



Safety Data Sheet: Cyanocobalamin Injection, USP

1. IDENTIFICATION

Product Identifier:	Cyanocobalamin Injection, USP 1000 mcg/ml
Synonyms:	Vitamin B12 Injection
National Drug Code (NDC):	69680-112-01 (1 mL vial) 69680-112-25 (25 x 1 mL vials) 69680-112-10 (10 x 1 mL vials) 69680-113-99 (10 x 10 mL vials) 69680-113-10 (10 mL vial) 69680-121-30 (30 mL vial) 69680-121-05 (5 x 30 mL vials) 69680-121-10 (10 x 30 mL vials)
Recommended Use:	Pharmaceutical Cyanocobalamin is indicated for vitamin B12 deficiencies due to malabsorption. Cyanocobalamin Injection, USP is also suitable for the vitamin B12 absorption test (Schilling test).
Company:	Vitruvias Therapeutics, Inc. Auburn, AL 36830 USA
Contact Telephone:	1-844-451-5944
Email:	info@vitruvias.com
Emergency Phone:	1-256-653-1629

2. HAZARD(S) INFORMATION

Classification:	Not classified
GHS Label Elements:	
Signal Word:	No signal word.
Hazard Statements:	No known significant effects or critical hazards.
Precautionary statements:	
Prevention:	Not applicable.
Response:	Not applicable.
Storage:	Not applicable.



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Disposal: Not applicable.

Hazards not

otherwise classified: None known.

Hazards not

otherwise classified (HNOC): None known.

3. SECTION 3. COMPOSITION/INFORMATION ON INGREDIENTS

Substance/mixture:

Mixture

<u>Ingredient name</u>	<u>Percent</u>	<u>CAS number</u>
Water	97 – 97.5	7732-18-5
Benzyl alcohol	1.5	100-51-6
Sodium chloride	0.9	7647-14-5
Cyanocobalamin	0.1	68-19-9
Sodium hydroxide	0 - 0.1 (to adjust pH)	1310-73-2
Hydrochloric acid	0 - 0.1 (to adjust pH)	7647-01-0

There are no ingredients present which, within the current knowledge of the supplier and in the concentrations applicable, are classified as hazardous to health or the environment and hence require reporting in this section.

Occupational exposure limits, if available, are listed in Section 8.

4. First Aid Measures

Description of necessary first aid measures

Eye Contact: Immediately flush eyes with plenty of water, occasionally lifting the upper and lower eyelids. Check for and remove any contact lenses. Get medical attention if irritation occurs.

Inhalation: Remove victim to fresh air and keep at rest in a position comfortable for breathing. Get medical attention if symptoms occur.

Skin Contact: Flush contaminated skin with plenty of water. Get medical attention if symptoms occur.

Ingestion: Wash out mouth with water. Remove victim to fresh air and keep at rest in a position comfortable for breathing. If material has been swallowed and the exposed person is conscious, give small quantities of water to drink. Do not induce vomiting unless directed to do so by medical personnel. Get medical attention if symptoms occur.



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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 may be harmful or have adverse effects.

May cause gastrointestinal irritation, nausea, vomiting and diarrhea.

Chronic Symptoms: None expected under normal conditions of use.

Indication of Any Immediate Medical Attention and Special Treatment Needed:

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

Notes to physician: Treat symptomatically. Contact poison treatment specialist immediately if large quantities have been ingested or inhaled.

Specific treatments: No specific treatment.

Protection of first-aiders: No action shall be taken involving any personal risk or without suitable training.

5. FIRE-FIGHTING MEASURES

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

Unsuitable Extinguishing Media: None known.

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.

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.

6. ACCIDENTAL RELEASE MEASURES

Personal Precautions, Protective Equipment and Emergency Procedures

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



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For Non-Emergency Personnel

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

Emergency Procedures: Evacuate unnecessary personnel.

For Emergency Responders

Protective Equipment: Equip cleanup crew with proper protection.

Emergency Procedures: Stop leak if safe to do so.

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

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.

Reference to Other Sections

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

7. HANDLING AND STORAGE

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.

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.

Specific End Use(s): Pharmaceutical.

8. EXPOSURE CONTROLS/PERSONAL PROTECTION

Control parameters



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Occupational exposure limits

Ingredient name Exposure limits

Benzyl alcohol AIHA WEEL (United States, 10/2011). TWA: 10 ppm 8 hours.

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.

9. 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

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Viscosity	No data available
Other Information	
VOC content:	1.5 % (Benzyl alcohol used as a preservative)

10. STABILITY AND REACTIVITY

Reactivity: Hazardous reactions will not occur under normal conditions.

Chemical Stability: Stable under recommended handling and storage conditions.

Possibility of Hazardous Reactions: Hazardous polymerization will not occur.

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

Incompatible Materials: Strong oxidizers. Strong acids.

Hazardous Decomposition Products: Thermal decomposition generates: Carbon oxides (CO, CO₂), Nitrogen oxides, Phosphorus oxides, Cobalt oxides.

11. TOXICOLOGICAL INFORMATION

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

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)	
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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 may be harmful or have adverse effects. May cause gastrointestinal irritation, nausea, vomiting and diarrhea.

Chronic Symptoms: None expected under normal conditions of use.

12. ECOLOGICAL INFORMATION

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)

Persistence and Degradability: No additional information available.

Bioaccumulative Potential

Cyanocobalamin Injection, USP	
Bioaccumulative potential	Not expected to accumulate.
Benzyl alcohol (100-51-6)	
Low Pow	1.1
Sodium chloride (7647-14-5)	
BCF fish 1	(no bioaccumulation)



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Mobility in soil: No additional information available.

Other Adverse Effects: Do not release to environment.

13. DISPOSAL CONSIDERATIONS

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.

14. TRANSPORT INFORMATION

In Accordance with DOT: Not regulated for transport

In Accordance with IMDG: Not regulated for transport

In Accordance with IATA: Not regulated for transport

15. REGULATORY INFORMATION

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

US State Regulations

U. S.- California Proposition 65 - Not Listed

Benzyl alcohol (100-51-6)



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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

16. OTHER INFORMATION

Vitruvias Revision Date: March 16, 2020

Revision Number: 7

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