Luitpold Pharmaceuticals

AMERICAN REGENT, INC.

MATERIAL SAFETY DATA SHEET

Section 1: PRODUCT AND COMPANY INFORMATION

Luitpold Pharmaceuticals, Inc.
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PRODUCT NAME: **Bacteriostatic Sodium Chloride Injection USP**

PRODUCT CODE (NDC): **0.9%: 0517-0648-25**

Section 2: HAZARDS IDENTIFICATION

EMERGENCY OVERVIEW

Appearance / Odor	Clear, colorless solution with an odor of Benzyl Alcohol.
WARNING!	
Skin, eye and respiratory irritant	Causes irritation of the eyes, skin and respiratory tract.
Toxicity to fish/aquatic organisms	Product is not known to be toxic to fish.
Potential Health Effects: See Section 11 for more information	
Likely Routes of Exposure	Eye contact, skin contact, inhalation and ingestion.
Eye	Causes irritation of the eye.
Skin	Causes irritation of the skin.
Inhalation	Can cause mild irritation of the respiratory tract.
Ingestion	Ingestion of large amounts may cause irritation of the gastrointestinal tract.
Skin Absorption	Can be absorbed through the skin.
Medical Conditions Aggravated by Exposure	Hypersensitivity to the product.
Target Organs	Eyes, skin, and respiratory tract.

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Section 2: HAZARDS IDENTIFICATION (continued)	
Potential Environmental Effects: See Section 12 for more information	This product is not known to be toxic to fish.

This product does not contain any carcinogens or potential carcinogens as listed by OSHA, IARC or NTP.

This material is considered hazardous by the OSHA Hazard Communication Standard (29 CFR 1910.1200).

Section 3: COMPOSITION AND INFORMATION ON INGREDIENTS		
Component	CAS Number	Percentage (%) by Weight
Sodium Chloride	7647-14-5	0.9 percent
Benzyl Alcohol	100-51-6	0.9 percent
Hydrochloric Acid	7647-01-0	used for pH adjustment
Sodium Hydroxide	1310-73-2	used for pH adjustment
Water for Injection	7732-18-5	98.2 percent

Section 4: FIRST AID MEASURES	
Eye Contact	Can cause irritation. Flush for 15 minutes with copious quantities of water. Seek medical attention.
Skin Contact	Can cause irritation. Remove contaminated clothing. Flush area with copious quantities of water for 15 minutes. Seek medical attention.
Inhalation	May cause mild irritation of respiratory tract. Remove person to fresh air. Remove contaminated clothing. Seek medical attention.
Ingestion	May cause irritation. Flush mouth out with water. Do not induce vomiting unless directed by emergency medical personnel. Seek medical attention.
Injection	See prescribing information.
Note to Physicians	Inhalation of product may cause mild irritation. Ingestion of product may result in nausea, vomiting and diarrhea. Skin rash may be observed following direct contact. See prescribing information. This product contains Benzyl Alcohol that is used as a preservative. Benzyl Alcohol has been associated with "Gasping Syndrome" in neonates.

Section 5: FIRE FIGHTING MEASURES	
Suitable Extinguishing Media	Water spray, foam, dry chemical or Carbon Dioxide (CO_2). **Caution:** CO_2 will displace air in confined spaces and may cause an oxygen deficient atmosphere.
Unsuitable Extinguishing Media	None.
Hazardous Combustion Products	When heated, sodium chloride thermally decomposes to form acrid and toxic vapors.

Protection for Firefighters: Sodium Chloride solution thermally decomposes to form toxic vapors. Vapors may be irritating to eyes and skin and toxic to respiratory tract. Firefighters are to wear self-contained breathing apparatus (SCBA) and full turn out gear (Bunker gear). Cool containers with water spray and use caution when approaching.

Section 6: ACCIDENTAL RELEASE MEASURES	
Personnel Precautions	Use personal protective equipment recommended in Section 8 of this document and isolate the hazard area.
Environmental Precautions	This material is not known to be a water pollutant. However, it is recommended to prevent spilled or leaking material from entering waterways. Minimize the use of water to prevent environmental contamination.
Methods of Containment	Absorb material with suitable materials such as clay absorbent or absorbent pads for aqueous solutions.
Methods of Clean Up	Vacuum spillage with a vacuum cleaner having a high efficiency particulate (HEPA) filter, or absorb liquid with clay absorbent, absorbent pads or paper towels. Use plastic tools to scoop up, sweep or containerize spilled material. Use plastic drums to contain spilled materials. Wipe working surfaces to dryness, and then wash with soap and water.
Other Information	A spill of this material does not need to be reported to the National Response Center.

Section 7: HANDLING AND STORAGE

Handling:

As a general rule, when handling pharmaceutical products, avoid all contact and inhalation of mists or vapors associated with the product. Avoid contact with skin, eyes or clothing.

Use in a well ventilated area. Wash thoroughly after handling.

Storage:

Store in a well ventilated area. Keep containers closed when not in use. Product residue may remain in empty containers. Observe all label precautions until container is cleaned, discarded or destroyed.

Section 8: EXPOSURE CONTROLS / PERSONAL PROTECTION			
Exposure Guidelines	OSHA PEL	ACGIH TLV	OTHER
Sodium Chloride	Not Listed	Not Listed	
Benzyl Alcohol	Not Listed	Not Listed	
Sodium Hydroxide	2 milligrams / cubic meter - 8 hour TWA	2 milligrams / cubic meter - Ceiling	
Hydrochloric Acid	5 parts per million - Ceiling	2 parts per million - Ceiling	
Water for Injection	Not Listed	Not Listed	

Personal Protective Equipment	Description
Ventilation	Local exhaust or general ventilation is recommended.
Respiratory Protection	Under normal conditions, respiratory protection is not required. When required, use a NIOSH approved air purifying respirator with P-100 cartridges.
Eye Protection	Wear ANSI approved chemical splash goggles or safety glasses.
Skin Protection	When administering this product to patients, wear nitrile or latex gloves. Wear Tyvek™ SL or equivalent coveralls, PVC booties and nitrile gloves for clean up activities.

Section 9: PHYSICAL AND CHEMICAL PROPERTIES	
Color	Clear, colorless solution
Odor / Odor Threshold	Odor of Benzyl Alcohol
Physical State	Liquid
pH	4.5 to 7.0
Freezing Point	Approximately 32 degrees Fahrenheit
Boiling Point	Approximately 214 degrees Fahrenheit
Flash Point	Not applicable
Evaporation Rate	Not applicable
Flammability	Nonflammable, noncombustible
Upper Flammable Limit	Not applicable
Lower Flammable Limit	Not applicable
Vapor Pressure	Not applicable
Vapor Density	Not applicable
Specific Gravity	Approximately 1.0
Solubility (water)	Freely soluble in water
Partition Coefficient	Not applicable
Auto-ignition Temperature	Not applicable
Percent Volatile	0.9 percent (Benzyl Alcohol used as a preservative)
Volatile Organic Compounds (%)	0.9 percent (Benzyl Alcohol used as a preservative)

Section 10: STABILITY AND REACTIVITY	
Stability	Stable.
Conditions to Avoid	Avoid heat, light and humidity. Keep away from flames, thermally decomposes to form toxic vapors.
Incompatible Materials	Reactive with metals, lithium and concrete. Electrolysis of Sodium Chloride in the presence of nitrogenous compounds can lead to the formation of explosive Nitrogen Trichloride. Sodium Chloride in the presence of Dichloromaleic Anhydride and urea results in an explosive reaction.
Hazardous Decomposition Products	Acrid and toxic vapors may be released by thermal decomposition.
Possibility of Hazardous Reactions	Hazardous polymerization will not occur.

Section 11: TOXICOLOGY INFORMATION		
Acute Effects		
Oral (LD_{50})	LD_{50}:	4000 mg/kg oral - mouse
	LD_{50}:	3000 mg/kg oral - rat
Intravenous (LD_{50})	LD_{50}:	645 mg/kg intravenous - mouse
Intraperitoneal (LD_{50})	LD_{50}:	2602 mg/kg intraperitoneal - mouse
Dermal (LD_{50})	No data available	
Subcutaneous (LD_{50})	LD_{50}:	3000 mg/kg subcutaneous - mouse
Inhalation	Respiratory irritation is possible.	
Eye Irritation	Eye irritation is possible.	
Skin Irritation	Skin irritation is possible.	
Sensitization	Sensitization is possible.	
Chronic Effects		
Organ Systems	Potential impact to eyes, mucous membranes (pulmonary and gastrointestinal tract), cardiovascular system and mucous membranes.	
Carcinogenicity	No evidence that Sodium Chloride is classified as a carcinogen.	
Mutagenicity	Sodium Chloride is considered mutagenic for mammalian somatic cells, bacteria and yeast. Benzyl Alcohol used as a preservative is considered mutagenic for bacteria and yeast.	

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Section 11: TOXICOLOGY INFORMATION (continued)	
Reproductive Effects	No adequate and well controlled studies in humans.
Developmental Effects	No adequate and well controlled studies in humans. Classified as Pregnancy Category C.

Section 12: ECOLOGICAL INFORMATION	
Ecotoxicity	No data available.
Persistence / Degradability	Short term products of biodegradation are not likely. Long term degradation products may arise that may be more hazardous than product.
Bioaccumulation / Accumulation	No appreciable bioaccumulation is expected in the environment.
Mobility in Environment	Appreciable volatilization is not expected into the air.

Section 13: DISPOSAL CONDITIONS	
Disposal	Do not mix with other substances. Dispose of in accordance with Federal, state and local regulations. Contact your state or local government environmental and / or sanitation department for guidance on disposal.

Section 14: TRANSPORTATION INFORMATION	
Regulatory Agency	**Shipping Description**
US DOT (ground)	Not considered a DOT regulated material - Non hazardous for shipment.
Canadian TDG (ground)	See US DOT.
IATA (air)	Not considered a DOT regulated material - Non hazardous for shipment.

Section 15: REGULATORY INFORMATION	
STATE RIGHT TO KNOW	Refer to the applicable state to determine applicability.
California Safe Drinking Water & Toxic Enforcement Act (Prop 65)	This material is not known to contain any chemicals currently listed as carcinogens or reproductive toxins under California Proposition 65.
RTECS Number	VZ4725000
TSCA	8b Inventory - Yes - Sodium Chloride
NFPA Rating	Health - 1, Fire - 0, Reactivity - 0
WHMIS (Canada)	Not Controlled.

Section 16: OTHER INFORMATION

Bacteriostatic Sodium Chloride Injection, USP is used for preparing and diluting sterile solutions.

Refer to Luitpold / American Regent's prescribing information for further information at http://www.americanregent.com/product_index.asp

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The information above is believed to be accurate and represents the best information currently available to American Regent. The information has not been verified and we cannot, therefore, guarantee its accuracy or completeness or adequacy for all persons and situations or as to the results to be obtained by use of the information. It is the user's obligation to evaluate and use this product safely and to comply with all applicable laws and regulations. WE MAKE NO WARRANTY OF MERCHANTABILITY, FITNESS FOR A PARTICULAR USE OR ANY OTHER WARRANTY, EXPRESSED OR IMPLIED, WITH RESPECT TO SUCH INFORMATION AND WE ASSUME NO LIABILITY RESULTING FROM ITS USE. Users should make their own investigations to determine the suitability of the information for their own particular purposes. The user assumes all risks from use of the product. In no event shall Luitpold, its subsidiaries, its affiliates and its contractors be liable for any claims, losses or damages of any third party, or for lost profits, or for any special, indirect, incidental, consequential or exemplary damages however arising, even if Luitpold has been advised of the possibility of such damages.