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

**Product identifier**

**Product Name** Mafenide Acetate for 5% topical solution.

**Other means of identification**

**Synonyms** Sulfamylon acetate.

**Recommended use of the chemical and restrictions on use**

**Recommended Use** Adjunctive topical antimicrobial agent to control bacterial infection when used under moist dressings over meshed autografts on excised burn wounds.

**Uses Advised Against** Not available.

**Details of the supplier of the safety data sheet**

**Supplier Address**

Par Pharmaceutical  
130 Vintage Drive  
Huntsville, AL 35811

**Emergency telephone number**

**24 Hour Emergency Phone Number** Chemtrec (US): 1-800-424-9300  
**Emergency Telephone** 1-845-425-7100

2. HAZARDS IDENTIFICATION

**Classification**

**Health Hazards**
Not classified.

**Physical Hazards**
Not classified.

**OSHA Regulatory Status**

This product is not considered hazardous by the 2012 OSHA Hazard Communication Standard/Globally Harmonized System of Classification and Labelling of Chemicals (GHS); (29 CFR 1910.1200; Revision 3).

**Label elements**

**Emergency Overview**

**Appearance** Colorless solution.  
**Physical State** Liquid.  
**Odor** Not available.

**Hazards not otherwise classified (HNOC)**

Not available.

**Other information**

Not available.
3. COMPOSITION/INFORMATION ON INGREDIENTS

This product is not considered hazardous by the 2012 OSHA Hazard Communication Standard/Globally Harmonized System of Classification and Labelling of Chemicals (GHS); (29 CFR 1910.1200; Revision 3).

Synonyms
Sulfamylon acetate.

<table>
<thead>
<tr>
<th>Chemical Name</th>
<th>CAS No.</th>
<th>Weight-%</th>
</tr>
</thead>
<tbody>
<tr>
<td>Mafenide acetate</td>
<td>13009-99-9</td>
<td>5</td>
</tr>
<tr>
<td>Purified Water, USP</td>
<td>7732-18-5</td>
<td>95</td>
</tr>
</tbody>
</table>

4. FIRST AID MEASURES

First aid measures

General Advice
Consult a physician. Show this safety data sheet to the doctor in attendance.

Eye Contact
In case of eye contact, immediately flush eyes with fresh water for at least 15 minutes while holding the eyelids open. Remove contact lenses if worn. Get medical attention if irritation persists.

Skin Contact
In case of contact, remove contaminated clothing. Immediately flush skin with copious amounts of water for at least 15 minutes. Obtain medical attention if skin reaction occurs.

Inhalation
Inhalation is not an anticipated route for liquid handling. For the intended use, see product label.

Ingestion
In case of accidental ingestion, wash out mouth with copious amounts of water. Seek medical attention immediately. Do not induce vomiting unless directed by medical personnel. Never give anything by mouth to an unconscious person.

Self-Protection of the First Aider
Do not use mouth-to-mouth methods if victim ingested or inhaled the substance; give artificial respiration with the aid of a pocket mask equipped with a one-way valve or another proper respiratory medical device.

Most important symptoms and effects, both acute and delayed

Symptoms
Adverse reactions reported include pain or burning sensation, rash and pruritus (often localized to the area covered by the wound dressing), erythema, skin maceration from prolonged wet dressings, facial edema, swelling, hives, blisters, eosinophilia, tachypnea, hyperventilation and decrease in pCO2, metabolic acidosis, and increase in serum chloride.

Indication of any immediate medical attention and special treatment needed

Note to Physicians
Treat symptomatically.

5. FIRE-FIGHTING MEASURES

Suitable extinguishing media
Use extinguishing measures that are appropriate to local circumstances and the surrounding environment.

Unsuitable Extinguishing Media
None known.

Specific hazards arising from the chemical
Not available.
Hazardous Combustion Products Not available.

Explosion data
Sensitivity to Mechanical Impact None known.
Sensitivity to Static Discharge None known.

Protective equipment and precautions for firefighters
As in any fire, wear self-contained breathing apparatus pressure-demand, MSHA/NIOSH (approved or equivalent) and full protective gear.

6. ACCIDENTAL RELEASE MEASURES

Personal precautions, protective equipment and emergency procedures

Personal Precautions Avoid excessive contact. Avoid contact with eyes.

Environmental precautions
Environmental Precautions See Section 12 for additional ecological information.

Methods and material for containment and cleaning up

Methods for Containment Collect and place in a suitable container. Sorbents may be used.

Methods for Cleaning Up Dispose of in accordance with local, state, and national regulations.

7. HANDLING AND STORAGE

Precautions for safe handling

Advice on Safe Handling Handle in accordance with good industrial hygiene and safety practice.

Conditions for safe storage, including any incompatibilities

Storage Conditions Store prepared solution at a temperature of 20° to 25°C (68° to 77°F) with excursions permitted to 15° to 30°C (59° to 86°F).

Incompatible Materials Not available.

8. EXPOSURE CONTROLS/PERSONAL PROTECTION

Control parameters

Exposure Guidelines This product, as supplied, does not contain any hazardous materials with Occupational Exposure Limits (OEL) established by the region-specific regulatory bodies.

Appropriate engineering controls

Engineering Controls The health hazard risks of handling this material are dependent on factors, such as physical form and quantity. Site-specific risk assessments should be conducted to determine the appropriate exposure control measures. Good general ventilation should be used. Ventilation rates should be matched to conditions. If applicable, use process enclosures, local exhaust ventilation, or other engineering controls to maintain airborne levels below recommended exposure limits. If exposure limits have not been established, maintain airborne levels as low as reasonably achievable.

Individual protection measures, such as personal protective equipment
Eye/Face Protection
None required for consumer use. In laboratory, medical or industrial settings, safety glasses with side shields are highly recommended. The use of goggles or full face protection may be required depending on the industrial exposure setting. Contact a health and safety professional for specific information.

Skin and Body Protection
None required for consumer use. In laboratory, medical or industrial settings, gloves and lab coats are recommended. The use of additional personal protective equipment such as shoe coverings, gauntlets, and hood or head coverings may be necessary. Contact a health and safety professional for specific information.

Respiratory Protection
None required for consumer use. Respirators may be required for certain laboratory and manufacturing tasks if engineering controls do not maintain airborne concentrations below recommended exposure limits (where applicable) or to an acceptable level (where the exposure limits have not been established). Workplace risk assessments should be completed before specifying and implementing respirator usage. All respirators must conform to specifications for efficiency and performance indicated by OSHA Standard 29 CFR 1910.134.

General Hygiene Considerations
Always observe good personal hygiene measures, such as washing after handling the material and before eating, drinking, and/or smoking. Routinely wash work clothing and protective equipment.

9. PHYSICAL AND CHEMICAL PROPERTIES

Information on basic physical and chemical properties

<table>
<thead>
<tr>
<th>Property</th>
<th>Values</th>
<th>Remarks</th>
</tr>
</thead>
<tbody>
<tr>
<td>Physical State</td>
<td>Liquid.</td>
<td></td>
</tr>
<tr>
<td>Appearance</td>
<td>Colorless solution.</td>
<td></td>
</tr>
<tr>
<td>Color</td>
<td>Colorless.</td>
<td>Odor</td>
</tr>
<tr>
<td>Odor Threshold</td>
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<td></td>
</tr>
<tr>
<td>pH</td>
<td>Not available.</td>
<td></td>
</tr>
<tr>
<td>Melting Point/Freezing Point</td>
<td>Not available.</td>
<td></td>
</tr>
<tr>
<td>Boiling Point / Boiling Range</td>
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<td></td>
</tr>
<tr>
<td>Flash Point</td>
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<td></td>
</tr>
<tr>
<td>Evaporation Rate</td>
<td>Not available.</td>
<td></td>
</tr>
<tr>
<td>Flammability (Solid, Gas)</td>
<td>Not available.</td>
<td></td>
</tr>
<tr>
<td>Flammability Limit in Air</td>
<td>Not available.</td>
<td></td>
</tr>
<tr>
<td>Upper Flammability Limit:</td>
<td>Not available.</td>
<td></td>
</tr>
<tr>
<td>Lower Flammability Limit:</td>
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<td></td>
</tr>
<tr>
<td>Vapor Pressure</td>
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<td></td>
</tr>
<tr>
<td>Vapor Density</td>
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<td></td>
</tr>
<tr>
<td>Specific Gravity</td>
<td>Not available.</td>
<td></td>
</tr>
<tr>
<td>Water Solubility</td>
<td>Freely soluble.</td>
<td></td>
</tr>
<tr>
<td>Solubility in Other Solvents</td>
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<td></td>
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<tr>
<td>Partition Coefficient</td>
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<td></td>
</tr>
<tr>
<td>Autoignition Temperature</td>
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<td></td>
</tr>
<tr>
<td>Decomposition Temperature</td>
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<td></td>
</tr>
<tr>
<td>Kinematic Viscosity</td>
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<td></td>
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<tr>
<td>Dynamic Viscosity</td>
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<td></td>
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<tr>
<td>Explosive Properties</td>
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<tr>
<td>Oxidizing Properties</td>
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<td></td>
</tr>
</tbody>
</table>

Other Information
- Softening Point: Not available.
- Molecular Weight: Not available.
- VOC Content (%): Not available.
- Density: Not available.
- Bulk Density: Not available.

10. STABILITY AND REACTIVITY
Reactivity
Stable at normal conditions.

Chemical stability
Stable at ambient temperatures and atmospheric pressures under recommended storage and handling conditions.

Possibility of hazardous reactions
None under normal processing.

Hazardous Polymerization
Hazardous polymerization does not occur.

Conditions to avoid
Not available.

Incompatible materials
Not available.

Hazardous decomposition products
Not available.

11. TOXICOLOGICAL INFORMATION

Acute Toxicity

<table>
<thead>
<tr>
<th>Chemical Name</th>
<th>Oral LD50</th>
<th>Dermal LD50</th>
<th>Inhalation LC50</th>
<th>Intravenous LD50</th>
</tr>
</thead>
<tbody>
<tr>
<td>Mafenide acetate</td>
<td>= 9212 mg/kg (Rat)</td>
<td>-</td>
<td>-</td>
<td>= 1730 mg/kg (Rat)</td>
</tr>
<tr>
<td>13009-99-9</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

Information on toxicological effects

Symptoms
Adverse reactions reported include pain or burning sensation, rash and pruritus (often localized to the area covered by the wound dressing), erythema, skin maceration from prolonged wet dressings, facial edema, swelling, hives, blisters, eosinophilia, tachypnea, hyperventilation, and decrease in pCO2, metabolic acidosis, and increase in serum chloride.

Delayed and immediate effects as well as chronic effects from short and long-term exposure

Skin Corrosion/Irritation
No data available.

Serious Eye Damage/Eye Irritation
No data available.

Irritation
No data available.

Corrosivity
No data available.

Sensitization
No data available.

Germ Cell Mutagenicity
Mafenide acetate did not induce mutations in L5178Y mouse lymphoma cells at the TK locus.

Carcinogenicity
No long-term animal studies have been performed to evaluate the carcinogenic potential of Mafenide acetate.

Reproductive Toxicity
Animal studies have not been performed to evaluate the potential effects of Mafenide acetate on fertility. There is no adequate data regarding the potential reproductive toxicity of Mafenide acetate in a non-rodent species, nor are there adequate and well-controlled studies in pregnant women. Mafenide acetate should be used during pregnancy only if the potential benefit justifies the potential risk to the fetus.
U.S. FDA Pregnancy Category: C

Developmental Toxicity
No data available.

Teratogenicity
A teratology study performed in rats using oral doses of up to 600 mg/kg/day revealed no evidence of harm to the fetus due to Mafenide acetate.

STOT - Single Exposure
Not classified.

STOT - Repeated Exposure
Not classified.

Aspiration Hazard
No data available.

12. ECOLOGICAL INFORMATION

Ecotoxicity
Not available.

Persistence and degradability
Not available.

Bioaccumulation
Not available.

Other adverse effects
Not available.

13. DISPOSAL CONSIDERATIONS

Waste treatment methods

Disposal of Wastes
Disposal should be in accordance with applicable regional, national and local laws and regulations.

Contaminated Packaging
Disposal should be in accordance with applicable regional, national and local laws and regulations.

US EPA Waste Number
Not available.

California Hazardous Waste Codes
Not available.

14. TRANSPORT INFORMATION

DOT
Not regulated.

IATA
Not regulated.

15. REGULATORY INFORMATION

US Federal Regulations

SARA 313
Section 313 of Title III of the Superfund Amendments and Reauthorization Act of 1986 (SARA). This product does not contain any chemicals subject to the reporting requirements of the Act and Title 40 of the Code of Federal Regulations, Part 372.

SARA 311/312 Hazard Categories
Acute Health Hazard
No
Chronic Health Hazard
No
CWA (Clean Water Act)
This product does not contain any substances regulated as pollutants pursuant to the Clean Water Act (40 CFR 122.21 and 40 CFR 122.42).

CERCLA
This material, as supplied, does not contain any substances regulated as hazardous substances under the Comprehensive Environmental Response Compensation and Liability Act (CERCLA) (40 CFR 302) or the Superfund Amendments and Reauthorization Act (SARA) (40 CFR 355). There may be specific reporting requirements at the local, regional, or state level pertaining to releases of this material.

US State Regulations

California Proposition 65
No component is on the Proposition 65 list.

U.S. State Right-to-Know Regulations
This product does not contain any substances regulated by state right-to-know regulations.

U.S. EPA Label Information
EPA Pesticide Registration Number  Not applicable.

16. OTHER INFORMATION

Prepared By  IES Engineers.
Revision Date  Not applicable.
Revision Note  Not applicable.

Disclaimer
This SDS is intended to provide a brief summary of our knowledge and guidance regarding the use of this material. It is not meant to be an all-inclusive document on worldwide hazard communications regulations. This information is offered in good faith. Each user of this material needs to evaluate the conditions of use and design the appropriate mechanisms to prevent employee exposures, property damage or release to the environment.

End of Safety Data Sheet