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: Cyanocobalamin 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

<table>
<thead>
<tr>
<th>Name</th>
<th>Product Identifier</th>
<th>%</th>
<th>Classification (GHS-US)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Water for Injection</td>
<td>(CAS No) 7732-18-5</td>
<td>97.5</td>
<td>Not classified</td>
</tr>
<tr>
<td>Benzyl alcohol</td>
<td>(CAS No) 100-51-6</td>
<td>1.5</td>
<td>Flam. Liq. 4, H227</td>
</tr>
<tr>
<td>Sodium chloride</td>
<td>(CAS No) 7647-14-5</td>
<td>0.9</td>
<td>Acute Tox. 4 (Oral), H302</td>
</tr>
<tr>
<td>Cyanocobalamin</td>
<td>(CAS No) 68-19-9</td>
<td>0.1</td>
<td>Acute Tox. 4 (Inhalation), H332</td>
</tr>
<tr>
<td>Sodium hydroxide</td>
<td>(CAS No) 1310-73-2</td>
<td></td>
<td>Eye Irrit. 2A, H319</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>Aquatic Acute 2, H401</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>Not classified</td>
</tr>
</tbody>
</table>

Added to adjust pH
Met. Corr. 1, H290
Skin Corr. 1A, H314
Eye Dam. 1, H318
Aquatic Acute 3, H402

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| 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.

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).


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.
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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.


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).

<table>
<thead>
<tr>
<th>Substance</th>
<th>USA ACGIH</th>
<th>USA NIOSH</th>
<th>USA IDLH</th>
<th>USA OSHA</th>
</tr>
</thead>
<tbody>
<tr>
<td>Sodium hydroxide (1310-73-2)</td>
<td>ACGIH</td>
<td>NIOSH REL</td>
<td>US IDLH</td>
<td>OSHA PEL</td>
</tr>
<tr>
<td>ACGIH Ceiling (mg/m³)</td>
<td>2 mg/m³</td>
<td>2 mg/m³</td>
<td>10 mg/m³</td>
<td>2 mg/m³</td>
</tr>
<tr>
<td>Hydrochloric acid (7647-01-0)</td>
<td>ACGIH</td>
<td>NIOSH REL</td>
<td>US IDLH</td>
<td>OSHA</td>
</tr>
<tr>
<td>ACGIH Ceiling (ppm)</td>
<td>2 ppm</td>
<td>7 mg/m³</td>
<td>50 ppm</td>
<td>7 mg/m³</td>
</tr>
<tr>
<td>ACGIH chemical category</td>
<td>Not Classifiable as a Human Carcinogen</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

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.


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.

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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.

SECTION 11: TOXICOLOGICAL INFORMATION

11.1. Information On Toxicological Effects
Acute Toxicity: Not classified

<table>
<thead>
<tr>
<th>Substance</th>
<th>Acute Toxicity</th>
<th>LD50 Oral Rat</th>
<th>LC50 Inhalation Rat</th>
</tr>
</thead>
<tbody>
<tr>
<td>Benzyl alcohol (100-51-6)</td>
<td></td>
<td>1230 mg/kg</td>
<td>&gt; 4.178 mg/l/4h</td>
</tr>
<tr>
<td>LD50 Dermal Rabbit</td>
<td></td>
<td>&gt; 2000 mg/kg</td>
<td></td>
</tr>
<tr>
<td>LC50 Inhalation Rat</td>
<td></td>
<td>&gt; 4.178 mg/l/4h</td>
<td></td>
</tr>
<tr>
<td>ATE (Vapors)</td>
<td></td>
<td>11.00 mg/l/4h</td>
<td></td>
</tr>
<tr>
<td>ATE (Dust/Mist)</td>
<td></td>
<td>1.50 mg/l/4h</td>
<td></td>
</tr>
<tr>
<td>Sodium chloride (7647-14-5)</td>
<td></td>
<td>3 g/kg</td>
<td>&gt; 42 g/m³ (Exposure time: 1 h)</td>
</tr>
<tr>
<td>LD50 Oral Rat</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>LC50 Inhalation Rat</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Sodium hydroxide (1310-73-2)</td>
<td></td>
<td>1350 mg/kg</td>
<td></td>
</tr>
<tr>
<td>LD50 Dermal Rabbit</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Hydrochloric acid (7647-01-0)</td>
<td></td>
<td>238 - 277 mg/kg</td>
<td></td>
</tr>
<tr>
<td>LD50 Oral Rat</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>LD50 Dermal Rabbit</td>
<td></td>
<td>&gt; 5010 mg/kg</td>
<td></td>
</tr>
<tr>
<td>LC50 Inhalation Rat</td>
<td>1.68 mg/l (Exposure time: 1 h)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>LC50 Inhalation Rat</td>
<td>1411 ppm</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
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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

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

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

Sodium chloride (7647-14-5)

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

Sodium hydroxide (1310-73-2)

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

Hydrochloric acid (7647-01-0)

<table>
<thead>
<tr>
<th>Benzyl alcohol (100-51-6)</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>LC50 Fish 1</td>
<td>3.25 - 3.5 mg/l (Exposure time: 96 h - Species: Lepomis macrochirus)</td>
</tr>
<tr>
<td>EC50 Daphnia 1</td>
<td>4.92 mg/l (Exposure time: 48 h - Species: Daphnia magna)</td>
</tr>
</tbody>
</table>

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.
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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.

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
Benzy l 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
Benzy l 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
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<table>
<thead>
<tr>
<th>Aquatic Acute 3</th>
<th>Hazardous to the aquatic environment - Acute Hazard Category 3</th>
</tr>
</thead>
<tbody>
<tr>
<td>Eye Dam. 1</td>
<td>Serious eye damage/eye irritation Category 1</td>
</tr>
<tr>
<td>Eye Irrit. 2A</td>
<td>Serious eye damage/eye irritation Category 2A</td>
</tr>
<tr>
<td>Flam. Liq. 4</td>
<td>Flammable liquids Category 4</td>
</tr>
<tr>
<td>Met. Corr. 1</td>
<td>Corrosive to metals Category 1</td>
</tr>
<tr>
<td>Skin Corr. 1A</td>
<td>Skin corrosion/irritation Category 1A</td>
</tr>
<tr>
<td>STOT SE 3</td>
<td>Specific target organ toxicity (single exposure) Category 3</td>
</tr>
</tbody>
</table>

| 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)