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: **Nitroglycerin Injection, USP**

PRODUCT CODE (NDC): **5 mg/mL: 0517-4810-25**

Section 2: HAZARDS IDENTIFICATION

EMERGENCY OVERVIEW

Appearance / Odor	Clear, colorless solution with odor of alcohol.
WARNING!	**Nitroglycerin solution should be considered flammable.**
Skin, eye and respiratory irritant	Causes irritation of the eyes, skin, gastrointestinal and respiratory tracts.
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	Causes irritation of the respiratory tract.
Ingestion	Causes irritation of the gastrointestinal tract.
Skin Absorption	Product is absorbed through the skin.
Medical Conditions Aggravated by Exposure	Personnel with impaired liver, kidney, central nervous and cardiovascular systems should minimize their exposure to this product. Personnel taking medications for hypotension and cardiac abnormalities should avoid this product.
Target Organs	Eyes, skin, lungs, liver, kidneys, central nervous system, cardiovascular and hemopoietic systems.

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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** contain a carcinogen listed by IARC but not by OSHA 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
Nitroglycerin	55-63-0	0.5 percent
Ethyl Alcohol	64-17-5	30.0 percent
Propylene Glycol	57-55-6	30.0 percent
Sodium Hydroxide	1310-73-2	used for pH adjustment
Hydrochloric Acid	7647-01-0	used for pH adjustment
Water for Injection	7732-18-5	39.5 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 and dermatitis. Product is absorbed through the skin. 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	Ingestion of product causes gastric irritation, nausea, vomiting and diarrhea. Flush mouth out with water. Seek medical attention.
Injection	See prescribing information.
Note to Physicians	Exposure to this product may result in headache, light-headedness, vertigo, syncope, palpitations, dyspnea, bradycardia, nausea, vomiting, diarrhea and hypotension. Methemoglobinemia, leukopenia and abnormal liver function tests may be observed following exposure. See prescribing information.

Section 5: FIRE FIGHTING MEASURES	
Suitable Extinguishing Media	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	Water. Water allows nitroglycerin to precipitate from ethyl alcohol and propylene glycol.
Hazardous Combustion Products	**Nitroglycerin solution should be considered flammable!** When heated, Nitroglycerin solution thermally decomposes to form toxic vapors. (i.e. Carbon Monoxide, Carbon Dioxide and Nitrogen Oxides).
Protection for firefighters: Nitroglycerin solution thermally decomposes to form toxic vapors. Vapors can 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 considered a water pollutant. However, it is recommended to prevent spilled or leaking material from entering waterways. Minimize use of water to prevent environmental contamination.
Methods of Containment	Absorb product with suitable materials such as clay absorbent or absorbent pads for alcohol based solutions.
Methods of Clean Up	Absorb liquid with clay absorbent, absorbent pads or paper towels. Use plastic tools to scoop up, sweep or containerize spilled material. Vacuum remaining spillage with an explosion proof vacuum cleaner having an activated carbon filter. Use polyethylene drums to contain spilled materials. Wipe working surfaces to dryness, and then wash with soap and water.
Other Information	Depending on the quantity, a spill of this material may need to be reported to the National Response Center. (800-424-8802).

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 and clothing. Do not mix with other drugs.

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

Storage:

Consider nitroglycerin solution a flammable liquid! 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
Nitroglycerin	0.2 parts per million - Ceiling	0.05 parts per million - 8 hour TWA	
Ethyl Alcohol	1000 parts per million	1000 parts per million	
Propylene Glycol	Not listed	Not listed	
Water for Injection	Not listed	Not listed	
Hydrochloric Acid	5 parts per million - Ceiling	2 parts per million - Ceiling	
Sodium Hydroxide	2 milligrams / cubic meter - 8 hour TWA	2 milligrams / cubic meter - Ceiling	

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 combination P-100 / organic vapor / acid gas 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 4-H or Silver Shield gloves for clean up activities.

Section 9: PHYSICAL AND CHEMICAL PROPERTIES

Color	Clear to colorless solution.
Odor / Odor Threshold	Alcohol odor
Physical State	Liquid
pH	3.0 to 6.5
Freezing Point	Approximately -114 degrees Centigrade (ethyl alcohol)
Boiling Point	Approximately 78.4 degrees Centigrade (ethyl alcohol)
Flash Point	13 degrees Centigrade (ethyl alcohol)

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Section 9: PHYSICAL AND CHEMICAL PROPERTIES (continued)	
Evaporation Rate	1.4 (ethyl alcohol)
Flammability	Flammable
Upper Flammable Limit	19 percent
Lower Flammable Limit	3.3 percent
Vapor Pressure	40.0 mm Hg (68 Degrees Fahrenheit)
Vapor Density	1.59
Specific Gravity	Approximately 1.0
Solubility (water)	Freely soluble in alcohol or propylene glycol.
Partition Coefficient	Not determined
Auto-ignition Temperature	Not applicable
Percent Volatile	30 percent
Volatile Organic Compounds (%)	30 percent

Section 10: STABILITY AND REACTIVITY	
Stability	Stable.
Conditions to Avoid	**Flammable Liquid!** Avoid heat, static electricity, flame, sparks, light and humidity. Do not mix with other drugs. Keep away from flames, thermally decomposes to form toxic vapors.
Incompatible Materials	Incompatible with reactive metals, oxidizers, acids and alkalis. May cause fire and explosion when combined with sodium hydrazide or bromine pentaflouride. Vigorous and explosive when reacting with oxidizers.
Hazardous Decomposition Products	Carbon Monoxide, Carbon Dioxide and Nitrogen 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}:	105 mg/kg - rat
	LD_{50}:	115 mg/kg - mouse
Intravenous (LD_{50})	LD_{50}:	28.2 mg/kg - rat
	LD_{50}:	10.6 mg/kg - mouse
Intraperitoneal (LD_{50})	LD_{50}:	102 mg/kg - rat
	LD_{50}:	104 mg/kg - mouse
Dermal (LD_{50})	LD_{50}:	280 mg/kg - rabbit
Inhalation	Causes respiratory irritation.	
Eye Irritation	Causes eye irritation.	
Skin Irritation	Causes skin irritation.	
Sensitization	Product is considered a skin sensitizer.	

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Section 11: TOXICOLOGY INFORMATION (continued)	
Chronic Effects	
Organ Systems	Prolonged or repeated exposure may lead to damage to the liver, lungs, kidneys, pancreas, cardiovascular, hemopoietic and central nervous system.
Carcinogenicity	Animal studies illustrated that nitroglycerin is considered carcinogenic. No adequate and well controlled studies in humans have been conducted. Ethyl alcohol is classified by IARC as a human carcinogen.
Mutagenicity	Based on the AMES test, nitroglycerin is mutagenic. No adequate and well controlled studies in humans regarding the mutagenic effects of Nitroglycerin have been conducted. Ethyl alcohol is mutagenic to somatic mammalian cells, bacteria and yeast.
Reproductive Effects	Ethyl alcohol is considered a reproductive toxin. No adequate and well controlled studies in humans or animals regarding the reproductive effects of Nitroglycerin have been conducted.
Developmental Effects	Ethyl alcohol is considered a teratogen. Causes detrimental effects in offspring. Ethyl alcohol passes through the placenta and is excreted in breast milk of nursing mothers. Nitroglycerin is not considered a teratogen. No adequate and well controlled studies in humans or animals regarding the teratogenic effects of Nitroglycerin have been conducted. 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.
Bioaccumulation / Accumulation	No applicable bioaccumulation is expected in the environment.
Mobility in Environment	Appreciable volatilization should be expected into the air. The product is freely mobile through 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)	DOT Class 3 Flammable Liquid - UN 1204. Refer to US DOT for quantities and packaging requirements.
Canadian TDG (ground)	See US DOT.
IATA (air)	See US DOT - Refer to US DOT for quantities and packaging requirements.

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)	Ethyl alcohol found in alcoholic beverages is currently listed as a carcinogen and a teratogen under California Proposition 65.
RTECS Number	QX2100000
TSCA	8b Inventory - Nitroglycerin
SARA 313	Notify and report release if above threshold quantity of 10 pounds.
NFPA Rating	Health - 2, Fire - 3, Reactivity - 4
WHMIS (Canada)	D-1 B: Causes immediate and serious toxic effects.

Section 16: OTHER INFORMATION

Nitroglycerin Injection, USP is indicated for treatment of peri-operative hypertension; for control of congestive heart failure in the setting of acute myocardial infarction; for treatment of angina pectoris in patients who have not responded to sublingual Nitroglycerin and β-blockers; and for induction of intraoperative hypotension.

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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