SAFETY DATA SHEET

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

Product Identifier

Material Name: PEDIOTIC Suspension Sterile (neomycin and polymyxin B sulfates and hydrocortisone otic suspension, USP)

Trade Name: PEDIOTIC
Synonyms: Neomycin and polymyxin b sulfates and hydrocortisone otic suspension, usp suspension
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:

EU Classification:

EU Indication of danger: Not classified

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
Precautionary Statements:

P201 - Obtain special instructions before use
P202 - Do not handle until all safety precautions have been read and understood
P261 - Avoid breathing dust/fume/gas/mist/vapors/spray
P272 - Contaminated work clothing should not be allowed out of the workplace
P280 - Wear protective gloves/protective clothing/eye protection/face protection
P284 - Wear respiratory protection
P304 + P311 - IF INHALED: Remove victim 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 + P352 - IF ON SKIN: Wash with plenty of soap and water
P333 + P313 - If skin irritation or rash occurs: Get medical advice/attention
P362 - Take off contaminated clothing and wash before reuse
P302+ P352 - IF exposed or concerned: Get medical attention/advice
P405 - Store locked up
P501 - Dispose of contents/container in accordance with all local and national regulations

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>Cetyl alcohol</td>
<td>36653-82-4</td>
<td>253-149-0</td>
<td>Not Listed</td>
<td>Not Listed</td>
<td>*</td>
</tr>
<tr>
<td>Hydrocortisone acetate</td>
<td>50-03-3</td>
<td>200-004-4</td>
<td>Not Listed</td>
<td>Not Listed</td>
<td>1</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>0.35</td>
</tr>
<tr>
<td>Polymyxin B sulfate</td>
<td>1405-20-5</td>
<td>215-774-7</td>
<td>Xn;R22 Xn;R42 Xr; R43</td>
<td>Acute Tox.4 (H302) Skin Sens.1 (H317) Resp Sens.1 (H334)</td>
<td>0.1</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>
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>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>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</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:
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. 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 product

8. EXPOSURE CONTROLS / PERSONAL PROTECTION

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

Cetyl alcohol:
- Germany - TRGS 900 - TWAs: 20 ppm, 200 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
### 8. EXPOSURE CONTROLS / PERSONAL PROTECTION

<table>
<thead>
<tr>
<th>Material Name</th>
<th>Exposure Control/Personal Protection</th>
</tr>
</thead>
<tbody>
<tr>
<td>PEDIOTIC Suspension Sterile (neomycin and polymyxin B sulfates and hydrocortisone otic suspension, USP)</td>
<td>conducted under the control of a medical professional.</td>
</tr>
</tbody>
</table>

Sulfuric acid

<table>
<thead>
<tr>
<th>Material Name</th>
<th>Exposure Control/Personal Protection</th>
</tr>
</thead>
<tbody>
<tr>
<td>ACGIH Threshold Limit Value (TWA)</td>
<td>0.2 mg/m³</td>
</tr>
<tr>
<td>Australia STEL</td>
<td>3 mg/m³</td>
</tr>
<tr>
<td>Australia TWA</td>
<td>1 mg/m³</td>
</tr>
<tr>
<td>Austria OEL - MAKs</td>
<td>0.1 mg/m³</td>
</tr>
<tr>
<td>Belgium OEL - TWA</td>
<td>1 mg/m³</td>
</tr>
<tr>
<td>Bulgaria OEL - TWA</td>
<td>0.05 mg/m³</td>
</tr>
<tr>
<td>Cyprus OEL - TWA</td>
<td>0.05 mg/m³</td>
</tr>
<tr>
<td>Czech Republic OEL - TWA</td>
<td>1 mg/m³</td>
</tr>
<tr>
<td>Denmark OEL - TWA</td>
<td>0.05 mg/m³</td>
</tr>
<tr>
<td>Estonia OEL - TWA</td>
<td>0.05 mg/m³</td>
</tr>
<tr>
<td>Finland OEL - TWA</td>
<td>0.05 mg/m³</td>
</tr>
<tr>
<td>France OEL - TWA</td>
<td>0.05 mg/m³</td>
</tr>
<tr>
<td>Germany - TRLS 900 - TWAs</td>
<td>0.1 mg/m³</td>
</tr>
<tr>
<td>Germany (DFG) - MAK</td>
<td>0.1 mg/m³</td>
</tr>
<tr>
<td>Greece OEL - TWA</td>
<td>0.05 mg/m³</td>
</tr>
<tr>
<td>Hungary OEL - TWA</td>
<td>0.05 mg/m³</td>
</tr>
<tr>
<td>Ireland OEL - TWAs</td>
<td>1 mg/m³</td>
</tr>
<tr>
<td>Japan - OELs - Ceilings</td>
<td>1 mg/m³</td>
</tr>
<tr>
<td>Latvia OEL - TWA</td>
<td>0.05 mg/m³</td>
</tr>
<tr>
<td>Lithuania OEL - TWA</td>
<td>0.05 mg/m³</td>
</tr>
<tr>
<td>Luxembourg OEL - TWA</td>
<td>0.05 mg/m³</td>
</tr>
<tr>
<td>Malta OEL - TWA</td>
<td>0.05 mg/m³</td>
</tr>
<tr>
<td>Netherlands OEL - TWA</td>
<td>0.05 mg/m³</td>
</tr>
<tr>
<td>OSHA - Final PELS - TWAs:</td>
<td>1 mg/m³</td>
</tr>
<tr>
<td>Poland OEL - TWA</td>
<td>1 mg/m³</td>
</tr>
<tr>
<td>Portugal OEL - TWA</td>
<td>0.05 mg/m³</td>
</tr>
<tr>
<td>Romania OEL - TWA</td>
<td>0.05 mg/m³</td>
</tr>
<tr>
<td>Slovakia OEL - TWA</td>
<td>0.1 mg/m³</td>
</tr>
<tr>
<td>Slovenia OEL - TWA</td>
<td>0.05 mg/m³</td>
</tr>
<tr>
<td>Spain OEL - TWA</td>
<td>0.05 mg/m³</td>
</tr>
<tr>
<td>Sweden OEL - TWAs</td>
<td>0.1 mg/m³</td>
</tr>
<tr>
<td>Switzerland OEL -TWAs</td>
<td>0.1 mg/m³</td>
</tr>
<tr>
<td>Vietnam OEL - TWAs</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)
8. EXPOSURE CONTROLS / PERSONAL PROTECTION

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 air contamination levels below the exposure limits or within the OEB range listed above in this section.

Personal Protective Equipment:

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: Whenever excessive air contamination (dust, mist, vapor) is generated, respiratory protection, with appropriate protection factors, should be used to minimize exposure.

9. PHYSICAL AND CHEMICAL PROPERTIES

Physical State: Suspension
Odor: No data available.
Color: No data available.
Molecular Formula: Mixture
Odor Threshold: No data available.
Molecular Weight: Mixture

Solvent Solubility: No data available
Water Solubility: No data available
pH: 4.1
Melting/Freezing Point (°C): No data available
Boiling Point (°C): No data available.

Partition Coefficient: (Method, pH, Endpoint, Value)

Polymyxin B sulfate
No data available

Hydrocortisone acetate
No data available

Thimerosal
No data available

Polysorbate 80
No data available

Water for injection
No data available

Neomycin Sulfate
Predicted 7.4 Log D 1.20

Sulfuric acid
No data available

Cetyl alcohol
No data available

Propylene glycol
No data available

Material Name: PEDIOTIC Suspension Sterile (neomycin and polymyxin B sulfates and hydrocortisone otic suspension, USP)
Revision date: 12-Apr-2015
Version: 1.1

PZ02105
9. PHYSICAL AND CHEMICAL PROPERTIES

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 the developing fetus (based on components)

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

**Polymyxin 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

**Thimerosal**
- **Rat** Oral LD50 75 mg/kg
- **Mouse** Oral LD50 91 mg/kg
11. TOXICOLOGICAL INFORMATION

Polysorbate 80
Rat Oral LD50 25 g/kg

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

Sulfuric acid
Rat Oral LD50 2140 mg/kg

Cetyl alcohol
Rat Oral LD50 5000 mg/kg
Rabbit Dermal LD50 > 2,600 mg/kg
Mouse Oral LD50 3200 mg/kg

Propylene glycol
Rat Oral LD50 22,000 mg/kg
Mouse Oral LD50 24,900mg/kg
Rabbit Dermal LD50 20,800mg/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)

Thimerosal
Eye Irritation Rabbit Mild

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

Sulfuric acid
Eye Irritation Rabbit Severe

Propylene glycol
Skin Irritation Rabbit Mild
Eye Irritation Rabbit Mild

Repeated Dose Toxicity: (Duration, Species, Route, Dose, End Point, Target Organ)
11. TOXICOLOGICAL INFORMATION

Neomycin Sulfate

<table>
<thead>
<tr>
<th>Study Type</th>
<th>Species</th>
<th>Route</th>
<th>Dose</th>
<th>Effect(s)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Reproductive &amp; Fertility</td>
<td>Mouse</td>
<td>Oral</td>
<td>4000 mg/L</td>
<td>NOAEL</td>
</tr>
<tr>
<td>Reproductive &amp; Fertility</td>
<td>Rat</td>
<td>Oral</td>
<td>25 mg/kg/day</td>
<td>NOAEL</td>
</tr>
<tr>
<td>Reproductive &amp; Fertility</td>
<td>Rat</td>
<td>Subcutaneous</td>
<td>6 mg/kg/day</td>
<td>LOAEL</td>
</tr>
<tr>
<td>Prenatal &amp; Postnatal Development</td>
<td>Rat</td>
<td>Subcutaneous</td>
<td>28 mg/kg</td>
<td>LOAEL</td>
</tr>
</tbody>
</table>

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

<table>
<thead>
<tr>
<th>Study Type</th>
<th>Species</th>
<th>Route</th>
<th>Dose</th>
<th>Effect(s)</th>
</tr>
</thead>
<tbody>
<tr>
<td>2 Year(s)</td>
<td>Rat</td>
<td>Oral</td>
<td>25 mg/kg/day</td>
<td>NOAEL</td>
</tr>
</tbody>
</table>

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
SAFETY DATA SHEET

Material Name: PEDIOTIC Suspension Sterile (neomycin and polymyxin B sulfates and hydrocortisone otic suspension, USP)
Revision date: 12-Apr-2015

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

Persistence and Degradability: No data available
Bio-accumulative Potential:
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:
Class D, Division 2, Subdivision A
15. REGULATORY INFORMATION

Cetyl alcohol
- 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: 253-149-0

Hydrocortisone acetate
- 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 2
- EU EINECS/ELINCS List: 200-004-4

Neomycin Sulfate
- CERCLA/SARA 313 Emission reporting: Not Listed
developmental toxicity initial date 10/1/92 internal use
- California Proposition 65: Not Listed
- Inventory - United States TSCA - Sect. 8(b): Present
- Australia (AICS): Present
- EU EINECS/ELINCS List: 215-773-1

Polymyxin B sulfate
- CERCLA/SARA 313 Emission reporting: Not Listed
- California Proposition 65: Not Listed
- Australia (AICS): Present
- EU EINECS/ELINCS List: 215-774-7

Propylene glycol
- 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:
  - 1000 lb
  - 454 kg
- CERCLA/SARA - Section 302 Extremely Hazardous TPOs: 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
15. REGULATORY INFORMATION

**Australia (AICS):** Present
**Standard for the Uniform Scheduling for Drugs and Poisons:** Schedule 6
**EU EINECS/ELINCS List**

**Thimerosal**
- **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 XVII - Restrictions on Certain Dangerous Substances:** Use restricted. See item 18.
- **EU EINECS/ELINCS List** 231-639-5

**Polyolsorbate 80**
- **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** Not Listed

**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**

- Acute toxicity, oral-Cat.2; H300 - Fatal if swallowed
- Acute toxicity, oral-Cat.4; H302 - Harmful if swallowed
- Acute toxicity, dermal-Cat.1; H310 - Fatal in contact with skin
- Skin corrosion/irritation-Cat.1A; H314 - Causes severe skin burns and eye damage
- Sensitization, skin-Cat.1; H317 - May cause an allergic skin reaction
- Acute toxicity, inhalation-Cat.2; H330 - Fatal if inhaled
- 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
- Specific target organ toxicity, repeated exposure-Cat.2; H373 - May cause damage to organs through prolonged or repeated exposure
- Hazardous to the aquatic environment, acute toxicity-Cat.1; H400 - Very toxic to aquatic life
- Hazardous to the aquatic environment, acute toxicity-Cat.3; H402 - Harmful to aquatic life
- Hazardous to the aquatic environment, chronic toxicity-Cat.1; H410 - Very toxic to aquatic life with long lasting effects
- Hazardous to the aquatic environment, chronic toxicity-Cat.3; H412 - Harmful to aquatic life with long lasting effects
SAFETY DATA SHEET

Material Name: PEDIOTIC Suspension Sterile (neomycin and polymyxin B sulfates and hydrocortisone otic suspension, USP)

Revision date: 12-Apr-2015

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

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 7 - Handling and Storage. Updated Section 8 - Exposure Controls / Personal Protection.

Revision date: 12-Apr-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