

**SAFETY DATA SHEET**

Sodium Chloride Inhalation/Irrigation USP 0.9%

SDS DATE: 15 Sept 2016

**SECTION 1: PRODUCT AND COMPANY IDENTIFICATION**

**Product Name:** Sodium Chloride Inhalation Solution, USP 0.9%; Sodium Chloride Irrigation Solution, USP 0.9%

**Generic Names:** Table salt, salt solution, saline solution

**Legal Category:** For respiratory therapy, for irrigation of respiratory devices, 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.

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**SECTION 2: COMPOSITION/INFORMATION ON INGREDIENTS**

MATERIALS	CAS No.	EXPOSURE LIMITS		
		TVL (µg/m <sup>3</sup> )	PEL (mg/m <sup>3</sup> )	% Content
<b>Active Ingredients:</b>				
Sodium Chloride	7647-14-5	not established	not established	0.9%
<b>Excipients:</b>				
Water for Injection	7732-18-5	not established	not established	Balance

**Toxicological Data on Ingredients:**

Sodium chloride:

ORAL (LD50): Acute: 3000 mg/kg [Rat.], 4000 mg/kg [Mouse].

DERMAL (LD50): Acute: >10000 mg/kg [Rabbit]. DUST (LC50): Acute: >42000 mg/m 1 hours [Rat].

**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.

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**SECTION 4: FIRST AID MEASURES**

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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.

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**SECTION 5: FIRE-FIGHTING MEASURES**

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**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 wear self-contained

breathing apparatus and protective clothing. Use water spray to keep fire-exposed containers cool.

**Special Remarks on Explosion Hazards:**

Electrolysis of sodium chloride in presence of nitrogenous compounds to produce chlorine may lead to formation of explosive nitrogen trichloride. Potentially explosive reaction with dichloromaleic anhydride + urea. (Sodium chloride)

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**SECTION 6: ACCIDENTAL RELEASE MEASURES**

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**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.

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**SECTION 7: HANDLING AND STORAGE**

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This material should be handled and stored per label and other instructions for use 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 (pink clear LDPE vials) at room temperature. Avoid excessive heat.

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**SECTION 8: EXPOSURE CONTROLS/PERSONAL PROTECTION**

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**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.

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**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.

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**SECTION 9: PHYSICAL AND CHEMICAL PROPERTIES**

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**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

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**SECTION 9: PHYSICAL AND CHEMICAL PROPERTIES (con't)**

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**SECTION 10: STABILITY AND REACTIVITY**

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**Stability:** The product is stable.**Instability Temperature:** Not available.**Conditions of Instability:** Incompatible materials**Incompatibility with various substances:** Not available.**Corrosivity:** Not considered to be corrosive for metals and glass.**Special Remarks on Reactivity:**

Hygroscopic. Reacts with most nonnoble metals such as iron or steel, building materials (such as cement) Sodium chloride is

rapidly attacked by bromine trifluoride. Violent reaction with lithium. (Sodium chloride)

**Special Remarks on Corrosivity:** Not available.**Polymerization:** Will not occur.

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**SECTION 11: TOXICOLOGICAL INFORMATION**

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**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. exposure can produce coma, dehydration, and internal organ congestion.
- Inhalation: May cause respiratory tract irritation.
- Chronic: No information found.

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**SECTION 12: ECOLOGICAL INFORMATION**

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

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**SECTION 13: DISPOSAL CONSIDERATIONS**

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**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

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**SECTION 14: TRANSPORT INFORMATION**

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**DOT Classification:** Not a DOT controlled material (United States).**Identification:** Not applicable.**Special Provisions for Transport:** Not applicable.

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**SECTION 15: REGULATORY INFORMATION**

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**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**Other Regulations:** Not available.**Other Classifications:****WHMIS (Canada):** Not controlled under WHMIS (Canada).**DSCL (EEC):**

This product is not classified according to the EU regulations. Not applicable.

**HMIS (U.S.A.):****Health Hazard:** 1**Fire Hazard:** 0**Reactivity:** 0**Personal Protection:** a**National Fire Protection Association (U.S.A.):****Health:** 1**Flammability:** 0**Reactivity:** 0**Specific hazard:** N/A**Protective Equipment:**

Lab coat.

Safety glasses.

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**SECTION 16: OTHER INFORMATION**

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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 all-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.