

SAFETY DATA SHEETS

This SDS packet was issued with item:

078636182

N/A

MSDS# L-AR-00018

Product: **Cyanocobalamin Injection, USP**

Effective: 10/01/2009

Revision: 1



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: **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.

WARNING!

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.

*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 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 B₁₂.

Target Organs

Eyes, mucous membranes, upper and lower respiratory tract.

continued on next page

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 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
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

Section 4: FIRST AID MEASURES

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.

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, Cyanocobalamin solution thermally decomposes to form toxic vapors. (i.e. Carbon Monoxide, Carbon Dioxide, Nitrogen Oxides, Phosphorus Oxides and Cobalt Oxides).
Protection for Firefighters: 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.	

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 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 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 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

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Section 9: PHYSICAL AND CHEMICAL PROPERTIES (continued)

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)

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 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.

Section 11: TOXICOLOGY INFORMATION

Acute Effects	
Oral (LD ₅₀)	LD ₅₀ : 5000 mg/kg oral - mouse
Subcutaneous (LD _{Lo})	LD _{Lo} : 2.727 mg/kg subcutaneous - mouse
Intraperitoneal (LD _{Lo})	LD _{Lo} : 1.364 mg/kg intraperitoneal - mouse
Intravenous (LD ₅₀)	LD ₅₀ : 2000 mg/kg intravenous - mouse
Dermal (LD ₅₀)	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.

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Section 11: TOXICOLOGY INFORMATION (continued)	
Chronic Effects	
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.

Section 12: ECOLOGICAL INFORMATION	
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.

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	GL7030000
TSCA	8b Inventory - Cyanocobalamin
NFPA Rating	Health - 1, Fire - 1, Reactivity - 0
WHMIS (Canada)	D-2A - Causes other toxic effects

Section 16: OTHER INFORMATION
<p>Cyanocobalamin is indicated for Vitamin B₁₂ deficiencies due to malabsorption which may be associated with the following conditions:</p> <ul style="list-style-type: none"> 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>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.</p> <p>Requirements of Vitamin B₁₂ in excess of normal (due to pregnancy, thyrotoxicosis, hemolytic anemia, hemorrhage, malignancy, hepatic and renal disease) can usually be met with oral supplementation.</p> <p><u>Cyanocobalamin Injection, USP</u> is also suitable for the Vitamin B₁₂ absorption test (Schilling test).</p> <p>Refer to Luitpold / American Regent's prescribing information for further information at http://www.americanregent.com/product_index.asp</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.



**The
HARVARD DRUG GROUP, u.c.
MAJOR PHARMACEUTICALS @**

Rx Brands/Generics & MAJOR Consumer Products

November 8, 2012

Cyanocobalamin MDV 1000mg

Dear Valued Customer:

This letter is in reference to your request for Material Safety Data Sheet(s) (MSDS).

We are not required to hold MSDS information on these items. The reason for this is as follows:

Ethical, over-the-counter, supplemental and cosmetic products in final dosage forms that are supplied for patient care are not subject to hazardous materials standards, since they do not pose a danger to those handling the products in the forms in which they are supplied. Therefore, these products are exempt from MSDS Requirements under OSHA Hazard Communication Standards 1910.1200(b)(6)(vii) and/or 1910.1200(b)(5)(iii) which provide the following exemptions:

1. Products which are in "solid," final form for direct administration to the patient,
2. Foods, drugs, supplements and cosmetics which are packaged for retail sale to the customer.
3. Food, food additive, color additive, drug, cosmetic, or medical or veterinary device or product, including materials intended for use as ingredients in such products (e.g. flavors and fragrances).

Our Pharmaceutical drug products are prescribed, stored, prepared, dispensed and administered according to the directions in the product labeling and packaging and they are regulated by the Food and Drug Administration.

If you have any questions or require additional information, please feel free to contact us.

31778 Enterprise Drive, Livonia, MI 48150

Phone: 734.743.6000 • Fax: 734.743.7000

Obtained by Global Safety Management, 1-813-435-5161 - www.GSMSDS.com

English:

3E verified with the supplier provided that no SDS has been created for this product.

3E will periodically contact the supplier to reconfirm no SDS is available.

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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: 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

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

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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
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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.

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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.

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/m ³)	2 mg/m ³
USA NIOSH	NIOSH REL (ceiling) (mg/m ³)	2 mg/m ³
USA IDLH	US IDLH (mg/m ³)	10 mg/m ³
USA OSHA	OSHA PEL (TWA) (mg/m ³)	2 mg/m ³
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/m ³)	7 mg/m ³
USA NIOSH	NIOSH REL (ceiling) (ppm)	5 ppm
USA IDLH	US IDLH (ppm)	50 ppm
USA OSHA	OSHA PEL (Ceiling) (mg/m ³)	7 mg/m ³
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.

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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	: \approx 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, CO₂), 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/m ³ (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

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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

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

Cyanocobalamin 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.

Cyanocobalamin Injection, USP

Safety Data Sheet

According to Federal Register / Vol. 77, No. 58 / Monday, March 26, 2012 / Rules and Regulations

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

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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)