nephron pharmaceuticals corporation

Revision date: 02-01-2017

SAFETY DATA SHEET

SECTION 1: IDENTIFICATION

Nephron Pharmaceuticals Corporation
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(800) 443-4313 (24 hour contact)

PRODUCT NAME:	Sodium Chloride Inhalation Solution, USP 0.9%
COMMON NAME:	Sodium Chloride Inhalation Solution, 0.9%
CHEMICAL NAME:	Sodium Chloride
INN:	Sodium Chloride
SUBSTANCE CLASS:	
INTENDED USE:	Pharmaceutical Use for Inhalation

SECTION 2: HAZARD(S) IDENTIFICATION

Carcinogenicity: (NTP) No (IARC) No (OSHA) No
Eye: No known significant effects or critical hazards, may cause irritation.
Skin: No known significant effects or critical hazards, may cause irritation.
Ingestion: No known significant effects or critical hazards.
Inhalation: No known significant effects or critical hazards, may cause respiratory irritation.
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.
(See Section 11, “Toxicological Information”)

SECTION 3: COMPOSITON / INFORMATION ON INGREDIENTS

NAME:	Sodium Chloride
CAS#:	7647-14-5
% w/v	0.9%
GW Limits	Not Established
Other Limits:	Not Established
Name:	Water for Injection
CAS#	7732-18-5
% w/v	99.1%

SECTION 4: FIRST AID MEASURES

If In Eyes:	Flush with large amounts of cool water for at least 15 minutes. Obtain medical attention.
If On Skin:	Wash affected areas with soap and water after removing contaminated clothing. Obtain medical attention if contamination is significant and/or a skin reaction is evident.
If Inhaled:	If not breathing, give artificial respiration or CPR. If breathing is difficult, give oxygen. Obtain medical

attention and remove to fresh air.

If Ingested: Flush mouth out with water, drink several glasses of water. Never give anything by mouth if unconscious or having convulsions. Obtain medical attention.

SECTION 5: FIRE FIGHTING MEASURES

FLASH POINT/TEST METHOD:	Unknown.
LEL/UEL:	Unknown.
SPECIAL PROPERTIES RELATED TO FIRE HAZARD:	None.
STORAGE OR HANDLING CONDITIONS TO BE AVOIDED:	Extreme Heat.
EXTINGUISHING MEDIA:	Water Spray, Multipurpose Dry Chemical, carbon dioxide, and foam on surrounding materials.
FIRE-FIGHTING PROCEDURES:	Wear full protective clothing and use self-contained breathing apparatus (SCBA). Use water spray to keep fire exposed containers cool.

SECTION 6: ACCIDENTAL RELEASE MEASURES

SPILL RESPONSE PROCEDURES (Liquid, Solid, Gas/Vapor):

Protective equipment may be necessary for spills, (See Section 8, “Exposure Controls / Personal Protection” for guidance).

Use personal protective equipment. Contain the spill to prevent drainage into sewers,drains or streams. Use absorbent materials 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

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

STORAGE: Store between 59° and 86° F. Discard if solution becomes discolored.

SECTION 8: EXPOSURE CONTROLS / PERSONAL PROTECTION

ENGINEERING CONTROLS: In manufacturing plant, provide adequate ventilation for the raw material handling and compounding process which will keep 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 Safety Data Sheets.

PERSONAL PROTECTION:

Respiratory:	Not required under normal conditions of therapeutic use. See Section 5 “ Fire-Fighting Measures” for respiratory protection in the event of a fire.
Eye:	Not required for recommended dosage and administration. Workers should wear goggles or adequate eye protection if splash hazard exists.
Clothing:	Adequate protective clothing should be worn to prevent occupational skin contact.
Gloves:	When routine handling or spill cleanup may result in skin contact, impermeable (e.g., latex) gloves should be worn.

Work Practices: Special care should be taken to ensure that contaminated clothing, equipment and work surfaces are properly cleaned after use. Wash hands and other areas of skin contact thoroughly with soap and water. Release rinse water into an approved wastewater system according to Federal,State and Local regulations.
handling this material. Contaminated clothing should be cleaned or disposed of.

SECTION 9: PHYSICAL AND CHEMICAL PROPERTIES

APPEARANCE AND ODOR:	Clear, colorless aqueous solution; odorless.
PHYSICAL STATE:	Liquid.
MELTING POINT:	Not determined.
BOILING POINT:	Not determined.
SOLUBILITY/MISCIBILITY (%w/v):	Not determined. Water soluble

SECTION 10: STABILITY AND REACTIVITY

CHEMICAL STABILITY:	Stable.
CONDITIONS TO AVOID:	Strong acids and strong bases.
INCOMPATIBILITY WITH OTHER MATERIALS:	None known
HAZARDOUS DECOMPOSITION PRODUCTS:	None

SECTION 11: TOXICOLOGICAL INFORMATION

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

ENVIRONMENTAL FATE:	Not known
ENVIRONMENTAL EFFECTS:	Not known
ENVIRONMENTAL TEST RESULTS:	N/A

SECTION 13: DISPOSAL CONSIDERATIONS

ROUTINE	Unused product should be disposed of at an approved facility in accordance with federal, state and local regulations.
ACCIDENTAL RELEASE:	Clean up spills immediately, observing precautions in Section 8 - “Exposure Controls / Personal Protection”. Remove or decontaminate all residues in accordance with federal, state and local regulations.

SECTION 14: TRANSPORT INFORMATION

Component 1 or Formulation 1: Sodium Chloride Inhalation Solution 0.9%

US Department of Transportation
Proper Shipping Name: Pharmaceutical Medical Device

IATA/ICAO
Proper Shipping Name: Not Regulated

IMDG
Proper Shipping Name: Not Regulated

RQ: None Marine Pollutant: No

SECTION 15: REGULATORY INFORMATION

EC PACKAGING AND LABELING FOR SUPPLY: Not applicable.

OTHER LEGISLATION: Not regulated.

SECTION 16: OTHER INFORMATION

REVISION DATE 06-19-2014

REVISION DATE: 07-22-2004 SUPERSEDES: 01-23-2003
REVISION DATE: 03-10-2014 SUPERSEDES: 07-22-2004

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