MATERIAL SAFETY DATA SHEET

SECTION 1: PRODUCT AND COMPANY IDENTIFICATION

Product Name: Sodium Chloride Inhalation Solution, USP 0.9%
Generic Name: Sodium Chloride Inhalation Solution, 0.9%
NDC No: 0487-9301-02, 0487-9301-03, 0487-9301-33
Legal Category: For respiratory therapy, not for parenteral administration.
Drug Composition: Inhalation via nebulization, dilution of compatible drugs for nebulization, and tracheal lavage and irrigation.
Product Use: Sterile, non-pyrogenic, preservative-free single-use vials for respiratory therapy. No bacteriostatic agent or other preservative added.

Nephron Pharmaceuticals Corporation
4121 South West 34th Street
Orlando, FL 32811-6458
Information: (800) 443-4313, (407) 246-1389 (M-F) 8am-5pm EST

SECTION 2: COMPOSIION/ INFORMATION ON INGREDIENTS

MATERIAL:	EXPOSURE LIMITS		
	TVL (µg/m^3)	**PEL (mg/m^3)**	**% Content**
Active Ingredients:			
Sodium Chloride	not established	not established	0.9%
Excipients:			
Water for Injection	not established	not established	Balance

SECTION 3: HAZARDS IDENTIFICATION

EMERGENCY OVERVIEW

LDPE vial, clear colorless and odorless solution. Generally is not hazardous during normal handling. However, good laboratory practices should always be used.

POTENTIAL HEALTH HAZARDS

Carcinogenicity: **(NTP)** No **(IARC)** No **(OSHA)** No
Eye: No known significant effects or critical hazards.
Skin: No known significant effects or critical hazards.
Ingestion: No known significant effects or critical hazards.
Inhalation: No known significant effects or critical hazards.
Chronic Effects: No known significant effects or critical hazards.
Target Organs: No known significant effects or critical hazards.
Medical Conditions Aggravated by long Exposure: No known significant effects or critical hazards.

SECTION 4: FIRST AID MEASURES

Not hazardous in normal handling, however good laboratory practices should always be used. Avoid long term exposure to skin or by inhalation.

Eye: Remove contact lenses if necessary. Flush eyes with large amounts of running water for at least 15 minutes. Contact a physician.

Skin: Removed contaminated clothing. Flush affected area with copious amounts of soap and water for at least 15 minutes. Contact a physician, if irritation or rash develops.

Ingestion: Flush out mouth with water drink several glasses of water. Vomiting may occur, but it is not necessary to induce.

Inhalation: Remove person to fresh air, and if breathing stops use artificial respiration. Contact a physician.

Note to Physicians: Additional details are available on the package insert or in the Physicians Desk Reference.

SECTION 5: FIRE/EXPLOSION HAZARDS & FIRE-FIGHTING MEASURES

Flammable Properties:	Flash point: NE	Method: NE
Flammable Limits:	Lower flammable limit: N/A	Upper flammable limit: N/A
Hazardous Products:	None	
Extinguishing Media:	Dry chemical, carbon dioxide, water spray or fog, and foam on surrounding materials.	
Fire fighting Instructions:	As with all fires, evacuate personnel to safe area. Firefighters should ware self-contained breathing apparatus and protective clothing. Use water spray to keep fire-exposed containers cool.	

SECTION 6: SPILL AND LEAK PROCEDURES

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

SECTION 7: HANDLING AND STORAGE

This material should be handled and stored per label and other instructions to ensure product integrity.

Handling: No special protective equipment or procedures are required in the clinical or home environment. Wash thoroughly after handling

Storage: Store product in original container (3mL pink clear LDPE vials) at room temperature. Avoid excessive heat. **KEEP THIS AND ALL DRUGS OUT OF THE REACH OF CHILDREN.**

SECTION 8: EXPOSURE CONTROLS / PERSONAL PROTECTION

Engineering Controls: In manufacturing plant, provide adequate ventilation for the raw material handling and compounding process which will maintain the dust and vapor levels below the TLV, STEL, and PEL values for the ingredients. Ventilation fans should be explosion proof. Use adequate personal protective equipment e.g. NIOSH-approved respirators, goggles or safety glasses, gloves and protective clothing. Ensure training in the handling of chemical material and use current Material Safety Data Sheets.

Eye Protection: (29 CFR 1910.133) Recommend goggles or chemical safety glasses.

Skin Protection: Latex rubber gloves recommended and protective clothing.

Respiratory Protection: (29 CFR 1910.134) NIOSH approved respirator, with organic vapor, acid gas and HEPA filter recommended for handling raw material.
Warning: Do not use air purifying respirators in oxygen depleted environments. No respiratory protection is required in the clinical or home environment.

Other: None.

Ventilation: Recommended.

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

SECTION 9: CHEMICAL/ PHYSICAL PROPERTIES

Appearance & Odor: Clear, colorless aqueous solution and odorless.

Boiling Point:	not established	**Evaporation Rate**:	not established
Specific Gravity:	1.0048	**Physical State**:	Liquid
Viscosity:	not established	**Water Solubility**:	Soluble
pH:	approximately 4 – 7.0		

SECTION 10 STABILITY AND REACTIVITY

Chemical Stability: Stable.

Conditions to avoid: Strong acids and strong bases.

Incompatibility: None.

Hazardous Decomposition Products: None.

Hazardous Polymerization: Should not occur.

SECTION 11 TOXICOLOGICAL INFORMATION

Summary of Risks: Toxicological information refers to raw materials product. Concentrations and toxicological effects are substantially reduced in the product. For more detailed information see MSDS on chemical material.

CAS# 7647-14-5, Sodium Chloride:
Sodium Chloride raw material may have the following potential health effects:

- Eyes: may cause eye irritation.
- Ingestion: large amounts may cause gastrointestinal irritation, nausea, vomiting and rigidity or convulsions. Continued exposure can produce coma, dehydration, and internal organ congestion.
- Inhalation: May cause respiratory tract irritation.
- Chronic: No information found.

SECTION 12 ECOLOGICAL INFORMATION

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

SECTION 13 WASTE DISPOSAL

Dispose of material according to Federal, State, and Local regulations:	The method typically used is incineration.
EPA Designation:	RCRA Hazardous Waste: Not Listed
SARA Title III:	Not Listed

SECTION 14 TRANSPORTATION INFORMATION

Transportation Data: Not classified as hazardous by DOT regulations.

SECTION 15 REGULATORY INFORMATION

DOT Designations:	Not classified as hazardous by DOT regulations.
EPA Designations:	RCRA Hazardous Waste (40 CFR 261.33) Not Listed
FDA Designations:	For respiratory therapy, not for parenteral administration.
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 16 OTHER INFORMATION

None

The information contained herein is furnished without warranty of any kind. The above information is believed to be correct but does not purport to be al-inclusive and should be used only as a guide. Users should make independent determinations of the suitability and completeness of information from all sources to assure proper use and disposal of these materials and the safety and health of employees and customers.

NE - Not Established
< - Less Than
> - Greater Than

SEE CURRENT PACKAGE INSERT FOR FURTHER INFORMATION