SAFETY DATA SHEET

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

2. HAZARDS IDENTIFICATION

Classification of the Substance or Mixture

- GHS - Classification: Not classified as hazardous

Label Elements

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

Other Hazards

- An Occupational Exposure Value has been established for one or more of the ingredients (see Section 8).

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>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></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>GHS Classification</th>
<th>%</th>
</tr>
</thead>
<tbody>
<tr>
<td>White petrolatum</td>
<td>8009-03-8</td>
<td>232-373-2</td>
<td>Not Listed</td>
<td>*</td>
</tr>
<tr>
<td>Stearyl Alcohol</td>
<td>112-92-5</td>
<td>204-017-6</td>
<td>Not Listed</td>
<td>*</td>
</tr>
<tr>
<td>Methylparaben</td>
<td>99-76-3</td>
<td>202-785-7</td>
<td>Not Listed</td>
<td>*</td>
</tr>
<tr>
<td>Silver sulfadiazine</td>
<td>22199-08-2</td>
<td>244-834-5</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>*</td>
</tr>
<tr>
<td>Isopropyl myristate</td>
<td>110-27-0</td>
<td>203-751-4</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>*</td>
</tr>
<tr>
<td>Water, purified</td>
<td>7732-18-5</td>
<td>231-791-2</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.

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**

**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 firefighting 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

<table>
<thead>
<tr>
<th>Measures for Cleaning / Collecting:</th>
<th>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.</th>
</tr>
</thead>
<tbody>
<tr>
<td>Additional Consideration for Large Spills:</td>
<td>Non-essential personnel should be evacuated from affected area. Report emergency situations immediately. Cleanup operations should only be undertaken by trained personnel.</td>
</tr>
</tbody>
</table>

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

<table>
<thead>
<tr>
<th>Storage Conditions:</th>
<th>Store as directed by product packaging.</th>
</tr>
</thead>
<tbody>
<tr>
<td>Specific end use(s):</td>
<td>Pharmaceutical drug product</td>
</tr>
</tbody>
</table>

8. EXPOSURE CONTROLS / PERSONAL PROTECTION

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

Silver sulfadiazine
- Pfizer OEL TWA-8 Hr: 2000µg/m³
- ACGIH Threshold Limit Value (TWA): 5 mg/m³ (oil mist, mineral)
- ACGIH Threshold Limit Value (STEL): 10 mg/m³ (oil mist, mineral)

Propylene glycol
- Australia TWA: 150 ppm
- Ireland OEL - TWAs: 150 ppm
- 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
- Germany - TRGS 900 - TWAs: 20 ppm
- ACGIH Threshold Limit Value (STEL): 224 mg/m³

Exposure Controls
Engineering Controls: Engineering controls should be used as the primary means to control exposures.
8. EXPOSURE CONTROLS / PERSONAL PROTECTION

**Personal Protective Equipment:** Refer to applicable national standards and regulations in the selection and use of personal protective equipment (PPE). Contact your safety and health professional or safety equipment supplier for assistance in selecting the correct protective clothing/equipment based on an assessment of the workplace conditions, other chemicals used or present in the workplace and specific operational processes.

**Hands:** Impervious gloves (e.g. Nitrile, etc.) are recommended if skin contact with drug product is possible and for bulk processing operations. (Protective gloves must meet the standards in accordance with EN374, ASTM F1001 or international equivalent.)

**Eyes:** Wear safety glasses or goggles if eye contact is possible. (Eye protection must meet the standards in accordance with EN166, ANSI Z87.1 or international equivalent.)

**Skin:** Impervious protective clothing is recommended if skin contact with drug product is possible and for bulk processing operations. (Protective clothing must meet the standards in accordance with EN13982, ANSI 103 or international equivalent.)

**Respiratory protection:** Under normal conditions of use, 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 (e.g. particulate respirator with a half mask, P3 filter). (Respirators must meet the standards in accordance with EN140, EN143, ASTM F2704-10 or international equivalent.)

9. PHYSICAL AND CHEMICAL PROPERTIES

<table>
<thead>
<tr>
<th>Physical State:</th>
<th>Cream</th>
<th>Color:</th>
<th>White to off-white</th>
</tr>
</thead>
<tbody>
<tr>
<td>Odor:</td>
<td>No data available.</td>
<td>Odor Threshold:</td>
<td>No data available.</td>
</tr>
<tr>
<td>Molecular Formula:</td>
<td>Mixture</td>
<td>Molecular Weight:</td>
<td>Mixture</td>
</tr>
<tr>
<td>Solvent Solubility:</td>
<td>No data available</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Water Solubility:</td>
<td>No data available</td>
<td></td>
<td></td>
</tr>
<tr>
<td>pH:</td>
<td>No data available.</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Melting/Freezing Point (°C):</td>
<td>No data available</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Boiling Point (°C):</td>
<td>No data available</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Partition Coefficient: (Method, pH, Endpoint, Value)</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Silver sulfadiazine</td>
<td>No data available</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Water, purified</td>
<td>No data available</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Methylparaben</td>
<td>No data available</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Isopropyl myristate</td>
<td>No data available</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Sorbitan monooleate</td>
<td>No data available</td>
<td></td>
<td></td>
</tr>
<tr>
<td>PEG-40 Stearate</td>
<td>No data available</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Propylene glycol</td>
<td>No data available</td>
<td></td>
<td></td>
</tr>
<tr>
<td>White petrolatum</td>
<td>No data available</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Stearyl Alcohol</td>
<td>No data available</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Decomposition Temperature (°C):</td>
<td>No data available.</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Evaporation Rate (Gram/s):</td>
<td>No data available</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Vapor Pressure (kPa):</td>
<td>No data available</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
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

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 LD50 22,000 mg/kg
- Mouse Oral LD50 24,900 mg/kg
- Rabbit Dermal LD50 20,800 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.
SAFETY DATA SHEET

Material Name: Silvadene Cream (Silver sulfadiazine)  
Revision date: 07-Nov-2017  
Version: 2.0

11. TOXICOLOGICAL INFORMATION

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

Propylene glycol
Skin Irritation  Rabbit  Mild  
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

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
- Australia (AICS): Present
- Standard for the Uniform Scheduling for Drugs and Poisons: Schedule 4
- EU EINECS/ELINCS List: 244-834-5

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
15. REGULATORY INFORMATION

White petrolatum
- 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
- 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

PEG-40 Stearate
- 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

White petrolatum
- 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:
- REACH - Carcinogens Category 2: Use restricted. See item 28.
- EU EINECS/ELINCS List: 232-373-2

Stearyl 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: 204-017-6

Water, purified
- 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:
- 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

**Data Sources:** Pfizer proprietary drug development information. Publicly available toxicity information. Safety data sheets for individual ingredients.

**Reasons for Revision:** Updated Section 2 - Hazard Identification. Updated Section 3 - Composition / Information on Ingredients. Updated Section 8 - Exposure Controls / Personal Protection. Updated Section 16 - Other Information.

**Revision date:** 07-Nov-2017

**Prepared by:** Product Stewardship Hazard Communication

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