
Revision date: 01-Sep-2015

3. COMPOSITION / INFORMATION ON INGREDIENTS

<table>
<thead>
<tr>
<th>Ingredient</th>
<th>CAS Number</th>
<th>EU EINECS/ELINCS List</th>
<th>GHS Classification</th>
<th>%</th>
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</thead>
<tbody>
<tr>
<td>White petrolatum</td>
<td>8009-03-8</td>
<td>232-373-2</td>
<td>Carc. 1B (H350)</td>
<td>*</td>
</tr>
<tr>
<td>Bacitracin Zinc</td>
<td>1405-89-6</td>
<td>215-787-8</td>
<td>Not Listed</td>
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<tr>
<td>Hydrocortisone acetate</td>
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<td>200-004-4</td>
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<td>Neomycin Sulfate</td>
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<td>Skin Sens.1 (H317)</td>
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<td>Repro. 2 (H361d)</td>
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<td>Acq. Acute 3 (H402)</td>
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<td></td>
<td></td>
<td></td>
<td>Acq. Chronic 3 (H412)</td>
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<tr>
<td>Polymyxin B sulfate</td>
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<td>215-774-7</td>
<td>Acute Tox.4 (H302)</td>
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<td>Skin Sens.1 (H317)</td>
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<tr>
<td></td>
<td></td>
<td></td>
<td>Resp Sens.1 (H334)</td>
<td></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 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.
SAFETY DATA SHEET

Material Name: CORTISPORIN Ointment (neomycin and polymyxin B sulfates, bacitracin zinc, and hydrocortisone ointment, USP)
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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): Antibiotic agent

8. EXPOSURE CONTROLS / PERSONAL PROTECTION

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

White petrolatum
ACGIH Threshold Limit Value (TWA) 5 mg/m³ (oil mist, mineral)
ACGIH Threshold Limit Value (STEL) 10 mg/m³ (oil mist, mineral)

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.

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

Polymyxin B sulfate
8. EXPOSURE CONTROLS / PERSONAL PROTECTION

**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).

- **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:** Ointment

- **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)**

- **Neomycin Sulfate**
  - Predicted Log D 1.20

- **Bacitracin Zinc**
  - No data available

- **Polymyxin B sulfate**
  - No data available

- **Hydrocortisone acetate**
  - No data available

- **White petrolatum**
  - 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
SAFETY DATA SHEET

Material Name: CORTISPORIN Ointment (neomycin and polymyxin B sulfates, bacitracin zinc, and hydrocortisone ointment, USP)
Revision date: 01-Sep-2015

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).
Known Clinical Effects: Drugs of this class may cause hypersensitivity reactions allergic skin rash, kidney toxicity (nephrotoxicity). May cause ototoxicity (harmful effects on the ear).

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

Bacitracin Zinc
- Rat Oral LD50 > 2000 mg/kg

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

Hydrocortisone acetate
- Mouse IP LD50 2300 mg/kg
- Rat SC LD50 449 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.
11. TOXICOLOGICAL INFORMATION

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

**Neomycin Sulfate**
- Skin Irritation: Rabbit, Moderate
- Eye Irritation: Rabbit, Minimal
- 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))

**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.

PZ01690
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

Bacitracin Zinc
Algae EC50 72 Hours 1.832 mg/L
Oncorhynchus mykiss (Rainbow Trout) LC50 72 Hours > 1000 mg/L
Daphnia Magna (Water Flea) EC50 48 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

**White petrolatum**

<table>
<thead>
<tr>
<th>Regulation</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>
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<td>Inventory - United States TSCA - Sect. 8(b)</td>
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<td>Australia (AICS):</td>
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<tr>
<td>REACH - Carcinogens Category 2:</td>
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<td>EU EINECS/ELINCS List</td>
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**Bacitracin Zinc**

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<th>Regulation</th>
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<td>CERCLA/SARA 313 Emission reporting</td>
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<td>Inventory - United States TSCA - Sect. 8(b)</td>
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**Hydrocortisone acetate**

<table>
<thead>
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<th>Regulation</th>
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<td>CERCLA/SARA 313 Emission reporting</td>
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<td>California Proposition 65</td>
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<td>Australia (AICS):</td>
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<tr>
<td>Standard for the Uniform Scheduling for Drugs and Poisons:</td>
<td>Schedule 2</td>
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**Neomycin Sulfate**

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<td>EU EINECS/ELINCS List</td>
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**Polymyxin B sulfate**

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<td>Australia (AICS):</td>
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<td>EU EINECS/ELINCS List</td>
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</tbody>
</table>

**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 CLP/GHS Classification abbreviations mentioned in Section 3

Carcinogenicity-Cat.1B; H350 - May cause cancer
Sensitization, respiratory-Cat.1; H334 - May cause allergy or asthma symptoms or breathing difficulties if inhaled
Sensitization, skin-Cat.1; H317 - May cause an allergic skin reaction
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
Acute toxicity, oral-Cat.4; H302 - Harmful 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. Updated Section 1 - Identification of the Substance/Preparation and the Company/Undertaking.

Revision date: 01-Sep-2015


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