

SAFETY DATA SHEET

**According to Globally Harmonized System of Classification and Labelling of Chemicals (GHS),
Third Revised Edition UNITED NATIONS
New York and Geneva, 2019**

Cyanocobalamin Injection USP (1000 mcg/ml, 10000 mcg/10 ml, 30000 mcg/30 ml)

1. IDENTIFICATION

GHS Product identifier: Vitamin B12

Product code: #

Chemical Description: cobalt(3+);[(2R,3S,4R,5S)-5-(5,6-dimethylbenzimidazol-1-yl)-4-hydroxy-2-(hydroxymethyl)oxolan-3-yl] [(2R)-1-[3-[(1R,2R,3R,4Z,7S,9Z,12S,13S,14Z,17S,18S,19R)-2,13,18-tris(2-amino-2-oxoethyl)-7,12,17-tris(3-amino-3-oxopropyl)-3,5,8,8,13,15,18,19-octamethyl-2,7,12,17-tetrahydro-1H-corrin-21-id-3-yl]propanoylamino]propan-2-yl] phosphate;cyanide

Other means of identification: -

Recommended use of the injection:

- Cyanocobalamin is indicated for vitamin B12 deficiencies due to malabsorption.
- Cyanocobalamin Injection, USP is also suitable for the vitamin B12 absorption test (Schilling test).

Restrictions on use: The product should be used only for the above-mentioned use and may not be used for any other purpose than stated above.

Manufactured by:

Mankind Pharma Ltd.,
Unit III, Opp. Dental College, Rampur Ghat,
Teh. -Paonta Sahib (HP-173025), India.
CIN No.: U74899DL1991PLC044843

Emergency phone number: +91 1704227600

2. HAZARDS IDENTIFICATION

Classification

Globally Harmonized System, UN (GHS)

Not classified as hazardous

Labelling

None

Classification	
Signal Word	Not classified
Hazard Statements:	No known significant effects or critical hazards
Precautionary Statements:	Not applicable.
Other hazards	None

3. COMPOSITION / INFORMATION ON INGREDIENTS

Chemical nature: Mixture

Hazardous ingredients	CAS	Content
Cyanocobalamin	68-19-9	0.1%
Other ingredients		
Benzyl alcohol Emprove	100-51-6	<2.0%
Sodium Chloride	7647-14-5	<1.0 %
Sodium acetate	6131-90-4	< 1.0 %
Acetic acid 98/100%	64-19-7	< 1.0 %
Sodium hydroxide	1310-73-2	q.s.
Hydrochloric acid	7647-01-0	q.s.

4. FIRST-AID MEASURES

Inhalation

Move person into fresh air. If not breathing, give artificial respiration. Consult a physician.

Skin contact

Wash off with soap and plenty of water.

Eye contact

Immediately flush eyes with water for at least 15 minutes. If irritation occurs or persists, get medical attention

Ingestion

If this product is swallowed, call physician or Poison Control Centre. Rinse mouth with water. Never give anything by mouth to an unconscious person.

5. FIRE-FIGHTING MEASURES

Fire extinguishing agents

Use water spray, dry chemical or carbon dioxide.

Fire/explosion hazard

Product is not explosive but may burn at high temperatures.

Specific hazards arising from the chemical

Decomposition products may include carbon dioxide and carbon monoxide.

Personal protection

Appropriate protective clothing. Fire-fighters must wear self-contained breathing apparatus for firefighting if necessary.

Special exposure hazards

Do not release chemically contaminated water into drains, soil, or surface water. Dispose contaminated water and soil according to local regulations.

6. ACCIDENTAL RELEASE MEASURES

Personal protection

Wear respiratory protection.

Environmental precautions

Prevent product from entering sewer or confined spaces, waterways, soil or public waters. Do not flush to sewer.

7. HANDLING AND STORAGE

Handling

Occupational hygiene

Follow recommendations for handling pharmaceutical agents (i.e., use of engineering controls and/or other personal protective equipment if needed).

Conditions for safe storage

Keep away from heat/sparks/open flames/hot surfaces – No smoking.

Storage facilities

Store away from light, in a cool, dry area. Keep tightly closed.

Segregation

Store locked up.

8. EXPOSURE CONTROLS AND PERSONAL PROTECTION

Exposure limit values

Components with occupational exposure limits

CAS No	Name	Limits
100-51-6	Benzyl alcohol	TWA - 10 ppm (8 hr)
1310-73-2	Sodium hydroxide	ACGIH Ceiling 2 mg/m ³
7647-01-0	Hydrochloric acid	ACGIH Ceiling 2 ppm

Occupational exposure controls

Appropriate engineering controls

Good general ventilation should be sufficient to control worker exposure to airborne contaminants.

General Personal Protection

Goggles, gloves, protective clothing.

Respiratory protection

Based on the hazard and potential for exposure, select a respirator that meets the appropriate standard or certification. Respirators must be used according to a respiratory protection program to ensure proper fitting, training, and other important aspects of use.

Hand protection

Protective gloves.

Eye protection

Safety eyewear complying with an approved standard should be used when a risk assessment indicates this is necessary to avoid exposure to liquid splashes, mists, gases or dusts.

Skin and body protection

Gloves must be inspected prior to use. Use proper glove removal technique (without touching glove's outer surface) to avoid skin contact with this product. Dispose of contaminated gloves after use in accordance with applicable laws and good laboratory practices. Wash and dry hands.

9. PHYSICAL AND CHEMICAL PROPERTIES

Appearance & Colour: Clear Red liquid in amber glass vials.

Form: Injection

Odour: Odourless

pH: 4.5-7

Melting point: Not applicable

Boiling point: Not available

Flash point: Not applicable

Flammability (solid): Not available

Vapour pressure: Not available

Auto-ignition temperature: Not available

Decomposition temperature: Not available

Density: 1

Solubility in water: Soluble

Solubility in solvents: Not known

n-Octanol/Water Partition Coefficient: Not known

Viscosity: Not applicable.

10. STABILITY AND REACTIVITY

Chemical stability

Stable under recommended storage conditions

Conditions to avoid

None in particular

Materials to avoid

Under normal conditions of storage and use, hazardous reactions will not occur.

Hazardous decomposition products

Under normal conditions of storage and use, hazardous decomposition products should not be produced.

11. TOXICOLOGICAL INFORMATION

Acute toxicity

Mixture is not classifiable for acute toxicity.

Benzyl alcohol - LD₅₀ Oral - 1230 mg/kg

Primary Irritation:

Skin/eye irritation - Benzyl alcohol – Mild irritant

Mixture is not classifiable for skin/eye irritation.

Respiratory or Skin sensitization

Mixture is not classifiable for respiratory or skin sensitization

CMR consideration:

Germ cell mutagenicity:

Not mutagenic. Mixture not classifiable.

Carcinogenicity

Not classifiable as human carcinogen.

Reproductive toxicity: Data not available

Specific target organ toxicity single exposure: Mixture is not classifiable for STOT-SE

Specific target organ toxicity repeated exposure:

Mixture is not classified for STOT-RE

Aspiration hazard:

GHS Classification is not possible.

12. ECOLOGICAL INFORMATION

Ecotoxicity- Unknown

Benzyl alcohol - Acute LC₅₀ (96 hrs) – 460 mg/L Fresh water (Fish - Pimephales promelas - Juvenile (Fledgling, Hatchling, Wearling)

Persistence and degradability

No information available.

Bioaccumulative Potential

Not expected to bioaccumulate.

Additional information

Do not discharge product uncontrolled into the environment.

13. DISPOSAL CONSIDERATIONS

Product disposal

All wastes containing the material should be properly labeled. Rinse waters resulting from spill cleanups should be discharged in an environmentally safe manner, e.g., appropriately permitted municipal or onsite wastewater treatment facility.

Contaminated packaging

Contaminated, empty containers must be disposed of as chemical waste.

14. TRANSPORT INFORMATION

DOT

Not regulated as dangerous goods.

IATA

Not regulated as dangerous goods.

IMDG

Not regulated as dangerous goods.

15. REGULATORY INFORMATION

CLASSIFICATION AND LABELLING

Compliance with following regulations:

- Globally Harmonized System of Classification and Labelling of Chemicals (GHS), UNECE 2021 as amended.
- UN Recommendations on the Transport of Dangerous Goods, UNECE 2009

16. OTHER INFORMATION

Recommended restrictions on use

This product should be stored, handled and used in accordance with good industrial hygiene practices and in conformity with any legal regulation. The information contained herein is based on the present state of our knowledge and is intended to describe our products from the point of view of safety requirements. It should not therefore be construed as guaranteeing specific properties.

MSDS Changes

Prepared on 07/08/2023