



Luitpold Pharmaceuticals

AMERICAN REGENT, INC.

MATERIAL SAFETY DATA SHEET**Section 1: PRODUCT AND COMPANY INFORMATION**

Luitpold Pharmaceuticals, Inc.
P.O. Box 9001
Shirley, New York 11967
(800) 645-1706
(631) 924-4000

Chemtrec 24/7 Emergency Telephone Number
Domestic North America: (800) 424-9300
International: +1 703-527-3887

PRODUCT NAME: Sodium Bicarbonate Injection, USP

PRODUCT CODE (NDC): 44.6 mEq/50mL: 0517-0639-25
50 mEq/50mL: 0517-1550-25

Section 2: HAZARDS IDENTIFICATION**EMERGENCY OVERVIEW**

Appearance / Odor

Clear, colorless, odorless solution.

WARNING!

Skin, eye, respiratory and
gastrointestinal irritant

Causes irritation of the eyes, skin, gastrointestinal and
respiratory tract.

Toxicity to fish/aquatic organisms

Product is known to be toxic to fish;
96 hour LC₅₀ for Bluegill - >5000 mg/L

*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

Causes irritation of the respiratory tract.

Ingestion

Causes irritation of the gastrointestinal tract.

Skin Absorption

Not absorbed through the skin.

Medical Conditions Aggravated by
Exposure

Personnel with electrolyte imbalance, impaired respiratory,
cardiovascular, liver and kidney functions.

Target Organs

Eyes, skin, respiratory tract, cardiovascular, central nervous
system, kidneys and liver.

continued on next page

Section 2: HAZARDS IDENTIFICATION (continued)	
<i>Potential Environmental Effects:</i> <i>See Section 12 for more information</i>	This product is known to be toxic to fish; 96 hour LC ₅₀ for Bluegill - >5000 mg/L
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 Bicarbonate	144-55-8	7.5 to 8.4 percent
Water for Injection	7732-18-5	91.6 to 92.5 percent

Section 4: FIRST AID MEASURES	
Eye Contact	Causes eye irritation. Flush for 15 minutes with copious quantities of water. Seek medical attention.
Skin Contact	Causes skin irritation. Remove contaminated clothing. Flush area with copious quantities of water for 15 minutes. Seek medical attention.
Inhalation	Causes irritation of respiratory tract. Remove person to fresh air. Remove contaminated clothing. Seek medical attention.
Ingestion	Causes irritation of gastrointestinal tract. Flush mouth out with water. Seek medical attention.
Injection	See prescribing information.
Note to Physicians	Inadvertent extravasation of intravenously administered hypertonic solutions may cause chemical cellulitis, tissue necrosis and sloughing at the site of infiltration. See prescribing information.

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 Bicarbonate solution thermally decomposes to form toxic vapors. (i.e. Carbon Monoxide, Carbon Dioxide and Metal Oxides).
Protection for Firefighters: Sodium Bicarbonate 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 known to be a water pollutant. Do not let spilled or leaking material enter waterways.
Methods of Containment	Absorb material with suitable materials such as clay absorbent or absorbent pads for water 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 needs to be reported to the National Response Center. 800-424-8802.

Section 7: HANDLING AND STORAGEHandling:

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 and clothing. Do not mix with other drugs.

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 Bicarbonate	Not listed	Not listed	
Water for Injection	Not listed	Not listed	
Personal Protective Equipment	Description		
Ventilation	Local exhaust or general ventilation is recommended.		
Respiratory Protection	Under normal conditions of product use, respiratory protection is not required. When required, use a NIOSH approved air purifying respirator with P-100 / organic vapor 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. Use 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	Odorless
Physical State	Liquid
pH	7.0 to 8.5
Freezing Point	Highest known value is 32 degrees Fahrenheit (Water for Injection)
Boiling Point	Lowest known value is 212 degrees Fahrenheit (Water for Injection)
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 1.1
Solubility (water)	Freely soluble in water
Partition Coefficient	Not applicable
Auto-ignition Temperature	Not applicable
Percent Volatile	0 percent
Volatile Organic Compounds (%)	0 percent

Section 10: STABILITY AND REACTIVITY

Stability	Stable.
Conditions to Avoid	Do not mix with other drugs. Avoid heat, light and humidity. Keep away from flames, thermally decomposes to form toxic vapors.
Incompatible Materials	Reactive with strong oxidizers, reactive metals and acids.
Hazardous Decomposition Products	Carbon Monoxide, Carbon Dioxide and Metal Oxides 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 : 3360 mg/kg oral - mouse LD ₅₀ : 4220 mg/kg oral - rat
Intravenous (LD ₅₀)	No data available.
Intraperitoneal (LD ₅₀)	No data available.
Subcutaneous (LD ₅₀)	No data available.
Dermal (LD ₅₀)	No data available.
Inhalation	Respiratory irritation is possible.
Eye Irritation	Eye irritation is possible.
Skin Irritation	Skin irritation is possible.
Sensitization	No data available on product's sensitivity.
Chronic Effects	
Organ Systems	May be toxic to cardiovascular system, kidneys and liver.
Carcinogenicity	Not considered carcinogenic. No adequate and well controlled studies in humans concerning the carcinogenic effects of Sodium Bicarbonate have been conducted.
Mutagenicity	Sodium Bicarbonate was found to be mutagenic in laboratory animals. No adequate and well controlled studies in humans concerning the mutagenic effects of Sodium Bicarbonate have been conducted.
Reproductive Effects	Not considered a reproductive toxin. No adequate and well controlled studies in humans concerning the reproductive effects of Sodium Bicarbonate have been conducted.
Developmental Effects	Sodium Bicarbonate was found to be teratogenic in laboratory animals. No adequate and well controlled studies in humans concerning the teratogenic effects of Sodium Bicarbonate have been conducted. Classified as Pregnancy Category C.

Section 12: ECOLOGICAL INFORMATION	
Ecotoxicity	Sodium Bicarbonate - 96 hour LC ₅₀ for Bluegill - >5000 mg/L
Persistence / Degradability	Short term products of biodegradation are not likely. No data available on the long term degradation of the product.
Bioaccumulation / Accumulation	No applicable bioaccumulation is expected in the environment.
Mobility in Environment	Appreciable volatilization is not expected into the air. Freely mobile in the aquatic environment.

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	Sodium Bicarbonate - VZ0950000
TSCA	8b Inventory - Sodium Bicarbonate
NFPA Rating	Health - 2, Fire - 1, Reactivity - 0
WHMIS (Canada)	Not controlled.

Section 16: OTHER INFORMATION

Sodium Bicarbonate Injection, USP is indicated in the treatment of metabolic acidosis which may occur in severe renal disease, uncontrolled diabetes, circulatory insufficiency due to shock or severe dehydration, extracorporeal circulation of blood, cardiac arrest and severe primary lactic acidosis. Sodium bicarbonate is further indicated in the treatment of certain drug intoxications, including barbiturates (where dissociation of the barbiturate-protein complex is desired), in poisoning by salicylates or methyl alcohol and in hemolytic reactions requiring alkalinization of the urine to diminish nephrotoxicity of blood pigments. Sodium bicarbonate also is indicated in severe diarrhea which is often accompanied by a significant loss of bicarbonate.

Treatment of metabolic acidosis should, if possible, be superimposed on measures designed to control the basic cause of the acidosis — e.g., insulin in uncomplicated diabetes, blood volume restoration in shock. But since an appreciable time interval may elapse before all of the ancillary effects are brought about, bicarbonate therapy is indicated to minimize risks inherent to the acidosis itself.

Vigorous bicarbonate therapy is required in any form of metabolic acidosis where a rapid increase in plasma total CO₂ content is crucial — e.g., cardiac arrest, circulatory insufficiency due to shock or severe dehydration, and in severe primary lactic acidosis or severe diabetic acidosis.

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

Prepared By: Christopher Seniuk CIH CSP

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