

SAFETY DATA SHEET

1. **Identification**

Product Identifier: Sodium Chloride Ophthalmic Ointment, USP 5%

Synonyms: Salt; Sea Salt

National Drug Code (NDC): 17478-622-35

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: Not classifiable.

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 Modified Lanolin, Mineral Oil, White Petrolatum 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 material in the product.
Notes to Physician:	Treat supportively and symptomatically.

5. Firefighting Measures

Suitable Extinguishing Media:	Water spray, dry chemical, carbon dioxide or foam as appropriate for surrounding fire and materials.
Unsuitable Extinguishing Media:	Not determined.

Specific Hazards Arising from the Chemical:

Hazardous Combustion Products: Toxic fumes.

Other Specific Hazards: Not determined.

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

Firefighting Instructions: As with all fires, evacuate personnel to safe area. Use water spray to keep fire-exposed containers cool. Do not spray water into burning material.

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 appropriate protective equipment. Carefully collect waste and place in a suitable, properly labeled container for disposal. Clean the area with a suitable detergent and water.

Environmental Precautions: No data available.

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 the product. Wash thoroughly after handling. Contaminated clothing should be laundered before reuse. 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 at controlled room temperature, 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.
Mineral Oil	TLV: 5 mg/m ³ (mist) PEL: 5 mg/m ³

SDS: Sodium Chloride Ophthalmic Ointment, USP 5%

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:	Wear 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:	Wear protective laboratory coat, apron, or disposable garment when working with large quantities.

9. Physical and Chemical Properties

Physical State/Color:	Colorless to light yellowish translucent ointment.
Odor:	Characteristic odor.
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):	Immiscible 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): Avoid exposure to extreme heat or cold.

Incompatible Materials: The product is incompatible with water, strong acids, bases, alkali metals, alkali hydrides and silver preparations.

Hazardous Decomposition Products: When heated to decomposition, material emits toxic fumes.

Hazardous Polymerization: Will not occur.

11. Toxicological Information

Information on the Likely Routes of Exposure:

Inhalation: May cause irritation and hyper-sensitivity in some individual.

Ingestion: May cause irritation and hyper-sensitivity in some individual. Ingestion of large quantities can induce gastric imbalance.

Skin Contact: Causes irritation, and hyper-sensitivity in some individual.

Eye Contact: May cause irritation, burning sensation and hyper-sensitivity in some individual.

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:

Compound	Species	Route	Type	Dose
Sodium Chloride	Man	Oral	LD _{Lo}	1,000 mg/kg
Sodium Chloride	Rat	Oral	LD ₅₀	3,000 mg/kg
Sodium Chloride	Mouse	Oral	LD ₅₀	4,000 mg/kg
Sodium Chloride	Rabbit	Dermal	LD ₅₀	>10,000 mg/kg
Sodium Chloride	Rat	Dust	LC ₅₀	>42,000 mg/m ³ 1 hour

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:	No data available.
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.

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 hazardous material.
International Air Transport Association (IATA):	Not regulated as dangerous good.
International Maritime Dangerous Good (IMDG):	Not regulated as dangerous good.

15. **Regulatory Information**

US Federal Regulations:

Toxic Substance Control Act (TSCA): Not listed.

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 rubber latex.

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