



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: Cyanocobalamin Injection, USP****PRODUCT CODE (NDC): 1000 mcg/mL: 0517-0031-25, 0517-0032-25, 0517-0130-05****Section 2: HAZARDS IDENTIFICATION****EMERGENCY OVERVIEW**

Appearance / Odor	Clear, dark red solution with a characteristic odor.
<b>WARNING!</b>	
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.
<i>Potential Health Effects: See Section 11 for more information</i>	
Likely Routes of Exposure	Eye contact, skin contact, inhalation and ingestion.
Eye	Causes irritation of the eye.
Skin	Causes slight irritation of the skin.
Inhalation	May cause irritation of the upper and lower respiratory tract.
Ingestion	May cause irritation of the gastrointestinal tract.
Skin Absorption	Not absorbed through the skin.
Medical Conditions Aggravated by Exposure	Personnel with sensitivity to Cobalt and Vitamin B <sub>12</sub> .
Target Organs	Eyes, mucous membranes, upper and lower respiratory tract.

*continued on next page*

<b>Section 2: HAZARDS IDENTIFICATION (continued)</b>	
<i>Potential Environmental Effects:</i> <i>See Section 12 for more information</i>	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).	

<b>Section 3: COMPOSITION AND INFORMATION ON INGREDIENTS</b>		
Component	CAS Number	Percentage (%) by Weight
Cyanocobalamin	68-19-9	0.1 percent
Benzyl Alcohol	100-51-6	1.5 percent
Sodium Chloride	7647-14-5	0.9 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	97.5 percent

<b>Section 4: FIRST AID MEASURES</b>	
Eye Contact	Causes irritation. Flush for 15 minutes with copious quantities of water. Seek medical attention.
Skin Contact	May cause irritation. Remove contaminated clothing. Flush area with copious quantities of water for 15 minutes. Seek medical attention.
Inhalation	May cause irritation of respiratory tract. Remove person to fresh air. Remove contaminated clothing. Seek medical attention.
Ingestion	May cause irritation, nausea, vomiting and diarrhea. Flush mouth out with water. Seek medical attention.
Injection	See prescribing information.
Note to Physicians	Adverse reactions to the product may result in nausea, vomiting and diarrhea.  This product contains Benzyl Alcohol that is used as a preservative. Benzyl Alcohol has been associated with "Gasping Syndrome" in neonates.

<b>Section 5: FIRE FIGHTING MEASURES</b>	
Suitable Extinguishing Media	Water spray, foam, dry chemical or Carbon Dioxide (CO <sub>2</sub> ). <b>Caution:</b> CO <sub>2</sub> will displace air in confined spaces and may cause an Oxygen deficient atmosphere.
Unsuitable Extinguishing Media	None.
Hazardous Combustion Products	When heated, Cyanocobalamin solution thermally decomposes to form toxic vapors. (i.e. Carbon Monoxide, Carbon Dioxide, Nitrogen Oxides, Phosphorus Oxides and Cobalt Oxides).
<u>Protection for Firefighters:</u> Cyanocobalamin 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.	

<b>Section 6: ACCIDENTAL RELEASE MEASURES</b>	
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 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. 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
Cyanocobalamin	Not listed	Not listed	
Benzyl Alcohol	Not listed	Not listed	
Water for Injection	Not listed	Not listed	
Sodium Chloride	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	

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 latex or nitrile gloves. Use Tyvek™ SL or equivalent coveralls, PVC booties and nitrile gloves for clean up activities.

**Section 9: PHYSICAL AND CHEMICAL PROPERTIES**

Color	Clear, dark red 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 212 degrees Fahrenheit
Flash Point	Not applicable
Evaporation Rate	Not applicable
Flammability	Nonflammable, noncombustible
Upper Flammable Limit	Not applicable
Lower Flammable Limit	Not applicable

*continued on next page*

<b>Section 9: PHYSICAL AND CHEMICAL PROPERTIES (continued)</b>	
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	1.5 percent (Benzyl Alcohol used as a preservative)
Volatile Organic Compounds (%)	1.5 percent (Benzyl Alcohol used as a preservative)

<b>Section 10: STABILITY AND REACTIVITY</b>	
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 acids and strong oxidizers.
Hazardous Decomposition Products	Carbon Monoxide, Carbon Dioxide, Nitrogen Oxides, Phosphorus Oxides & Cobalt Oxides may be released by thermal decomposition.
Possibility of Hazardous Reactions	Hazardous polymerization will not occur.

<b>Section 11: TOXICOLOGY INFORMATION</b>	
<b>Acute Effects</b>	
Oral (LD <sub>50</sub> )	LD <sub>50</sub> : 5000 mg/kg oral - mouse
Subcutaneous (LD <sub>Lo</sub> )	LD <sub>Lo</sub> : 2.727 mg/kg subcutaneous - mouse
Intraperitoneal (LD <sub>Lo</sub> )	LD <sub>Lo</sub> : 1.364 mg/kg intraperitoneal - mouse
Intravenous (LD <sub>50</sub> )	LD <sub>50</sub> : 2000 mg/kg intravenous - mouse
Dermal (LD <sub>50</sub> )	No data available.
Inhalation	Respiratory irritation is possible.
Eye Irritation	Eye irritation is possible.
Skin Irritation	Skin irritation is possible.
Sensitization	Allergic reactions may result in anaphylactic shock, pulmonary edema and congestive heart failure.

*continued on next page*

<b>Section 11: TOXICOLOGY INFORMATION (continued)</b>	
<b>Chronic Effects</b>	
Organ Systems	May be toxic to lungs and other mucous membranes.
Carcinogenicity	Cyanocobalamin is not considered carcinogenic.
Mutagenicity	Benzyl Alcohol used as a preservative is considered mutagenic for bacteria and yeast. Sodium Chloride is considered mutagenic for mammalian somatic cells, bacteria and yeast.
Reproductive Effects	No reproductive effects are listed. No adequate and well controlled studies in humans. Cyanocobalamin passes into breast milk of nursing mothers.
Developmental Effects	Not considered a teratogen. No adequate and well controlled studies in humans. Fetal harm associated with Cyanocobalamin is unknown.

<b>Section 12: ECOLOGICAL INFORMATION</b>	
Ecotoxicity	No data available.
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.

<b>Section 13: DISPOSAL CONDITIONS</b>	
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.

<b>Section 14: TRANSPORTATION INFORMATION</b>	
<b>Regulatory Agency</b>	<b>Shipping Description</b>
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.

<b>Section 15: REGULATORY INFORMATION</b>	
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	GL7030000
TSCA	8b Inventory - Cyanocobalamin
NFPA Rating	Health - 1, Fire - 1, Reactivity - 0
WHMIS (Canada)	D-2A - Causes other toxic effects

<b>Section 16: OTHER INFORMATION</b>
<p>Cyanocobalamin is indicated for Vitamin B<sub>12</sub> deficiencies due to malabsorption which may be associated with the following conditions:</p> <p>Addisonian (pernicious) anemia            Gastrointestinal pathology, dysfunction, or surgery, including gluten enteropathy or sprue, small bowel bacteria overgrowth, total or partial gastrectomy            Fish tapeworm infestation            Malignancy of pancreas or bowel            Folic acid deficiency</p> <p>It may be possible to treat the underlying disease by surgical correction of anatomic lesions leading to small bowel bacterial overgrowth, expulsion of fish tapeworm, discontinuation of drugs leading to vitamin malabsorption, use of a gluten-free diet in nontropical sprue, or administration of antibiotics in tropical sprue. Such measures remove the need for long-term administration of Cyanocobalamin. Requirements of Vitamin B<sub>12</sub> in excess of normal (due to pregnancy, thyrotoxicosis, hemolytic anemia, hemorrhage, malignancy, hepatic and renal disease) can usually be met with oral supplementation. <u>Cyanocobalamin Injection, USP</u> is also suitable for the Vitamin B<sub>12</sub> absorption test (Schilling test).</p> <p>Refer to Luitpold / American Regent's prescribing information for further information at <a href="http://www.americanregent.com/product_index.asp">http://www.americanregent.com/product_index.asp</a></p> <p>Prepared By: Christopher Seniuk CIH CSP</p>

*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.*