1. **Identification**

   **Product Identifier:** Sulfacetamide Sodium Ophthalmic Solution USP, 10%

   **Synonyms:** N-Sulfanilylacetamide Monosodium Salt Monohydrate; Acetamide, N-[(4-aminophenyl)sulfonyl]-, Monosodium Salt, Monohydrate; Sulfacetamide Na.

   **National Drug Code (NDC):** 17478-221-12

   **Recommended Use:** Pharmaceutical.

   **Company:** Akorn, Inc.
   1925 West Field Court, Suite 300
   Lake Forest, Illinois 60045

   **Contact Telephone:** 1-800-932-5676

   **E mail:** customer.service@akorn.com

   **Emergency Phone Number:** CHEMTREC 1-800-424-9300 (U.S. and Canada)

2. **Hazard(s) Identification**

   **Physical Hazards:** Not classifiable.

   **Health Hazards:**
   - Respiratory sensitization Category 1
   - Skin sensitization Category 1

   **Symbol(s):**

   **Signal Word:** Danger.

   **Hazard Statement(s):**
   - H317 May cause an allergic skin reaction.
   - H334 May cause allergy or asthma symptoms or breathing difficulties if inhaled.

   **Precautionary Statement(s):**
   - 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.
   - P302 IF ON SKIN: Wash with plenty of water.
SDS: Sulfacetamide Sodium Ophthalmic Solution
USP, 10%

P333 If skin irritation or rash occurs: Get medical advice/attention.
P313

P362 Take off contaminated clothing and wash it before reuse.
P364

P304 IF INHALED: Remove person to fresh air and keep comfortable for breathing.
P340

P304 IF INHALED: Call a POISON CENTER/doctor/physician.
P311

P321 Specific treatment (see Section 4).
P501 Dispose of contents/container in accordance with local/provincial/federal regulations.

Hazards Not Otherwise Classified: Not classifiable.
Supplementary Information: None.

3. Composition/Information on Ingredients

<table>
<thead>
<tr>
<th>Chemical Name</th>
<th>CAS Number</th>
<th>Synonyms</th>
<th>Chemical Formula</th>
<th>Molecular Weight</th>
<th>Percentage</th>
</tr>
</thead>
<tbody>
<tr>
<td>Acetamide, N-[(4-aminophenyl)sulfo-nyl]-, monosodium salt, monohydrate</td>
<td>6209-17-2</td>
<td>Sulfacetamide Sodium; N-Sulfanilylacetamide Monosodium Salt Monohydrate; Sulfacetamide Na</td>
<td>C$_9$H$_9$N$_2$NaO$_3$S$\cdot$H$_2$O</td>
<td>254.24</td>
<td>10%</td>
</tr>
</tbody>
</table>

*The formula also contains Methylparaben, 0.05% and Propylparaben, 0.01% as preservatives, Sodium Thiosulfate, 0.31%; Hydroxypropyl Methyl Cellulose, 0.5% and Monobasic Sodium Phosphate as buffer.

4. First Aid Measures

Ingestion: If a person vomits place them in the recovery position so that vomit will not reenter the mouth and throat. Rinse mouth with water. If swallowed, seek medical advice immediately and show the container or label. Treat symptomatically and supportively. Ensure that medical personnel are aware of the material(s) involved and take precautions to protect themselves.

Eye Contact: Remove from source of exposure. Flush with copious amounts of water for at least 15 minutes. If irritation persists or signs of toxicity occur, seek medical attention. Provide symptomatic/supportive care as necessary. Ensure that medical personnel are aware of the...
Skin Contact: Remove from source of exposure. Remove and isolate contaminated clothing and shoes. Flush with copious amounts of water for at least 20 minutes. Use soap. If irritation persists or signs of toxicity occur, seek medical attention. Provide symptomatic/supportive care as necessary. Ensure that medical personnel are aware of the material(s) involved and are aware of precautions to protect themselves.

Inhalation: Remove from source of exposure. Move individual(s) to fresh air. Give artificial respiration if individual(s) are not breathing and call emergency medical service. If signs of toxicity occur, seek medical attention. Provide symptomatic/supportive care as necessary. Ensure that medical personnel are aware of the material(s) involved and are aware of precautions to protect themselves.

Protection of First-Aiders: Use personal protective equipment (see section 8).

Signs and Symptoms: Nausea; vomiting; diarrhea; loss of appetite; dizziness; headache; skin rash; fever; itching; increased sensitivity of skin to sunlight; sore throat; unusual bleeding or bruising; difficulty swallowing; vision problems; yellow eyes or skin; lower back pain; difficult or painful urination; blood in urine; joint pain; muscle pain; redness, peeling or loosening of skin; fatigue. Fatalities have occurred, although rarely, due to severe reactions to sulfonamides.

Medical Conditions Aggravated by Exposure: Persons sensitive to sulfonamides or to furosemide, thiazide diuretics, sulfonylureas, or carbonic anhydrase inhibitors, or any other components of the preparation; allergies; asthma; HIV or AIDS; lupus erythematosus; blood disorders; impaired kidney or liver function; porphyria.

Notes to Physician: Treat supportively and symptomatically.

5. Firefighting Measures

Suitable Extinguishing Media: Use extinguishing media for type of surrounding fire.

Unsuitable Extinguishing Media: Not determined.

Specific Hazards Arising from the Chemical:

Hazardous Combustion Products: These products include carbon oxides, nitrogen oxides, sulfur oxides sodium oxides and toxic fumes.

Other Specific Hazards: Closed containers may explode from the heat of fire.
6. **Accidental Release Measures**

**Personal Precautions:** Keep unnecessary personnel away. Do not touch damaged containers or spilled material unless wearing appropriate personal protective equipment and clothing.

**Personal Protective Equipment:** For personal protection see section 8.

**Methods for Cleaning Up:** Dike ahead of liquid spills for later disposal. Absorb with inert material. Recover product and place in an appropriate container for disposal in accordance with local, state and federal regulations.

**Environmental Precautions:** Contain material and prevent release to basements, confined spaces, waterways or soil.

**Reference to Other Sections:** Refer to Sections 8, 12 and 13 for further information.

7. **Handling and Storage**

**Precautions for Safe Handling:** Handle in accordance with product label and/or product insert information. Handle in accordance with good industrial hygiene and safety practices.

**Conditions for Safe Storage, Including Any Incompatibilities:** Store according to label and/or product insert information. Store away from oxidizers, acids, and bases.

**Specific End Use:** Pharmaceuticals.

8. **Exposure Controls/Personal Protection**

**Occupational Exposure Guidelines:**

<table>
<thead>
<tr>
<th>Common or Chemical Name</th>
<th>Employee Exposure Limits</th>
</tr>
</thead>
<tbody>
<tr>
<td>Sulfacetamide Sodium</td>
<td>No data available.</td>
</tr>
</tbody>
</table>

**Engineering Controls:** Engineering controls should be used as the primary means to control exposures.

**Respiratory Protection:** Where respirators are deemed necessary to reduce or control occupational exposures, use NIOSH-approved respiratory protection and have an effective respirator program in place (applicable U.S. regulation OSHA 29 CFR 1910.134).
Eyes Protection: Safety glasses with side shields are recommended. Face shields or goggles may be required if splash potential exists or if corrosive materials are present. Approved eye protection (e.g., bearing the ANSI Z87 or CSA stamp) is preferred. Maintain eyewash facilities in the work area.

Hand Protection: Chemically compatible gloves. For handling solutions, ensure that the glove material is protective against the solvent being used. Use handling practices that minimize direct hand contact. Employees who are sensitive to natural rubber (latex) should use nitrile or other synthetic non-latex gloves. Use of powdered latex gloves should be avoided due to the risk of latex allergy.

Skin Protection: Protective laboratory coat, apron, or disposable garment.

9. Physical and Chemical Properties

Physical State/Color: Liquid/Colorless to slightly yellow.
Odor: No data available.
Odor Threshold: No data available.
\( pH \): No data available.
Melting Point: No data available.
Freezing Point: No data available.
Boiling Point: No data available.
Flash Point: No data available.
Evaporation Rate: No data available.
Flammability (solid, gas): No data available.
Flammability Limit - Lower: No data available.
Flammability Limit - Upper: No data available.
Vapor Pressure: No data available.
Vapor Density: No data available.
Relative Density: No data available.
Solubility(ies): Miscible in water.
Partition Coefficient (n-octanol/water): No data available.
Auto-Ignition Temperature: No data available.
Decomposition Temperature: No data available.
Viscosity: No data available.

10. Stability and Reactivity

Reactivity: No data available.
Chemical Stability: Stable under recommended storage conditions.
Possibility of Hazardous Reactions: No data available.
Conditions to Avoid (e.g., static discharge, shock, or vibration): No data available.
Incompatible Materials: Oxidizers, acids, bases.
Hazardous Decomposition Products: No data available.
11. **Toxicological Information**

**Information on the Likely Routes of Exposure:**

**Inhalation:** May be harmful if inhaled. May cause respiratory tract irritation. May cause irritation and hypersensitivity in some individuals.

**Ingestion:** May be harmful if swallowed. May cause irritation and hypersensitivity (anaphylactic) in some individuals. Hypersensitivity reactions include headache, rash, hives (urticaria), photosensitivity and central nervous system effects.

**Skin Contact:** May be harmful if absorbed through skin. May cause skin irritation. May cause irritation and hypersensitivity in some individuals. Hypersensitivity reactions include headache, rash, hives (urticaria), photosensitivity and central nervous system effects.

**Eye Contact:** May cause eye irritation. While the irritation may be transient, occasionally the treatment must be discontinued. Can cause hypersensitivity (anaphylactic) in some individuals.

**Symptoms Related to the Physical, Chemical and Toxicological Characteristics:** See Section 4. To the best of our knowledge, the chemical, physical and toxicological properties have not been thoroughly investigated.

**Delayed and Immediate Effects of Exposure:** No data available.

**Acute Toxicity:**

<table>
<thead>
<tr>
<th>Compound</th>
<th>Species</th>
<th>Route</th>
<th>Test Type</th>
<th>Dose</th>
</tr>
</thead>
<tbody>
<tr>
<td>Sulfacetamide Sodium</td>
<td>Mouse</td>
<td>Oral</td>
<td>LD₅₀</td>
<td>16,500 mg/kg</td>
</tr>
<tr>
<td>Sulfacetamide Sodium</td>
<td>Rabbit</td>
<td>Oral</td>
<td>LD₅₀</td>
<td>5,000 mg/kg</td>
</tr>
</tbody>
</table>

**Acute Toxicity – Dermal:** No data available.

**Acute Toxicity – Inhalation:** No data available.

**Corrosivity:** No data available.

**Dermal Irritation:** No data available.

**Eye Irritation:** No data available.

**Sensitization:** Prolonged or repeated exposure (via ingestion, inhalation or skin contact) may cause allergic skin and/or respiratory reactions in certain sensitive individuals. Hypersensitivity reactions include headache, rash, hives (urticaria), photosensitivity and central nervous system effects.

**Toxicokinetics/Metabolism:** No data available.

**Target Organ Effects:** No data available.

**Reproductive Effects:** No data available.

**Carcinogenicity:** No data available.
12. **Ecological Information**

Ecotoxicity

Aquatic: No data available.
Terrestrial: No data available.
Persistence and Degradability: No data available.
Bioaccumulative Potential: No data available.
Mobility in Soil: No data available.
Mobility in Environment: No data available.
Other Adverse Effects: No data available.

13. **Disposal Considerations**

Dispose of all waste in accordance with Federal, State and Local regulations.

14. **Transport Information**

UN Number: Not applicable.
UN Proper Shipping Name: Not applicable.
Transport Hazard Class(es): Not applicable.
Packing Group: Not applicable.

Department of Transportation: Not regulated as a hazardous material.

International Air Transport Association (IATA): Not regulated as a dangerous good.

International Maritime Dangerous Good (IMDG): Not regulated as a dangerous good.

15. **Regulatory Information**

**US Federal Regulations:**

Toxic Substance Control Act (TSCA): This product is a drug regulated by the Food and Drug Administration (FDA), and is not regulated by TSCA.

CERCLA Hazardous Substance and Reportable Quantity: Not listed.

SARA 313: Not listed.
SARA 302: Not listed.

State Regulations

Massachusetts: Not listed.
New Jersey: Sulfacetamide sodium.
Pennsylvania: Sulfacetamide sodium.
California Proposition 65: Not listed.

16. Other Information

Not made with natural latex rubber.

NFPA Rating:  
| Health:   | 0 |
| Flammability: | 0 |
| Reactivity: | 0 |

HMIS Classification:  
| Health:   | 0 |
| Flammability: | 0 |
| Physical Hazard: | 0 |

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Revision Number: 1

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