

SAFETY DATA SHEETS

This SDS packet was issued with item:

078859724

The safety data sheets (SDS) in this packet apply to the individual products listed below. Please refer to invoice for specific item number(s).

078549906

The safety data sheets (SDS) in this packet apply to one or more components included in the items listed below. Items listed below may require one or more SDS. Please refer to invoice for specific item number(s).

078459762



Manufacturer: Akorn Incorporated
150 S. Wyckles Road
Decatur, IL 62522
Telephone: 1-800-932-5676
Email: customer.service@akorn.com

Section 1 - IDENTIFICATION

TRADE NAME: Sodium Chloride Ophthalmic Solution, USP, 50mg/mL
Description: Sodium Chloride Ophthalmic Solution is a hypertonicity agent applied topically to the eye for temporary relief of corneal edema. It is a clear, colorless aqueous solution dispensed in a plastic bottle inside a cardboard box.

Table with 5 columns: Composition, CAS#, TLV (mg/m³), PEL (mg/m³), %Content. Rows include Sodium Chloride, Methylparaben, Propylparaben, Boric Acid, Hypromellose, Propylene Glycol, Sodium Borate, and Purified Water.

Inactive ingredients: Sodium Hydroxide and/or Hydrochloric acid for pH adjustment
Common name of active ingredient: Sodium Chloride
Legal Category: Over-the-Counter Pharmaceutical preparation

Section 2 - HAZARDOUS INGREDIENTS

POTENTIAL HEALTH HAZARDS

Carcinogenicity: (NTP) No (IARC) No (OSHA) No
Eye: May cause irritation, temporary burning sensation and hypersensitivity
Skin: May cause irritation and hypersensitivity in some individuals
Ingestion: May cause irritation and hypersensitivity in some individuals
Inhalation: May cause irritation and hypersensitivity in some individuals
Chronic Effects: May cause irritation and hypersensitivity
Target Organs: Eyes and digestive tract
Medical Conditions Aggravated by Long Term Exposure: Hypersensitivity to any of the components of the product



Section 3 - PHYSICAL AND CHEMICAL CHARACTERISTICS

Appearance:	Clear, colorless solution	Boiling Point:	Not Established
Specific Gravity:	1.04 g/mL	Melting Point:	Not Applicable
Vapor Pressure (mmHg at 20°C):	Not Established		
Vapor Density (g/m³):	Not Established	Latex Free:	Yes
Evaporation Rate:	Not Established	Viscosity:	7.0 to 15.0 cps
Solubility in Water:	Miscible	pH:	6.0 to 8.0

Section 4 - FIRST AID MEASURES

Eyes: Hold eyelids open and flush with a steady, gentle stream of water for 20 minutes. Consult an ophthalmologist or physician.

Skin: Remove contaminated clothing and clean before reuse. Wash exposed skin with plenty of soap and water. Seek medical attention if irritation develops.

Ingestion: Wash-out mouth and give plenty of water. Do not give anything to an unconscious person. Contact a physician or the Poison Control Center immediately.

Inhalation: Move individual to fresh air. Get medical attention if breathing difficulty occurs. If not breathing, provide artificial respiration assistance (mouth-to-mouth) and call a physician immediately.

Section 5 - FIRE AND EXPLOSION HAZARD DATA

Flash point: Not Established

Auto-ignition Temperature: Not Established

Extinguishing Media: Use water spray, carbon dioxide, dry chemical, foam, or halon

Unusual Fire and Explosion Hazards: No unusual fire or explosion hazards are expected

Fire Fighting Instructions: Wear self-contained breathing apparatus and protective clothing

Section 6 - STABILITY AND REACTIVITY DATA

Stability: Stable at normal temperatures and pressures

Conditions to avoid: Extreme heat or cold

Incompatibility: Strong acids, bases, alkali metals, alkali hydrides, silver preparations

Hazardous Decomposition: May emit toxic fumes when heated to decomposition

Hazardous Polymerization: Should not occur



Section 7 - PROTECTION INFORMATION

Ventilation and Engineering Controls: Follow standard medical product handling procedures.

Respiratory Protection: Not normally required for routine, medical administration

Eye Protection: Approved eye protection to safeguard against potential eye contact, irritation or injury is recommended.

Hand Protection: Use latex, nitrile, or rubber gloves. Wash hands before and after using.

Body Protection: No special body protection required for routine, medical administration

Contaminated Equipment: Wash contaminated clothing separately. Wash equipment with soap and water. Release rinse water into an approved wastewater system and according to Federal, State and Local regulations.

Section 8 - HANDLING AND STORAGE

Handling: Avoid contact with product. No special protective equipment or procedures are required in the clinical or home environment.

Storage: Store in original containers with the cap tightly closed at a controlled room temperature of 20° to 25°C (68° to 77° F).

KEEP THIS AND ALL DRUGS OUT OF THE REACH OF CHILDREN

Section 9 - ACCIDENTAL RELEASE MEASURES

Large/Small Spills: Use personal protective equipment. Use absorbent material to solidify the spill. Shovel or scoop up solidified waste. Dispose of material according to Federal, State and Local regulations.

Section 10 - TOXICOLOGY INFORMATION

Summary of Risk: Concentrations and toxicological effects are substantially reduced in the product. For more detailed information see MSDS on each chemical.

Section 11 - ECOLOGICAL INFORMATION

Chemical Fate Information: Product administered to patients presents a negligible impact on the environment.



Section 12 - REGULATORY INFORMATION

DOT Designations: Not classified as hazardous by DOT regulations
EPA Designations: RCRA Hazardous Waste (40 CFR 261.33) Not Listed
FDA Designations: OTC
NDC 17478-623-12
OSHA Designations: (29 CFR 1910.1000, Table Z) Not Listed
SARA Title III: Not listed under Section 313 of Toxic Release Reporting.
CALIFORNIA PROPOSITION 65: Not Listed

Section 13 - DISPOSAL INFORMATION

Dispose of material according to Federal, State, and Local regulations. The method typically used is incineration.

Section 14 - TRANSPORTATION INFORMATION

This material is not hazardous as defined by 49 CFR 172.101, U. S. Department of Transportation.

Section 15 - OTHER INFORMATION

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SAFETY DATA SHEET

1. Identification

Product Identifier: Sodium Chloride Ophthalmic Solution, USP 5%

Synonyms: Salt; Sea Salt

National Drug Code (NDC): 17478-623-12

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: Not classifiable.

Symbol(s): None.

Signal Word: None.

Hazard Statement(s): None.

Precautionary Statement(s): None.

Hazards Not Otherwise Classified: None.

Supplementary Information: While this material is not classifiable as hazardous under the OSHA standard, this SDS contains valuable information critical to safe handling and proper use of the product. This SDS should be retained and available for employees and other users of this product.

3. Composition/Information on Ingredients

Chemical Name	CAS Number	Synonyms	Chemical Formula	Molecular Weight	Percentage
Sodium Chloride	7647-14-5	Salt, Sea Salt	NaCl	58.44	5%

*The formula also contains Methylparaben, 0.23 mg (0.023%); Propylparaben, 0.1 mg (0.01%); Boric Acid, Hypromellose 2906, Propylene Glycol, Sodium Borate, Sodium Hydroxide and/or Hydrochloric Acid to adjust pH between 6.0 – 8.0, and Purified Water.

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 material(s) involved and are aware of precautions to protect themselves.
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:	Not determined.
Medical Conditions Aggravated by Exposure:	Hypersensitivity to any of the components of the product.
Notes to Physician:	Treat supportively and symptomatically.

5. Firefighting Measures

Suitable Extinguishing Media:	Use water spray, carbon dioxide, dry chemical, foam, or halon.
Unsuitable Extinguishing Media:	Not determined.

Specific Hazards Arising from the Chemical:

Hazardous Combustion Products: Not determined.

Other Specific Hazards: No unusual fire or explosion hazards are expected.

**Special Protective Equipment/
Precautions for Firefighters:** Wear self-contained breathing apparatus and full and protective gear.

6. Accidental Release Measures

Personal Precautions: Use personal protective equipment recommended in Section 8 of this document and isolate the hazard area.

Personal Protective Equipment: For personal protection see section 8.

Methods for Cleaning Up: Use personal protective equipment. Use absorbent material to solidify the spill. Shovel or scoop up solidified waste. Dispose of material according to Federal, State and Local regulations.

Environmental Precautions: Product administered to patients presents a negligible impact on the environment.

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

7. Handling and Storage

Precautions for Safe Handling: Avoid contact with product. 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 in original containers with the cap tightly closed at a controlled room temperature of 20°C – 25°C (68°F – 77°F). Store according to label and/or product insert information.

Specific End Use: Pharmaceuticals.

8. Exposure Controls/Personal Protection

Occupational Exposure Guidelines:

Common or Chemical Name	Employee Exposure Limits
Sodium Chloride	Not established.

Engineering Controls: Engineering controls should be used as the primary means to control exposures. Follow standard medical product handling procedures.

Respiratory Protection:	Not required for the normal use of this product. 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:	Use 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. Wash hands before and after use.
Skin Protection:	Not required for the normal use of this product. Wear protective laboratory coat, apron, or disposable garment when working with large quantities.
Contaminated Equipment:	Wash contaminated clothing separately. Wash equipment with soap and water. Release rinse water into an approved wastewater system and according to Federal, State and Local regulations.

9. Physical and Chemical Properties

Physical State/Color:	Clear, colorless solution.
Odor:	No data available.
Odor Threshold:	No data available.
pH:	6.0 – 8.0.
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:	7.0 to 15.0 cps.
Specific Gravity:	1.04 g/mL.

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):	Extreme heat or cold.
Incompatible Materials:	Strong acids, bases, alkali metals, alkali hydrides, silver preparations.
Hazardous Decomposition Products:	May emit toxic fumes when heated to decomposition.
Hazardous Polymerization:	Should not occur.

11. Toxicological Information**Information on the Likely Routes of Exposure:**

Inhalation:	May cause irritation and hypersensitivity in some individuals.
Ingestion:	May cause irritation and hypersensitivity in some individuals. Ingestion of large quantities can induce gastric disturbances.
Skin Contact:	May cause irritation and hypersensitivity in some individuals.
Eye Contact:	May cause irritation, temporary burning sensation and hypersensitivity.

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 – Oral:

No data available.

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:

No data available.

Toxicokinetics/Metabolism:

No data available.

Target Organ Effects:

Eyes and digestive tract.

Reproductive Effects:

No data available.

Carcinogenicity:	No data available.
National Toxicology Program (NTP):	Not considered to be a carcinogen.
International Agency for Research on Cancer (IARC):	Not considered to be a carcinogen.
Occupational Safety and Health Administration (OSHA):	Not considered to be a carcinogen.
Mutagenicity:	No data available.
Aspiration Hazard:	No data available.
Chronic Effects:	May cause irritation and hypersensitivity. Prolonged application can induce changes in vision.

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):	Not listed.
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SDS: Sodium Chloride Ophthalmic Solution, USP 5%

CERCLA Hazardous Substance and Reportable Quantity: Not listed.

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

State Regulations

California Proposition 65: Not listed.

16. Other Information

Not made with natural latex.

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