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

Product Identifier

Material Name: Silvadene Cream (Silver sulfadiazine)

Trade Name: SILVADENE
Chemical Family: Sulfonamide

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

Intended Use: Pharmaceutical product used as antimicrobial

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

Contact E-Mail: pfizer-MSDS@pfizer.com

2. HAZARDS IDENTIFICATION

Classification of the Substance or Mixture

GHS - Classification: Not classified as hazardous

EU Classification:

EU Indication of danger: Not classified

Label Elements

Hazard Statements: Not classified in accordance with international standards for workplace safety.

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

Hazardous
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>Propylene glycol</td>
<td>57-55-6</td>
<td>200-338-0</td>
<td>Not Listed</td>
<td>Not Listed</td>
<td>*</td>
</tr>
<tr>
<td>White petrolatum</td>
<td>8009-03-8</td>
<td>232-373-2</td>
<td>Carc. Cat.2; R45</td>
<td>Carc. 1B (H350)</td>
<td>*</td>
</tr>
<tr>
<td>Stearyl Alcohol</td>
<td>112-92-5</td>
<td>204-017-6</td>
<td>Not Listed</td>
<td>Not Listed</td>
<td>*</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Ingredient</th>
<th>CAS Number</th>
<th>EU EINECS/ELINCS List</th>
<th>EU Classification</th>
<th>GHS Classification</th>
<th>%</th>
</tr>
</thead>
<tbody>
<tr>
<td>Methylparaben</td>
<td>99-76-3</td>
<td>202-785-7</td>
<td>Not Listed</td>
<td>Not Listed</td>
<td>*</td>
</tr>
<tr>
<td>Silver sulfadiazine</td>
<td>22199-08-2</td>
<td>Not Listed</td>
<td>Not Listed</td>
<td>Not Listed</td>
<td>1</td>
</tr>
<tr>
<td>Sorbitan monooleate</td>
<td>1338-43-8</td>
<td>215-665-4</td>
<td>Not Listed</td>
<td>Not Listed</td>
<td>*</td>
</tr>
<tr>
<td>Isopropyl myristate</td>
<td>110-27-0</td>
<td>203-751-4</td>
<td>Not Listed</td>
<td>Not Listed</td>
<td>*</td>
</tr>
<tr>
<td>PEG-40 Stearate</td>
<td>9004-99-3</td>
<td>Not Listed</td>
<td>Not Listed</td>
<td>Not Listed</td>
<td>*</td>
</tr>
<tr>
<td>Water, purified</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  
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:  
Remove contaminated clothing. Flush area with large amounts of water. Use soap. Seek medical attention.

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:  
No data available

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
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: Contain the source of the spill if it is safe to do so. 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 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
Refer to available public information for specific member state Occupational Exposure Limits.

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

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

Stearyl Alcohol
### 8. EXPOSURE CONTROLS / PERSONAL PROTECTION

<table>
<thead>
<tr>
<th>Engineering Controls:</th>
<th>Personal Protective Equipment:</th>
</tr>
</thead>
<tbody>
<tr>
<td>Engineering controls should be used as the primary means to control exposures.</td>
<td>Refer to applicable national standards and regulations in the selection and use of personal protective equipment (PPE).</td>
</tr>
</tbody>
</table>

**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>Color:</th>
<th>Odor Threshold:</th>
<th>Molecular Weight:</th>
</tr>
</thead>
<tbody>
<tr>
<td>Cream</td>
<td>White to off-white</td>
<td>No data available</td>
<td>Mixture</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th></th>
<th></th>
<th></th>
<th></th>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>No data available</td>
<td>No data available</td>
<td>No data available</td>
<td>No data available</td>
<td>No data available</td>
<td>Silver sulfadiazine</td>
</tr>
<tr>
<td>Water, purified</td>
<td>No data available</td>
<td>No data available</td>
<td>No data available</td>
<td>No data available</td>
<td>No data available</td>
</tr>
<tr>
<td>Methylparaben</td>
<td>No data available</td>
<td>No data available</td>
<td>No data available</td>
<td>No data available</td>
<td>No data available</td>
</tr>
<tr>
<td>Isopropyl myristate</td>
<td>No data available</td>
<td>No data available</td>
<td>No data available</td>
<td>No data available</td>
<td>No data available</td>
</tr>
<tr>
<td>Sorbitan monooleate</td>
<td>No data available</td>
<td>No data available</td>
<td>No data available</td>
<td>No data available</td>
<td>No data available</td>
</tr>
<tr>
<td>PEG-40 Stearate</td>
<td>No data available</td>
<td>No data available</td>
<td>No data available</td>
<td>No data available</td>
<td>No data available</td>
</tr>
<tr>
<td>Propylene glycol</td>
<td>No data available</td>
<td>No data available</td>
<td>No data available</td>
<td>No data available</td>
<td>No data available</td>
</tr>
<tr>
<td>White petrolatum</td>
<td>No data available</td>
<td>No data available</td>
<td>No data available</td>
<td>No data available</td>
<td>No data available</td>
</tr>
<tr>
<td>Stearyl Alcohol</td>
<td>No data available</td>
<td>No data available</td>
<td>No data available</td>
<td>No data available</td>
<td>No data available</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Decomposition Temperature (°C):</th>
<th>Evaporation Rate (Gram/s):</th>
<th>Vapor Pressure (kPa):</th>
<th>Vapor Density (g/ml):</th>
<th>Relative Density:</th>
<th>Viscosity:</th>
</tr>
</thead>
<tbody>
<tr>
<td>No data available</td>
<td>No data available</td>
<td>No data available</td>
<td>No data available</td>
<td>No data available</td>
<td>No data available</td>
</tr>
</tbody>
</table>
SAFETY DATA SHEET

Material Name: Silvadene Cream (Silver sulfadiazine)  
Revision date: 10-May-2015  
Version: 1.0

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

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: Contact with sulfonamides may cause dermatitis. Allergic skin reaction may occur based on effects of other sulfonamides. Individuals sensitive to this chemical or other materials in its chemical class may develop allergic reactions.
Known Clinical Effects: As in all sulfonamide therapy, the following reactions may occur including nausea, vomiting, diarrhea, inflammation of the liver and pancreas, blood disorder, drug fever, skin rash, infection of the conjunctiva and sclera, blood in the urine and crystalluria.

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

Silver sulfadiazine
- Rat Oral LD50 > 10 g/kg

Isopropyl myristate
- Mouse Oral LD50 49,700 mg/kg
- Rabbit Dermal LD50 5000 mg/kg

PEG-40 Stearate
- Rat Oral LD50 > 20,000 mg/kg

Propylene glycol
- Rat Oral LD 50 22,000 mg/kg
- Mouse Oral LD 50 24,900mg/kg
- Rabbit Dermal LD 50 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)

Propylene glycol
- Skin Irritation Rabbit Mild
11. TOXICOLOGICAL INFORMATION

**Eye Irritation**
- Rabbit - Mild

**Stearyl Alcohol**
- Eye Irritation - Rabbit - Mild
- Skin Irritation - Rabbit - Mild

**Reproduction & Development Toxicity:** (Duration, Species, Route, Dose, End Point, Effect(s))

**Silver sulfadiazine**
- Embryo / Fetal Development - Rabbit - Oral - Dose not specified - NOAEL - Not teratogenic

**Genetic Toxicity:** (Study Type, Cell Type/Organism, Result)

**Silver sulfadiazine**
- Bacterial Mutagenicity (Ames) - *Salmonella, E. coli* - Negative

**Carcinogenicity:** (Duration, Species, Route, Dose, End Point, Effect(s))

**Silver sulfadiazine**
- 24 Month(s) - Rat - Dermal - NOAEL - Not carcinogenic
- 18 Month(s) - Mouse - Dermal - 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:** Environmental properties have not been investigated.

**Toxicity:** No data available

**Persistence and Degradability:** No data available

**Bio-accumulative Potential:** No data available

**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

#### Canada - WHMIS: Classifications

**WHMIS hazard class:**

None required

#### Methylparaben

- 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: 202-785-7

#### Silver sulfadiazine

- CERCLA/SARA 313 Emission reporting: Not Listed
- California Proposition 65: Not Listed
- Standard for the Uniform Scheduling for Drugs and Poisons: Schedule 4
- EU EINECS/ELINCS List: Not Listed

#### Sorbitan monoooleate

- 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: 215-665-4

#### Isopropyl myristate

- 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: 203-751-4

#### Propylene glycol

PZ02568
**SAFETY DATA SHEET**

Material Name: Silvadene Cream (Silver sulfadiazine)  
Revision date: 10-May-2015  
Page 8 of 9  
Version: 1.0

### 15. REGULATORY INFORMATION

<table>
<thead>
<tr>
<th>Substance</th>
<th>CERCLA/SARA 313 Emission reporting</th>
<th>California Proposition 65</th>
<th>Inventory - United States TSCA - Sect. 8(b)</th>
<th>Australia (AICS)</th>
<th>EU EINECS/ELINCS List</th>
</tr>
</thead>
<tbody>
<tr>
<td>White petrolatum</td>
<td></td>
<td></td>
<td>Present</td>
<td>Present</td>
<td>200-338-0</td>
</tr>
<tr>
<td>PEG-40 Stearate</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Stearyl Alcohol</td>
<td></td>
<td></td>
<td></td>
<td>Present</td>
<td>232-373-2</td>
</tr>
<tr>
<td>Water, purified</td>
<td></td>
<td></td>
<td></td>
<td>Present</td>
<td>231-791-2</td>
</tr>
</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 R phrases and GHS Classification abbreviations mentioned in Section 3**

Carcinogenicity-Cat.1B; H350 - May cause cancer

Carcinogenic: Category 2

R45 - May cause cancer.

PZ02568
SAFETY DATA SHEET

Material Name:  Silvadene Cream (Silver sulfadiazine)
Revision date:  10-May-2015

Data Sources:  Pfizer proprietary drug development information. Publicly available toxicity information. Safety data sheets for individual ingredients.
Revision date:  10-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