Cyanocobalamin Injection, USP

Safety Data Sheet

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SECTION 1: IDENTIFICATION

1.1. Product Identifier

Product Form: Solution

Product Name: Cyanocobalamin Injection, USP

Product Code: 0517-0031-25; 0517-0032-25; 0517-0130-05

1.2. Intended Use of the Product

Use of the substance/mixture: Cyancobalamin is indicated for vitamin B12 deficiencies due to malabsorption which may be associated with the following conditions: Addisonian (pernicious) anemia; gastrointestinal pathology, dysfunction, or surgery, including gluten enteropathy or sprue, small bowel bacterial overgrowth, total or partial gastrectomy; fish tapeworm infestation; malignancy of pancreas or bowel; folic acid deficiency.

1.3. Name, Address, and Telephone of the Responsible Party

Company

Luitpold Pharmaceuticals, Inc.
One Luitpold Drive
P.O. Box 9001
Shirley, NY 11967
1-800-645-1706
www.luitpold.com

1.4. Emergency Telephone Number

Emergency Number : CHEMTREC 1-800-424-9300

SECTION 2: HAZARDS IDENTIFICATION

2.1. Classification of the Substance or Mixture

Classification (GHS-US)

Not classified

2.2. Label Elements

GHS-US Labeling

No labeling applicable

2.3. Other Hazards

Exposure may aggravate those with pre-existing eye, skin, or respiratory conditions. May cause an allergic reaction in sensitive individuals. See package insert for additional information.

2.4. Unknown Acute Toxicity (GHS-US)

No data available

SECTION 3: COMPOSITION/INFORMATION ON INGREDIENTS

3.1. Substance

Not applicable

3.2. Mixture

Name	Product Identifier	%	Classification (GHS-US)
Water for Injection	(CAS No) 7732-18-5	97.5	Not classified
Benzyl alcohol	(CAS No) 100-51-6	1.5	Flam. Liq. 4, H227 Acute Tox. 4 (Oral), H302 Acute Tox. 4 (Inhalation), H332 Eye Irrit. 2A, H319 Aquatic Acute 2, H401
Sodium chloride	(CAS No) 7647-14-5	0.9	Not classified
Cyanocobalamin	(CAS No) 68-19-9	0.1	Not classified
Sodium hydroxide	(CAS No) 1310-73-2	Added to adjust pH	Met. Corr. 1, H290 Skin Corr. 1A, H314 Eye Dam. 1, H318 Aquatic Acute 3, H402

Hydrochloric acid	(CAS No) 7647-01-0	Added to adjust pH	Met. Corr. 1, H290 Skin Corr. 1A, H314 Eye Dam. 1, H318 STOT SE 3, H335 Aquatic Acute 2, H401

Full text of H-phrases: see section 16

SECTION 4: FIRST AID MEASURES

4.1. Description of First Aid Measures

First-aid Measures General: Never give anything by mouth to an unconscious person. If you feel unwell, seek medical attention (show the label if possible).

First-aid Measures After Inhalation: Remove to fresh air and keep at rest in a position comfortable for breathing. Obtain medical attention if breathing difficulty.

First-aid Measures After Skin Contact: Remove contaminated clothing and shoes. Flush with plenty of water for at least 15 minutes. Seek medical attention if irritation develops. Wash contaminated clothing before reuse.

First-aid Measures After Eye Contact: Rinse cautiously with water for at least 15 minutes. Remove contact lenses, if present and easy to do. Continue rinsing. Seek medical attention.

First-aid Measures After Ingestion: Do NOT induce vomiting. Rinse mouth. Immediately call a POISON CENTER and doctor/physician.

4.2. Most important symptoms and effects, both acute and delayed

Symptoms/Injuries: Not expected to present a significant hazard under anticipated conditions of normal use.

Symptoms/Injuries After Inhalation: Overexposure may be irritating to the respiratory system.

Symptoms/Injuries After Skin Contact: Contact during a long period may cause slight irritation.

Symptoms/Injuries After Eye Contact: Direct contact with the eyes is likely irritating.

Symptoms/Injuries After Ingestion: Ingestion is likely to be harmful or have adverse effects. May cause gastrointestinal irritation, nausea, vomiting and diarrhea.

Chronic Symptoms: None expected under normal conditions of use.

4.3. Indication of Any Immediate Medical Attention and Special Treatment Needed

If you feel unwell, seek medical advice (show the label where possible).

SECTION 5: FIRE-FIGHTING MEASURES

5.1. Extinguishing Media

Suitable Extinguishing Media: Use extinguishing media appropriate for surrounding fire.

Unsuitable Extinguishing Media: None known.

5.2. Special Hazards Arising From the Substance or Mixture

Fire Hazard: Not considered flammable but may burn at high temperatures.

Explosion Hazard: Product is not explosive.

Reactivity: Hazardous reactions will not occur under normal conditions.

5.3. Advice for Firefighters

Precautionary Measures Fire: Exercise caution when fighting any chemical fire. Under fire conditions, hazardous fumes will be present.

Firefighting Instructions: Use water spray or fog for cooling exposed containers.

Protection During Firefighting: Do not enter fire area without proper protective equipment, including respiratory protection.

Other Information: Refer to Section 9 for flammability properties.

SECTION 6: ACCIDENTAL RELEASE MEASURES

6.1. Personal Precautions, Protective Equipment and Emergency Procedures

General Measures: Avoid all contact with skin, eyes, or clothing. Avoid breathing (vapor, mist, spray).

6.1.1. For Non-emergency Personnel

Protective Equipment: Use appropriate personal protection equipment (PPE).

Emergency Procedures: Evacuate unnecessary personnel.

6.1.2. For Emergency Responders

Protective Equipment: Equip cleanup crew with proper protection.

Emergency Procedures: Stop leak if safe to do so.

6.2. Environmental Precautions

Prevent entry to sewers and public waters. Notify authorities if liquid enters sewers or public waters.

6.3. Methods and Material for Containment and Cleaning Up

For Containment: Contain any spills with dikes or absorbents to prevent migration and entry into sewers or streams.

Methods for Cleaning Up: Clean up spills immediately and dispose of waste safely. Spills should be contained with mechanical barriers. Transfer spilled material to a suitable container for disposal. If spilled directly onto the ground, remove sufficient soil to ensure material is fully recovered.

6.4. Reference to Other Sections

See Heading 8. Exposure controls and personal protection. For further information refer to section 13.

SECTION 7: HANDLING AND STORAGE

7.1. Precautions for Safe Handling

Additional Hazards When Processed: When handling pharmaceutical products, avoid all contact and inhalation of vapor, mist, spray. Do not mix with other drugs. This product contains benzyl alcohol as a preservative. Practice good housekeeping - spillage can be slippery on smooth surface either wet or dry.

Hygiene Measures: Handle in accordance with good industrial hygiene and safety procedures. Wash hands and other exposed areas with mild soap and water before eating, drinking or smoking and when leaving work.

7.2. Conditions for Safe Storage, Including Any Incompatibilities

Technical Measures: Comply with applicable regulations.

Storage Conditions: Store in a dry, well ventilated place at 20° -25°C (68°- 77°F) away from incompatible materials. Protect from light.

Incompatible Products: Strong acids. Strong oxidizers.

7.3. Specific End Use(s) Pharmaceutical

SECTION 8: EXPOSURE CONTROLS/PERSONAL PROTECTION

8.1. Control Parameters

For substances listed in section 3 that are not listed here, there are no established exposure limits from the manufacturer, supplier, importer, or the appropriate advisory agency including: ACGIH (TLV), NIOSH (REL), or OSHA (PEL).

Sodium hydroxide (1310-73-2)		
USA ACGIH	ACGIH Ceiling (mg/m³)	2 mg/m³
USA NIOSH	NIOSH REL (ceiling) (mg/m³)	2 mg/m³
USA IDLH	US IDLH (mg/m³)	10 mg/m³
USA OSHA	OSHA PEL (TWA) (mg/m³)	2 mg/m³

Hydrochloric acid (7647-01-0)		
USA ACGIH	ACGIH Ceiling (ppm)	2 ppm
USA ACGIH	ACGIH chemical category	Not Classifiable as a Human Carcinogen
USA NIOSH	NIOSH REL (ceiling) (mg/m³)	7 mg/m³
USA NIOSH	NIOSH REL (ceiling) (ppm)	5 ppm
USA IDLH	US IDLH (ppm)	50 ppm
USA OSHA	OSHA PEL (Ceiling) (mg/m³)	7 mg/m³
USA OSHA	OSHA PEL (Ceiling) (ppm)	5 ppm

8.2. Exposure Controls

Appropriate Engineering Controls : Ensure adequate ventilation, especially in confined areas. Emergency eye wash fountains and safety showers should be available in the immediate vicinity of any potential exposure. Ensure all national/local regulations are observed.

Personal Protective Equipment : Protective goggles. Gloves. Protective clothing.

Materials for Protective Clothing : Not required for normal conditions of use.

Hand Protection : Protective gloves.

Eye Protection : In case of splash hazard: chemical goggles or safety glasses.

Skin and Body Protection : Wear suitable protective clothing.

Respiratory Protection : Use a NIOSH-approved respirator or self-contained breathing apparatus whenever exposure may exceed established Occupational Exposure Limits.

Environmental Exposure Controls : Do not allow the product to be released into the environment.

Consumer Exposure Controls : Do not eat, drink or smoke during use.

SECTION 9: PHYSICAL AND CHEMICAL PROPERTIES

9.1. Information on Basic Physical and Chemical Properties

Physical State	: Liquid
Appearance	: Clear, dark red solution
Odor	: Odor of benzyl alcohol
Odor Threshold	: No data available
pH	: 4.5 - 7.0
Evaporation Rate	: No data available
Melting Point	: No data available
Freezing Point	: No data available
Boiling Point	: No data available
Flash Point	: Not flammable, Not combustible
Auto-ignition Temperature	: No data available
Decomposition Temperature	: No data available
Flammability (solid, gas)	: No data available
Vapor Pressure	: No data available
Relative Vapor Density at 20 °C	: No data available
Relative Density	: No data available
Specific Gravity	: ≈ 1.0
Solubility	: Water: Freely soluble
Partition Coefficient: N-Octanol/Water	: No data available
Viscosity	: No data available

9.2. Other Information

VOC content : 1.5 % (Benzyl alcohol used as a preservative)

SECTION 10: STABILITY AND REACTIVITY

10.1. Reactivity: Hazardous reactions will not occur under normal conditions.

10.2. Chemical Stability: Stable under recommended handling and storage conditions (see section 7).

10.3. Possibility of Hazardous Reactions: Hazardous polymerization will not occur.

10.4. Conditions to Avoid: Direct sunlight, high or low temperatures, and incompatible materials.

10.5. Incompatible Materials: Strong oxidizers. Strong acids.

10.6. Hazardous Decomposition Products: Thermal decomposition generates : Carbon oxides (CO, CO_2), Nitrogen oxides, Phosphorus oxides, Cobalt oxides.

SECTION 11: TOXICOLOGICAL INFORMATION

11.1. Information On Toxicological Effects

Acute Toxicity: Not classified

Benzyl alcohol (100-51-6)	
LD50 Oral Rat	1230 mg/kg
LD50 Dermal Rabbit	> 2000 mg/kg
LC50 Inhalation Rat	> 4.178 mg/l/4h
ATE (Vapors)	11.00 mg/l/4h
ATE (Dust/Mist)	1.50 mg/l/4h

Sodium chloride (7647-14-5)	
LD50 Oral Rat	3 g/kg
LC50 Inhalation Rat	> 42 g/m³ (Exposure time: 1 h)

Sodium hydroxide (1310-73-2)	
LD50 Dermal Rabbit	1350 mg/kg

Hydrochloric acid (7647-01-0)	
LD50 Oral Rat	238 - 277 mg/kg
LD50 Dermal Rabbit	> 5010 mg/kg
LC50 Inhalation Rat	1.68 mg/l (Exposure time: 1 h)
LC50 Inhalation Rat	1411 ppm

Skin Corrosion/Irritation: Not classified

pH: 4.5 - 7.0

Serious Eye Damage/Irritation: Not classified

pH: 4.5 - 7.0

Respiratory or Skin Sensitization: Not classified

Germ Cell Mutagenicity: Not classified

Carcinogenicity: Not classified

Hydrochloric acid (7647-01-0)	
IARC group	3

Reproductive Toxicity: Not classified

Specific Target Organ Toxicity (Single Exposure): Not classified

Specific Target Organ Toxicity (Repeated Exposure): Not classified

Aspiration Hazard: Not classified

Symptoms/Injuries After Inhalation: Overexposure may be irritating to the respiratory system.

Symptoms/Injuries After Skin Contact: Contact during a long period may cause slight irritation.

Symptoms/Injuries After Eye Contact: Direct contact with the eyes is likely irritating.

Symptoms/Injuries After Ingestion: Ingestion is likely to be harmful or have adverse effects. May cause gastrointestinal irritation, nausea, vomiting and diarrhea.

Chronic Symptoms: None expected under normal conditions of use.

SECTION 12: ECOLOGICAL INFORMATION

12.1. Toxicity

Benzyl alcohol (100-51-6)	
LC50 Fish 1	460 mg/l (Exposure time: 96 h - Species: Pimephales promelas [static])
EC50 Daphnia 1	23 mg/l (Exposure time: 48 h - Species: water flea)
LC 50 Fish 2	10 mg/l (Exposure time: 96 h - Species: Lepomis macrochirus [static])
ErC50 (algae)	770 mg/l

Sodium chloride (7647-14-5)	
LC50 Fish 1	5560 (5560 - 6080) mg/l (Exposure time: 96 h - Species: Lepomis macrochirus [flow-through])
EC50 Daphnia 1	1000 mg/l (Exposure time: 48 h - Species: Daphnia magna)
LC 50 Fish 2	12946 mg/l (Exposure time: 96 h - Species: Lepomis macrochirus [static])
EC50 Daphnia 2	340.7 (340.7 - 469.2) mg/l (Exposure time: 48 h - Species: Daphnia magna [Static])

Sodium hydroxide (1310-73-2)	
LC50 Fish 1	45.4 mg/l (Exposure time: 96 h - Species: Oncorhynchus mykiss [static])
EC50 Daphnia 1	40 mg/l

Hydrochloric acid (7647-01-0)	
LC50 Fish 1	3.25 - 3.5 mg/l (Exposure time: 96 h - Species: Lepomis macrochirus)
EC50 Daphnia 1	4.92 mg/l (Exposure time: 48 h - Species: Daphnia magna)

12.2. Persistence and Degradability

No additional information available

12.3. Bioaccumulative Potential

Cyancobalamin Injection, USP	
Bioaccumulative Potential	Not expected to bioaccumulate.

Benzyl alcohol (100-51-6)	
Log Pow	1.1

Sodium chloride (7647-14-5)	
BCF fish 1	(no bioaccumulation)

12.4. Mobility in Soil

No additional information available

12.5. Other Adverse Effects

Other Information : Avoid release to the environment.

SECTION 13: DISPOSAL CONSIDERATIONS

13.1. Waste treatment methods

Waste Disposal Recommendations: Dispose of waste material in accordance with all local, regional, national, and international regulations.

Ecology – Waste Materials: Avoid release to the environment.

SECTION 14: TRANSPORT INFORMATION

14.1. In Accordance with DOT Not regulated for transport

14.2. In Accordance with IMDG Not regulated for transport

14.3. In Accordance with IATA Not regulated for transport

SECTION 15: REGULATORY INFORMATION

15.1 US Federal Regulations

Cyanocobalamin (68-19-9)	
Listed on the United States TSCA (Toxic Substances Control Act) inventory	

Benzyl alcohol (100-51-6)	
Listed on the United States TSCA (Toxic Substances Control Act) inventory	

Sodium chloride (7647-14-5)	
Listed on the United States TSCA (Toxic Substances Control Act) inventory	

Sodium hydroxide (1310-73-2)	
Listed on the United States TSCA (Toxic Substances Control Act) inventory	
SARA Section 311/312 Hazard Classes	Immediate (acute) health hazard

Hydrochloric acid (7647-01-0)	
Listed on the United States TSCA (Toxic Substances Control Act) inventory Listed on the United States SARA Section 302 Listed on United States SARA Section 313	
SARA Section 302 Threshold Planning Quantity (TPQ)	500 (gas only)
SARA Section 311/312 Hazard Classes	Immediate (acute) health hazard
SARA Section 313 - Emission Reporting	1.0 % (acid aerosols including mists, vapors, gas, fog, and other airborne forms of any particle size)

Water (7732-18-5)	
Listed on the United States TSCA (Toxic Substances Control Act) inventory	

15.2 US State Regulations

Benzyl alcohol (100-51-6)
U.S. - Massachusetts - Right To Know List U.S. - Pennsylvania - RTK (Right to Know) List

Sodium hydroxide (1310-73-2)
U.S. - Massachusetts - Right To Know List U.S. - New Jersey - Right to Know Hazardous Substance List U.S. - Pennsylvania - RTK (Right to Know) - Environmental Hazard List U.S. - Pennsylvania - RTK (Right to Know) List

Hydrochloric acid (7647-01-0)
U.S. - Massachusetts - Right To Know List U.S. - New Jersey - Right to Know Hazardous Substance List U.S. - Pennsylvania - RTK (Right to Know) - Environmental Hazard List U.S. - Pennsylvania - RTK (Right to Know) List

SECTION 16: OTHER INFORMATION, INCLUDING DATE OF PREPARATION OR LAST REVISION

Revision Date : 11/12/2015

Other Information : This document has been prepared in accordance with the SDS requirements of the OSHA Hazard Communication Standard 29 CFR 1910.1200.

GHS Full Text Phrases:

Acute Tox. 4 (Inhalation)	Acute toxicity (inhalation) Category 4
Acute Tox. 4 (Oral)	Acute toxicity (oral) Category 4
Aquatic Acute 2	Hazardous to the aquatic environment - Acute Hazard Category 2

Aquatic Acute 3	Hazardous to the aquatic environment - Acute Hazard Category 3
Eye Dam. 1	Serious eye damage/eye irritation Category 1
Eye Irrit. 2A	Serious eye damage/eye irritation Category 2A
Flam. Liq. 4	Flammable liquids Category 4
Met. Corr. 1	Corrosive to metals Category 1
Skin Corr. 1A	Skin corrosion/irritation Category 1A
STOT SE 3	Specific target organ toxicity (single exposure) Category 3
H227	Combustible liquid
H290	May be corrosive to metals
H302	Harmful if swallowed
H314	Causes severe skin burns and eye damage
H318	Causes serious eye damage
H319	Causes serious eye irritation
H332	Harmful if inhaled
H335	May cause respiratory irritation
H401	Toxic to aquatic life
H402	Harmful to aquatic life

Refer to Luitpold/American Regent prescribing information for further information at: http://www.americanregent.com/AllProducts.aspx

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.

SDS US (GHS HazCom)