

# Scientific Documentation

## Mecobalamin, JP

Not appropriate for regulatory submission.

Please visit [www.spectrumchemical.com](http://www.spectrumchemical.com) or contact Tech Services for the most up-to-date information contained in this information package.

Spectrum Chemical Mfg Corp  
769 Jersey Avenue  
New Brunswick, NJ 08901  
Phone 732.214.1300



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## Specification for Mecobalamin, JP (M1804)

Item Number	M1804
Item	Mecobalamin, JP
CAS Number	13422-55-4
Molecular Formula	C <sub>63</sub> H <sub>91</sub> CoN <sub>13</sub> O <sub>14</sub> P
Molecular Weight	1344.40
MDL Number	
Synonyms	

Test	Specification	
	Min	Max
APPEARANCE		
IDENTIFICATION (1)	SPECTRUM MATCHES STANDARD	
IDENTIFICATION (2)	RED TO ORANGE-RED COLOR DEVELOPS DOES NOT DISAPPEAR	
ASSAY (ANHYDROUS)	98.0	101.0 %
CLARITY AND COLOR OF SOLUTION	CLEAR AND RED	
WATER		12 %
RELATED SUBSTANCES:		
ANY OTHER INDIVIDUAL IMPURITY		0.5 %
TOTAL IMPURITIES		2.0 %
RETEST DATE		
DATE OF MANUFACTURE		
MONOGRAPH EDITION		
RESIDUAL SOLVENTS	AS REPORTED	

### *Spectrum Chemical Mfg Corp*

<b>Corporate Headquarters:</b>	<b>West Coast Facility:</b>
769 Jersey Ave.	14422 S. San Pedro St.
New Brunswick, NJ 08901	Gardena, CA 90248
732.214.1300	310.516.8000

## Certificate Of Analysis

Item Number	M1804	Lot Number	4ID0008
Item	Mecobalamin, JP	Manufacturer Lot	SLL/MC/0319009
CAS Number	13422-55-4	Manufacturer Code	7068
Molecular Formula	C <sub>63</sub> H <sub>91</sub> CoN <sub>13</sub> O <sub>14</sub> P	Molecular Weight	1344.40

TEST	SPECIFICATION		RESULT
	MIN	MAX	
APPEARANCE			RED CRYSTALLINE POWDER
IDENTIFICATION (1)	SPECTRUM MATCHES STANDARD		SPECTRUM MATCHES STANDARD
IDENTIFICATION (2)	RED TO ORANGE-RED COLOR DEVELOPS DOES NOT DISAPPEAR		RED TO ORANGE-RED COLOR DEVELOPS DOES NOT DISAPPEAR
ASSAY (ANHYDROUS)	98.0	101.0 %	99.0 %
CLARITY AND COLOR OF SOLUTION	CLEAR AND RED		CLEAR AND RED
WATER		12 %	8.23 %
RELATED SUBSTANCES:			.
ANY OTHER INDIVIDUAL IMPURITY		0.5 %	0.25 %
TOTAL IMPURITIES		2.0 %	1.32 %
RETEST DATE			28-FEB-2023
DATE OF MANUFACTURE			01-MAR-2019
RESIDUAL SOLVENTS	AS REPORTED		AS REPORTED
CLASS 2 (solvent) / CHLOROFORM			<60 ppm
CLASS 2 (SOLVENT) / METHANOL			<3000 ppm
CLASS 3 (solvent) / ACETONE			<5000 ppm
CLASS 3 (solvent) / 2-BUTANOL			<5000 ppm

Certificate of Analysis Results Entered By:

HBERMUDEZ  
Hernan Bermudez  
12-AUG-21 14:23:09

Certificate of Analysis Results Approved By:

HBERMUDEZ  
Hernan Bermudez  
12-AUG-21 14:23:28

Spectrum Chemical Mfg Corp  
777 Jersey Avenue  
New Brunswick 08901 NJ



**All pharmaceutical ingredients are tested using current edition of applicable pharmacopeia.**

**Read and understand label and SDS before handling any chemicals. All Spectrum's chemicals are for manufacturing, processing, repacking or research purposes by experienced personnel only. It is the customer's responsibility to provide adequate hazardous material training and ensure that appropriate Personal Protective Equipment (PPE) is used before handling any chemical.**

Spectrum Chemical Mfg. Corp. repackages Active Pharmaceutical Ingredient chemicals provided by other manufacturers and suppliers. For traceability purposes, Spectrum's Certificate of Analysis contains an identifier code unique to each manufacturer or supplier, as well as the chemical's lot number provided on the original manufacturer Certificate of Analysis. This material is manufactured by Supriya Lifescience Limited at A - 5 / 2, Lote Parshuram Industrial Area, Ratnagiri, Maharashtra 415722, India. Copies of the original Certificate of Analysis are available upon request from your Spectrum Sales Representative or by calling Spectrum's Quality Department at 1-800-772-8786.

## SAFETY DATA SHEET

Preparation Date: 6/14/2017

Revision date 2/21/2019

Revision Number: G2

### 1. IDENTIFICATION

#### Product identifier

**Product code:** M1804  
**Product Name:** Methylcobalamin, JP

#### Other means of identification

**Synonyms:** Mecobalamin  
Methycobal  
Methyl-B12  
Methyl cobalamine  
Methyl vitamin B12  
**CAS #:** 13422-55-4  
**RTECS #** GG3745000  
**CI#:** Not available

#### Recommended use of the chemical and restrictions on use

**Recommended use:** No information available.  
**Uses advised against** No information available

**Supplier:** Spectrum Chemical Mfg. Corp  
14422 South San Pedro St.  
Gardena, CA 90248  
(310) 516-8000

**Order Online At:** <https://www.spectrumchemical.com>  
**Emergency telephone number** Chemtrec 1-800-424-9300  
**Contact Person:** Tom Tyner (USA - West Coast)  
**Contact Person:** Ibad Tirmiz (USA - East Coast)

### 2. HAZARDS IDENTIFICATION

#### Classification

This chemical is not considered hazardous by the 2012 OSHA Hazard Communication Standard (29 CFR 1910.1200)

Not a dangerous substance or mixture according to the Globally Harmonized System (GHS)

#### Label elements

Not classified

#### Hazards not otherwise classified (HNOC)

Not Applicable

#### Other hazards

Not available

### 3. COMPOSITION/INFORMATION ON INGREDIENTS

Component	CAS No	Weight-%
Methylcobalamin	13422-55-4	100

### 4. FIRST AID MEASURES

#### First aid measures

<b>General Advice:</b>	National Capital Poison Center in the United States can provide assistance if you have a poison emergency and need to talk to a poison specialist. Call 1-800-222-1222.
<b>Skin Contact:</b>	Wash off immediately with soap and plenty of water removing all contaminated clothing and shoes. Get medical attention if irritation develops. Consult a physician if necessary.
<b>Eye Contact:</b>	Flush eyes with water for 15 minutes. Get medical attention if irritation occurs. If symptoms persist, call a physician.
<b>Inhalation:</b>	Move to fresh air. If not breathing, give artificial respiration. If breathing is difficult, give oxygen. Get medical attention.
<b>Ingestion:</b>	Do not induce vomiting without medical advice. Never give anything by mouth to an unconscious person. Consult a physician if necessary.

#### Most important symptoms and effects, both acute and delayed

<b>Symptoms</b>	Health injuries are not known or expected under normal use
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#### Indication of any immediate medical attention and special treatment needed

<b>Notes to Physician:</b>	Treat symptomatically.
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#### Protection of first-aiders

First-Aid Providers: Avoid exposure to blood or body fluids. Wear gloves and other necessary protective clothing. Dispose of contaminated clothing and equipment as bio-hazardous waste.

### 5. FIRE-FIGHTING MEASURES

#### Extinguishing Media

<b>Suitable Extinguishing Media:</b>	Carbon dioxide (CO <sub>2</sub> ). Dry chemical. Water spray mist or foam.
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<b>Unsuitable Extinguishing Media:</b>	No information available.
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#### Specific hazards arising from the chemical

<b>Hazardous combustion products</b>	Carbon Monoxide, Carbon Dioxide. Nitrogen oxides (NO <sub>x</sub> ). Oxides of phosphorus. Cobalt/cobalt oxides.
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<b>Specific hazards</b>	May be combustible at high temperatures.
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#### Special Protective Actions for Firefighters

**Specific Methods:**

No information available

**Special Protective Equipment for Firefighters:**

As in any fire, wear self-contained breathing apparatus pressure-demand, MSHA/NIOSH (approved or equivalent) and full protective gear

## 6. ACCIDENTAL RELEASE MEASURES

**Personal precautions, protective equipment and emergency procedures****Personal Precautions:**

Ensure adequate ventilation. Use personal protective equipment. Avoid contact with skin, eyes and clothing. Avoid dust formation. Remove all sources of ignition.

**Environmental precautions**

Prevent further leakage or spillage if safe to do so. Prevent product from entering drains.

**Methods and material for containment and cleaning up****Methods for containment**

Stop leak if you can do it without risk. Cover with plastic sheet to prevent spreading.

**Methods for cleaning up**

Sweep up and shovel into suitable containers for disposal. Clean contaminated surface thoroughly.

## 7. HANDLING AND STORAGE

**Precautions for safe handling****Technical Measures/Precautions:**

Provide sufficient air exchange and/or exhaust in work rooms. Avoid dust formation. Keep away from incompatible materials.

**Safe Handling Advice**

Wear personal protective equipment. Avoid contact with skin, eyes and clothing. Keep away from heat and sources of ignition. Do not ingest. Do not breathe dust. Handle in accordance with good industrial hygiene and safety practice.

**Conditions for safe storage, including any incompatibilities****Technical Measures/Storage Conditions:**

Keep containers tightly closed in a cool, well-ventilated place. Protect from light. Sensitive to light. Store in light-resistant containers. Keep refrigerated. Store at 2-8 deg. C. Store away from incompatible materials.

**Incompatible Materials:**

Strong oxidizing agents

## 8. EXPOSURE CONTROLS/PERSONAL PROTECTION

**Control parameters****National occupational exposure limits****United States**

Component	CAS No	OSHA	NIOSH	ACGIH	AIHA WEEL
Methylcobalamin	13422-55-4	None	None	None	None

**Canada**

Component	CAS No	Canada - Alberta	Canada - British	Canada - Ontario	Canada - Quebec
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			<b>Columbia</b>		
Methylcobalamin	13422-55-4	None	None	None	None

### Australia and Mexico

Component	CAS No	<b>Australia</b>	<b>Mexico</b>
Methylcobalamin	13422-55-4	None	None

### Appropriate engineering controls

#### Engineering measures to reduce exposure:

Ensure adequate ventilation. Use process enclosures, local exhaust ventilation, or other engineering controls to keep airborne levels below recommended exposure limits. If user operations generate dust, fume or mist, use ventilation to keep exposure to airborne contaminants below the exposure limit.

### Individual protection measures, such as personal protective equipment

#### Personal Protective Equipment

<b>Eye protection:</b>	Safety glasses with side-shields. or Goggles
<b>Skin and body protection:</b>	Long sleeved clothing Chemical resistant apron Gloves
<b>Respiratory protection:</b>	Effective dust mask. Use a dust respirator under conditions where exposure to the substance is apparent (e.g. generation of high concentration of dust (dust clouds) , inadequate ventilation, development of respiratory tract irritation), and engineering controls are not feasible. Be sure to use an approved/certified respirator or equivalent.
<b>Hygiene measures:</b>	Avoid contact with skin, eyes and clothing. Wash hands before breaks and immediately after handling the product When using, do not eat, drink or smoke.

## 9. PHYSICAL AND CHEMICAL PROPERTIES

<b>Physical state:</b> Solid	<b>Appearance:</b> Crystals. Crystalline powder.	<b>Color:</b> Dark red.
<b>Odor:</b> No information available.	<b>Taste</b> No information available.	<b>Formula</b> C63H91CoN13O14P
<b>Molecular/Formula weight (g/mole):</b> 1344.40	<b>Flammability (solid, gas)</b> no data available	<b>Flashpoint (°C/°F):</b> No information available
<b>Flash Point Tested according to:</b> Not available	<b>Autoignition Temperature (°C/°F):</b> No information available	<b>Lower Explosion Limit (%):</b> No information available
<b>Upper Explosion Limit (%):</b> No information available	<b>Melting point/range(°C/°F):</b> No information available	<b>Decomposition temperature(°C/°F):</b> No information available
<b>Boiling point/range(°C/°F):</b> No information available	<b>Bulk density:</b> No information available	<b>Density (g/cm3):</b> No information available
<b>Specific gravity:</b> No information available	<b>pH</b> No information available	<b>Vapor pressure @ 20°C (kPa):</b> No information available

**Evaporation rate:**  
No information available

**Vapor density:**  
No information available

**VOC content (g/L):**  
No information available

**Odor threshold (ppm):**  
No information available

**Partition coefficient  
(n-octanol/water):**  
No information available

**Viscosity:**  
No information available

**Miscibility:**  
No information available

**Solubility:**  
Slightly soluble in water

## 10. STABILITY AND REACTIVITY

**Reactivity**  
May react with strong oxidizers

### Chemical stability

**Stability:** Stable under recommended storage conditions.

**Possibility of Hazardous Reactions:** Hazardous polymerization does not occur

**Conditions to avoid:** Excess Heat. Avoid dust formation. Incompatible materials.

**Incompatible Materials:** Strong oxidizing agents

**Hazardous decomposition products:** Carbon monoxide. Carbon dioxide. Nitrogen oxides (NOx). Phosphorus oxides. Cobalt oxides.

### Other Information

**Corrosivity:** No information available

**Special Remarks on Corrosivity:** No information available

## 11. TOXICOLOGICAL INFORMATION

### Information on likely routes of exposure

**Principal Routes of Exposure:**  
Ingestion. Inhalation.

### Acute Toxicity

### Component Information

Methylcobalamin	
CAS No	13422-55-4

LD50/oral/rat = > 5 g/kg Oral LD50 Rat  
LD50/oral/mouse = > 5 g/kg  
LD50/dermal/rabbit = No information available  
LD50/dermal/rat = No information available  
LC50/inhalation/rat = No information available  
LC50/inhalation/mouse = No information available  
Other LD50 or LC50 information = No information available

### Product Information

**LD50/oral/rat =**  
**Value - Acute Tox =** > 5000 mg/kg

**LD50/oral/mouse =**  
**Value - Acute Tox Oral =** > 5000 mg/kg

**LD50/dermal/rabbit**  
**Value - Acute Tox =** No information available

**LD50/dermal/rat**  
**VALUE - Acute Tox Dermal =** No information available

**LC50/inhalation/rat**  
**VALUE-Vapor =** No information available  
**VALUE-Gas =** No information available  
**VALUE-Dust/Mist =** No information available

**LC50/Inhalation/mouse**  
**VALUE-Vapor =** No information available  
**VALUE - Gas =** No information available  
**VALUE - Dust/Mist =** No information available

#### Symptoms

**Skin Contact:** May cause skin irritation.  
**Eye Contact:** May cause eye irritation.  
**Inhalation** May cause irritation of respiratory tract.  
**Ingestion** Health injuries are not known or expected under normal use.  
**Aspiration hazard** No information available.

#### Delayed and immediate effects as well as chronic effects from short and long-term exposure

**Chronic Toxicity** No information available.  
**Sensitization:** No information available.  
**Mutagenic Effects:** No information available

**Carcinogenic effects:** Not considered carcinogenic.

Component	CAS No	IARC	ACGIH - Carcinogens	NTP	OSHA HCS - Carcinogens	Australia - Notifiable Carcinogenic Substances	Australia - Prohibited Carcinogenic Substances
Methylcobalamin	13422-55-4	Not listed	Not listed	Not listed	Not listed	Not listed	Not listed

*ACGIH (American Conference of Governmental Industrial Hygienists)*

*IARC (International Agency for Research on Cancer)*

*NTP (National Toxicology Program)*

*OSHA (Occupational Safety and Health Administration of the US Department of Labor)*

**Reproductive toxicity** No data is available

**Reproductive Effects:** No information available  
**Developmental Effects:** No information available  
**Teratogenic Effects:** No information available

#### **Specific Target Organ Toxicity**

**STOT - single exposure** No information available.  
**STOT - repeated exposure** No information available.  
**Target Organs:** No information available.

### **12. ECOLOGICAL INFORMATION**

#### **Ecotoxicity**

**Ecotoxicity effects:** No data available.

**Persistence and degradability:** No information available

**Bioaccumulative potential:** No information available.

**Mobility in soil** No information available  
**Other adverse effects** No information available.

### **13. DISPOSAL CONSIDERATIONS**

#### **Disposal Methods**

**Waste from residues / unused products:**  
Waste must be disposed of in accordance with Federal, State and Local regulation.

**Contaminated packaging:**  
Empty containers should be taken for local recycling, recovery or waste disposal

Component	CAS No	RCRA - F Series Wastes	RCRA - K Series Wastes	RCRA - P Series Wastes	RCRA - U Series Wastes
Methylcobalamin	13422-55-4	None	None	None	None

### **14. TRANSPORT INFORMATION**

#### **DOT**

**UN-No:** Not Regulated  
**Proper Shipping Name:** No information available  
**Hazard Class** No information available  
**Subsidiary Class** No information available  
**Packing group:** No information available  
**Emergency Response Guide Number** No information available  
**Marine Pollutant** No data available  
**DOT RQ (lbs):** No information available  
**Special Provisions** No Information available  
**Symbol(s):** No information available  
**Description:** No information available

#### **TDG (Canada)**

**UN-No:** Not Regulated

**Proper Shipping Name:** No information available  
**Hazard Class** No information available  
**Subsidiary Risk:** No information available  
**Packing Group:** No information available  
**Marine Pollutant** No Information available  
**Description:** No information available

#### ADR

**UN Number** Not regulated  
**Proper Shipping Name:** No information available  
**Transport hazard class(es)** No information available  
**Packing group** No information available  
**Subsidiary Risk:** No information available

#### IMDG

**UN-No:** Not Regulated  
**Proper Shipping Name:** No information available  
**Hazard Class:** No information available  
**Subsidiary Risk:** No information available  
**Packing Group:** No information available  
**Marine Pollutant** No information available

#### RID

**UN Number** Not Regulated  
**Proper Shipping Name:** No information available  
**Transport hazard class(es)** No information available  
**Subsidiary Risk:** No information available  
**Packing group** No information available

#### ICAO (air)

**UN-No:** Not Regulated  
**Proper Shipping Name:** No information available  
**Hazard Class** No information available  
**Subsidiary Risk:** No information available  
**Packing Group:** No information available

#### IATA

**UN Number** Not Regulated  
**Proper Shipping Name:** No information available  
**Transport hazard class(es)** No information available  
**Subsidiary Risk:** No information available  
**Packing group** No information available  
**Precautionary Statements - Response** IF exposed or concerned  
**Special Provisions** No information available

### 15. REGULATORY INFORMATION

#### International Inventories

Component	CAS No	U.S. TSCA	KOREA KECL	Philippines (PICCS)	Japan ENCS	China IECSC	Australia AICS	EINECS-No.
Methylcobalamin	13422-55-4	Not Listed	Not present	Not present	Not present	Not listed	Present	Present 236-535-3

#### U.S. Regulations

Methylcobalamin

**New Jersey RTK Hazardous Substance List:** sn 2222 (cobalt compounds)  
**New Jersey (EHS) List:** sn 2222 500 lb. TPQ (cobalt compounds)  
**New Jersey - Discharge Prevention - List of Hazardous Substances:** Present (cobalt compounds)  
**Pennsylvania RTK:** Present (cobalt compounds)  
**Pennsylvania RTK - Environmental Hazard List** Present(cobalt compounds)

**California Prop. 65: Safe Drinking Water and Toxic Enforcement Act of 1986.**

**Chemicals Known to the State of California to Cause Cancer:**  
 This product does not contain a chemical requiring a warning under California Prop. 65. (See table below)

**Chemicals Known to the State of California to Cause Reproductive Toxicity:**  
 This product does not contain a chemical requiring a warning under California Prop. 65. (See table below)

Component	CAS No	Carcinogen	Developmental Toxicity	Male Reproductive Toxicity	Female Reproductive Toxicity:
Methylcobalamin	13422-55-4	Not Listed	Not Listed	Not Listed	Not Listed

**CERCLA/SARA**

Component	CAS No	CERCLA - Hazardous Substances and their Reportable Quantities	Section 302 Extremely Hazardous Substances and TPQs	Section 302 Extremely Hazardous Substances and RQs	Section 313 - Chemical Category	Section 313 - Reporting de minimis
Methylcobalamin	13422-55-4	None	None	None	Cobalt compounds	1.0%

**U.S. TSCA**

Component	CAS No	TSCA Section 5(a)2 - Chemicals With Significant New Use Rules (SNURS)	TSCA 8(d) -Health and Safety Reporting
Methylcobalamin	13422-55-4	Not Applicable	Not Applicable

**Canada**

**WHIMIS 2015 - GHS Classifications**

WHMIS 2015 Hazard Classification Information:
 Not a dangerous product according to HPR classification criteria.

**Canada Hazardous Products Regulation**
This product has been classified according to the hazard criteria of the HPR (Hazardous Products Regulation) and the SDS contains all of the information required by the HPR

**DSL/NDSL**

Component	CAS No	Canada (DSL)	Canada (NDSL)
Methylcobalamin	13422-55-4	Not Listed	Not Listed

Component	CAS No	CEPA Schedule I - Toxic Substances
Methylcobalamin	13422-55-4	Not listed
Component	CAS No	CEPA - 2010 Greenhouse Gases Subject to Mandatory Reporting
Methylcobalamin	13422-55-4	Not listed

**EU Classification**

EU GHS - SV - CLP 1272/2008

Component	CAS No	EU GHS - SV - CLP (1272/2008)
Methylcobalamin	13422-55-4	

EU - CLP (1272/2008)

**R-phrase(s)**

not determined (not applicable)

**S -phrase(s)**

none

Component	CAS No	Classification	Concentration Limits:	Safety Phrases
Methylcobalamin	13422-55-4		No information	

**The product is classified in accordance with Annex VI to Directive 67/548/EEC**

**Indication of danger:**

None

**16. OTHER INFORMATION**

Preparation Date: 6/14/2017  
Revision date: 2/21/2019  
Prepared by: Sonia Owen

**Disclaimer:**

All chemicals may pose unknown hazards and should be used with caution. This Safety Data Sheet (SDS) applies only to the material as packaged. If this product is combined with other materials, deteriorates, or becomes contaminated, it may pose hazards not mentioned in this SDS. The physical properties reported in this SDS are obtained from the literature and do not constitute product specifications. Information contained herein does not constitute a warranty, whether expressed or implied, as to the safety, merchantability or fitness of the goods for a particular purpose. Spectrum Chemicals & Laboratory Products, Inc. assumes no responsibility for results obtained or for incidental or consequential damages, including lost profits, arising from the use of these data. No warranty against infringement of any patent, copyright or trademark is made or implied. It shall be the user's responsibility to develop proper methods of handling and personal protection based on the actual conditions of use. While this SDS is based on technical data judged to be reliable, Spectrum assumes no responsibility for the completeness or accuracy of the information contained herein.

**End of Safety Data Sheet**



**Certification of Compliance with current Good Manufacturing Practices**

Dear Valued Customer:

Spectrum Chemical Mfg Corp certifies that the following product(s) is produced, processed, packaged and held in compliance with current Good Manufacturing Practices (cGMP) in accordance with the applicable parts of 21 CFR, parts 210 and 211 of the Code of Federal Regulations.

Catalog Number	Product Name
M1804	Mecobalamin, JP

Spectrum is an FDA registered and inspected Drug Establishment. Our United States Food and Drug Administration (USFDA) Registration numbers are as follows:

Spectrum-Gardena, CA: 2020632  
Spectrum-New Brunswick, NJ: 2246824

Thank you for your interest in Spectrum products. If we may be of further assistance, please feel free to contact the Quality Assurance department at 310-516-8000 or via email at [qualityassurance@spectrumchemical.com](mailto:qualityassurance@spectrumchemical.com)

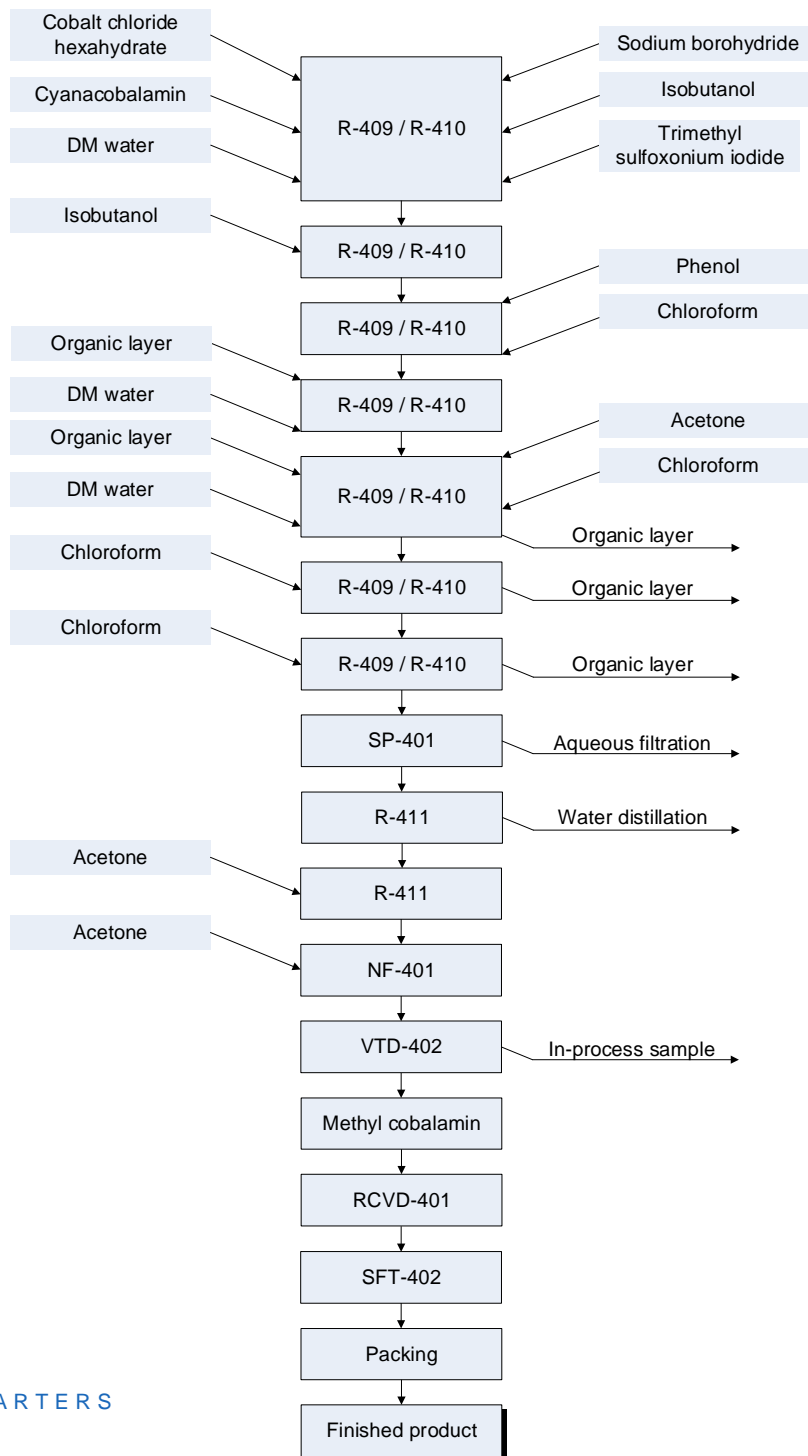
Sincerely,

A handwritten signature in black ink, appearing to read "Oralia Chavez", written in a cursive style.

Oralia Chavez  
Quality Assurance Specialist

## Manufacturing Process Flowchart

### Mecobalamin, JP - M1804



#### CORPORATE HEADQUARTERS

769 Jersey Avenue

New Brunswick, NJ 08901

PHONE 732.214.1300

FAX 732.246.7132

#### WEST COAST FACILITY

14422 South San Pedro Street

Gardena, California 90248

PHONE 310.516.8000

FAX 310.516.9843

## **M1804, Mecobalamin, JP**

### **Source Statement**

The above mentioned catalog item is manufactured by chemical synthesis. No animal or plant derived products are used in the manufacturing process.

### **BSE/TSE Statement**

The above mentioned catalog item does not contain nor is manufactured using any animal derived products and is therefore, BSE/TSE free.

### **Allergen Statement**

The above mentioned catalog item does not contain any of the following:

- Milk
- Egg
- Fish
- Shellfish
- Tree Nuts
- Wheat
- Peanuts
- Soy
- Cereals containing Gluten
- Celery
- Mustard
- Sesame Seed
- Corn
- Latex
- Sulfites > 10 ppm

### **EU Fragrance Allergen Statement**

The above mentioned catalog item does not contain any of the 26 EU fragrance allergens listed in Annex III lines 67-92. These substances are not intentionally added to the above mentioned catalog item and therefore are not expected to be present.

### **GMO Statement**

The above mentioned catalog item is manufactured without the use of genetically modified organisms and is therefore GMO free.

### **Melamine Statement**

The above mentioned catalog does not use or add melamine to the manufacturing process and is considered melamine-free.

## Nitrosamine Statement

Based on knowledge of the manufacturing process, nitrosamine impurities are not known or suspected to be present in this material.

## Animal Testing Statement

The above mentioned catalog item has not been tested on animals.

## Organic Compliance Statement

The above mentioned catalog item has not been produced using GMOs, irradiation, ethylene oxide (EtO) or sewage sludge.

## Shelf Life Statement

The above mentioned catalog item is typically assigned a shelf life of 48 months from the date of manufacture. The actual assigned shelf life for any specific lot should be referenced on the Certificate of Analysis.

## Other Chemicals Statement

Spectrum does not have any reason to suspect the above mentioned catalog item contains any of the following chemicals. This product does not come into contact with these chemicals during packaging or storage:

- |                     |                 |
|---------------------|-----------------|
| • Aflatoxins        | • Parabens      |
| • Antibiotics       | • Pesticides    |
| • Bisphenol A (BPA) | • Phthalates    |
| • CMR Substances    | • Preservatives |



**RE: Residual Solvents - Mecobalamin, JP (Cat# M1804)**

To Whom It May Concern:

Thank you for your interest in Spectrum high quality chemicals.

The above mentioned catalog item complies with the requirements of USP <467> Residual Solvents and ICH Q3C Residual Solvents Guideline. The following solvents are likely to be present:

Residual Solvent	Class	Expected Concentration
Chloroform	2	< 60 ppm
Methanol	2	< 3000 ppm
Acetone	3	< 5000 ppm
2-Butanol	4	< 5000 ppm

No Class 1 or other solvents are used or produced in the manufacturing process of this material.

For lot-specific information, please refer to the respective Certificate of Analysis.

If you have any further questions, please contact us by telephone at 1(800)772-8786 Option 2, or by email at [TechServices@spectrumchemical.com](mailto:TechServices@spectrumchemical.com).

Sincerely,

Technical Services  
Spectrum Chemical Mfg. Corp.

This document has been produced electronically and is valid without a signature.

CORPORATE HEADQUARTERS

769 Jersey Avenue

New Brunswick, NJ 08901

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WEST COAST FACILITY

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PHONE 310.516.8000

FAX 310.516.9843

## Label Information

The Spectrum label presents technical and safety information in an easily understood format. Our technical specialists stay abreast of the latest requirements of the Globally Harmonized System for Classification and Labelling of Chemicals (GHS), as well as the Occupational Safety and Health Administration (OSHA), the Food and Drug Administration (FDA) and other government regulatory agencies in order to ensure compliance, accuracy and concise hazard communication. Below you will find a typical label example for this catalog item.

**USE CARE:** This material has been evaluated per GHS/OSHA criteria and is not classified as hazardous. All chemicals may pose unknown hazards and must be used with caution. Use personal protection and safe handling methods consistent with proper workplace safety practices. Consult SDS for additional properties and precautions. If adverse reaction occurs seek medical attention.

**KEEP FROM CHILDREN**

**M1804**

**SIZ SY**

**Mecobalamin**

**JP**

CAS 13422-55-4

**CAUTION:** For manufacturing, processing or repacking.

**Read and understand the label and Safety Data Sheet (SDS) prior to use.**

**Chemical Emergency: (800)424-9300**

[www.SpectrumChemical.com](http://www.SpectrumChemical.com)

### REFRIGERATE

$C_{63}H_{91}CoN_{13}O_{14}P$  F.W. 1344.40

Manufacturer/Supplier Code ..... ?

Manufacturer Lot Number..... ?

Assay (Anhydrous Basis) ..... 98.0-101.0%

Clarity and Color of Solution ..... To pass test

#### MAXIMUM LIMITS

Water ..... 12%

Related Substances..... To pass test

Residual Solvents ..... To pass test

**LIGHT SENSITIVE:** Keep tightly closed in light-resistant containers.

Repackaged by Spectrum as:

G 5/16GHS-A ? Lot No. XQ####

### Spectrum Chemical Mfg Corp

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