

Material Safety Data Sheet (MSDS)

Product Name: Vitamin B12 (Methyl cobalamin) IP Grade

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Supplier:

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1. Identification of the Substance/Preparation and Company

- Product name: Vitamin B12 (Methyl cobalamin) — IP Grade
- Synonyms: Methyl cobalamin, MeCbl, Methyl B12
- Recommended use: Nutritional supplement ingredient, pharmaceutical intermediates, veterinary supplements, fortified foods where permitted by regulation.

2. Composition / Information on Ingredients

- Chemical identity: Methyl cobalamin (a cobalamin derivative).
- Purity: IP grade (specification as per purchaser/supplier certificate of analysis).
- Typical impurities: trace residual solvents or salts from manufacture (refer to COA).
- CAS number (commonly cited): 13422-55-4. *(If CAS is required for regulatory paperwork, verify with supplier COA.)*

3. Hazard(s) Identification

- Classification: Non-hazardous for most handling conditions. Not classified as a hazardous substance under common classification schemes when used as intended.
- GHS hazard statements: None required for the pure substance in typical forms.
- Main hazards: In powdered/dust form may cause mechanical irritation to eyes, skin, respiratory tract. Avoid creating dust.
- Environmental hazards: Not known to be environmentally hazardous at typical concentrate; large releases should be prevented.

4. First Aid Measures

- Inhalation: Remove to fresh air. If breathing difficulties occur, seek medical attention. For dust exposure, keep airway clear and rest.
- Skin contact: Wash affected area with soap and water. Seek medical attention if irritation persists.
- Eye contact: Rinse cautiously with water for several minutes. Remove contact lenses if present and easy to do — continue rinsing. Seek medical attention if irritation persists.
- Ingestion: Rinse mouth. Do not induce vomiting unless instructed by medical personnel. Seek medical advice if large quantities swallowed or if symptoms occur.
- Notes to physician: Treat symptomatically. This is a vitamin compound; systemic toxicity is unlikely at low doses.

5. Firefighting Measures

- Flammability: Non-flammable solid under normal conditions.
- Extinguishing media: Use water spray, foam, dry chemical or CO₂ as appropriate for surrounding fire.
- Special hazards: Decomposition in fire may generate nitrogen oxides, cobalt oxides, and other decomposition products.
- Protective equipment for firefighters: Self-contained breathing apparatus and full protective clothing. Avoid inhalation of combustion products.

6. Accidental Release Measures

- Personal precautions: Avoid dust formation. Use appropriate PPE (gloves, dust mask/respirator, eye protection). Keep unprotected persons away.
- Environmental precautions: Do not allow product to enter drains, surface water, or soil in large quantities.

- Clean-up methods: Sweep or vacuum (use HEPA vacuum) to avoid dust dispersal, or carefully scoop up. Place in suitable labeled containers for disposal or recovery. Wash spill area with water; avoid creating foaming wastewater. Follow local regulations for disposal.

7. Handling and Storage

- Handling: Avoid inhalation of dust and contact with eyes and skin. Use with adequate ventilation. Good personal hygiene — wash after handling. Do not eat, drink, or smoke in work area.
- Storage: Store in a cool, dry, well-ventilated place. Keep container tightly closed and protected from light and moisture. Recommended storage temperature per supplier (typically room temperature, protected from prolonged heat). Avoid storing with strong oxidizers.
- Shelf life: As per manufacturer COA; label with batch and expiry.

8. Exposure Controls / Personal Protection

- Occupational exposure limits: No specific OELs established for methyl cobalamin in most jurisdictions. Apply general dust exposure controls and local limits where applicable.
- Engineering controls: Provide adequate ventilation — local exhaust if dust is generated. Use closed systems where feasible.
- Personal protective equipment (PPE):
 - Respiratory: For dust — disposable dust mask (P2/P3) or respirator with particulate filter; for high concentrations use appropriate respirator per local standards.
 - Eyes: Safety glasses with side shields or goggles.
 - Skin: Protective gloves (nitrile or other chemical-resistant gloves) and protective clothing to avoid prolonged contact.
 - Hygiene: Wash hands and exposed skin after handling; change contaminated clothing.
- Additional measures: Use dust containment and housekeeping to minimize airborne particles.

9. Physical and Chemical Properties

- Appearance: Red to dark red crystalline powder or microcrystalline powder (typical of methyl cobalamin).

- Odor: Odorless or faint characteristic odor.
- pH: Not applicable (solid).
- Melting point / decomposition: Decomposes on heating; refer to supplier data.
- Solubility: Soluble in water (forms red solutions), sparingly soluble in some organic solvents — refer to COA.
- Bulk density and particle size: Variable by batch — refer to supplier specification.
- Flash point: Not applicable (non-flammable solid).
(Values can vary by manufacturer — consult COA for precise physicochemical data.)

10. Stability and Reactivity

- Chemical stability: Stable under recommended storage conditions (cool, dry, protected from light).
- Conditions to avoid: Prolonged exposure to light, heat and moisture may degrade the product. Avoid dust formation.
- Materials to avoid: Strong oxidizing agents, strong acids/bases; avoid reducing agents if not compatible.
- Hazardous decomposition products: On thermal decomposition may produce nitrogen oxides, cobalt oxides, and other potentially toxic oxides.

11. Toxicological Information

- Acute toxicity: Low acute toxicity by oral, dermal or inhalation routes at levels encountered in handling for formulations; vitamin cobalamins are essential nutrients.
- Skin corrosion/irritation: Not known to be corrosive; may cause mild mechanical irritation on prolonged contact.
- Serious eye damage/irritation: Dust may cause eye irritation.
- Respiratory or skin sensitization: Not known to be a sensitizer in humans, but dust can cause irritation.
- Chronic effects: No specific chronic toxicity reported for methyl cobalamin at occupational exposure levels. As with any chemical, long-term high concentration exposure data is limited — follow safe handling.
- Carcinogenicity, mutagenicity, reproductive toxicity: No convincing evidence of carcinogenic or mutagenic effects for methyl cobalamin in standard references; considered low risk when used appropriately as a vitamin.

- Notes: Toxicological data may vary with impurity profile and formulation — consult product-specific toxicology and COA.

12. Ecological Information

- Ecotoxicity: Not expected to be acutely toxic to aquatic organisms at environmental concentrations typical of accidental releases from normal handling. Large releases should be contained.
- Persistence and degradability: Organic vitamin molecule; may biodegrade.
- Bioaccumulative potential: Low bioaccumulation expected.
- Mobility: Soluble in water — may disperse in aqueous media.
- Advice: Prevent large quantities entering waterways or sewage systems.

13. Disposal Considerations

- Disposal methods: Dispose of in accordance with local, regional and national regulations. Small quantities: may be incinerated in approved facility or sent to licensed waste handler.
- Packaging disposal: Empty containers may retain product residues — follow label warnings and local rules; container rinsing and disposal per regulations.
- Regulatory considerations: Follow applicable regulations for pharmaceutical/chemical waste; consult local authorities.

14. Transport Information — (DETAILED)

General statement:

Methyl cobalamin (Vitamin B12) in pure, solid, or typical technical forms is **not normally classified as dangerous goods** for transport by road (ADR/RID), sea (IMDG), or air (IATA/ICAO) under international dangerous goods regulations. However, classification can change depending on form, concentration, packaging, and presence of hazardous impurities. The guidance below is comprehensive — verify with your shipping/transport authority and documentation for the specific batch and country of shipment.

A. UN Number / Proper Shipping Name

- Typical: **No UN number / Not regulated**. No special UN shipping name required.
- If shipped as a pharmaceutical/food ingredient in non-hazardous form, label as “Not Regulated” for dangerous goods. Use conventional commercial shipping name: *Vitamin B12 (Methyl cobalamin)*.

B. ADR / RID (Road / Rail — Europe)

- Classification: Not classified as dangerous for transport (unless combined with a regulated hazardous ingredient).
- Transport category: Not applicable for dangerous goods.
- Packaging: Use sturdy, sealed containers suitable for solids. Protect against moisture and light. Follow general packaging and labeling regulations for non-dangerous goods.
- Marking & documentation: Include commercial invoice, packing list and any required export/import documents. If product is within a regulated pharmaceutical/food supply chain, include COA and certificate of analysis where required.

C. IMDG (Sea)

- Classification: Generally not classified as dangerous for sea transport. No IMDG code UN number normally required.
- Marine pollutant: **Not classified as a marine pollutant.** However, avoid large releases to sea; treat as potentially harmful in large amounts.
- Stowage & segregation: Store in dry, well-ventilated cargo spaces, away from strong oxidizers and incompatible substances. Avoid stacking that may crush packaging.

D. IATA / ICAO (Air)

- Classification: Generally **not regulated** as dangerous goods for air transport.
- Packing instructions: Use standard non-dangerous goods packaging, ensuring containers are secure and protected from crushing. If shipped as part of a medicinal product, include necessary documentation and conform to airline/consignee requirements.
- Special provisions: If the material is intended for clinical or emergency medical use, check airline and destination country import rules for pharmaceuticals and required permits.

E. Special Precautions for Transport

1. **Packaging:** Use dust-tight, moisture-resistant sealed containers (e.g., HDPE drums, lined bags, or sealed bottles) and inner liners to prevent moisture/light exposure which can degrade the product. Cushioning to prevent damage is recommended.
2. **Labeling:** Even if not dangerous, label with product name, net weight, batch number, "Handle with care", and supplier contact details. For international shipments include HS/HTS code and any required regulatory data.
3. **Documentation:** Include COA, MSDS/SDS, commercial invoice, packing list, export/import permits (if required), and any statements required by regulators for vitamins or pharmaceutical ingredients. For shipments to/from certain countries, additional documentation for controlled substances or pharmaceuticals may be required.

— verify local rules.

4. **Handling:** Avoid dropping, crushing, or exposing packages to excessive heat or moisture. Handle to minimize dust generation. Use mechanical lifting aids for heavy drums/pallets.
5. **Temperature sensitivity:** While not extremely temperature-sensitive, prolonged exposure to high temperatures or moisture and light should be avoided. If a specified storage temperature is provided by supplier (e.g., 2–25 °C for formulated products), ship using temperature-controlled means when required.
6. **Emergency response information:** In case of accident during transport:
 - For spills: avoid dust formation; sweep up and contain spill; prevent entry to waterways. Use appropriate PPE.
 - For fire: treat as non-combustible solid; use extinguishers suitable for surrounding fire. Firefighters should use SCBA if decomposition products are inhaled.
 - Provide SDS to emergency responders and transport authorities.
7. **Customs & regulatory checks:** Vitamins / pharmaceutical ingredients sometimes face stricter import/export controls. Ensure customs classification, permits, and certificates (pharmaceutical/food grade) are prepared.
8. **Quantity limits:** For non-hazardous goods, typical commercial quantity limits apply. If combined with hazardous excipients or carried in bulk with other materials, classification may change.

F. If material is formulated or contains hazardous excipients

- Re-assess transport classification — presence of flammable solvents, corrosive agents, oxidizers, or other hazardous components may make the finished product regulated. In such cases, follow the appropriate UN numbers, packing group, label and documentation requirements.

G. Recommended shipper checklist (brief)

- Verify batch COA and product identity.
- Confirm packaging integrity and protective measures (liners, desiccants).
- Confirm whether destination requires import permits or registrations for pharmaceutical ingredients.
- Attach SDS, COA, and emergency contact to shipment documents.
- Declare as “Not regulated — non-hazardous” for dangerous goods if applicable; if unsure, consult a dangerous goods safety advisor.

Summary: Under normal circumstances methyl cobalamin is transported as a non-regulated, non-dangerous good. However, always confirm classification for your specific shipment (packaging, concentration, co-formulants, and destination rules) and carry SDS and COA with the shipment.

15. Regulatory Information

- Regulatory status: Listed as a vitamin / nutritional substance; regulatory controls vary by country for use levels and permitted applications (food, pharmaceutical, veterinary).
- Labeling: Comply with applicable national regulations for pharmaceuticals, food additives, or nutraceuticals.
- Safety/chemical inventories: Likely listed on many national chemical/product inventories — verify with local regulatory authority.
- Restrictions: Use in foods, supplements and medicines must meet local regulatory approvals and GMP/registration requirements.

16. Other Information / Preparation Details

- Disclaimer: The information in this SDS is believed to be accurate at the time of preparation. It is provided in good faith but without warranty. The customer must determine the suitability of the product for their intended use and comply with applicable laws/regulations. This SDS should be provided to anyone who handles, uses, stores, or transports the product. For product-specific information (COA, technical specs, expiry, storage temperature), consult the supplier certificate of analysis and product label.
- **MSDS Generate Date:** 20-05-2017
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- **Website:** www.rawpharmabiz.com
- MSDS are based on the manufacturer's provided information.