

# **Scientific Documentation**

# Cyanocobalamin, USP, bioCERTIFIED (TM)

Not appropriate for regulatory submission. Please visit 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





# **Table of Contents**

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# Specification for Cyanocobalamin, USP, bioCERTIFIED (TM) (CY901)

Item Number	CY901
Item	Cyanocobalamin, USP, bioCERTIFIED (TM)
CAS Number	68-19-9
Molecular Formula	C <sub>63</sub> H <sub>88</sub> CoN <sub>14</sub> O <sub>14</sub> P
Molecular Weight	1355.37
MDL Number	
Synonyms	Vitamin B12 ; Cyanocobalamin

Test	Sp	ecification
	Min	Max
ASSAY (DRIED BASIS)	96.0	102.0 %
LOSS ON DRYING		12.0 %
RELATED COMPOUNDS:		
7B,8B-LACTOCYANOCOBALAMIN		1.0 %
50-CARBOXYCYANOCOBALAMIN		0.5 %
34-METHYLCYANOCOBALAMIN		2.0 %
32-CARBOXYCYANOCOBALAMIN		1.0 %
8-EPI-CYANOCOBALAMIN		1.0 %
ANY OTHER UNIDENTIFIED IMPURITY		0.5 %
TOTAL IMPURITIES		3.0 %
ELEMENTAL IMPURITIES		AS REPORTED
MICROBIAL LIMITS:		
BACTERIAL ENDOTOXIN		0.4 USP EU/ug
TOTAL AEROBIC MICROBIAL COUNT		10³cfu/g
TOTAL YEASTS AND MOLDS COUNT		10²cfu/g
IDENTIFICATION	TO PASS TEST	
EXPIRATION DATE		
DATE OF MANUFACTURE		
APPEARANCE		

Test	Specification	
	Min	Max
RESIDUAL SOLVENTS		TO PASS TEST

#### Spectrum Chemical Mfg Corp

Corporate Headquarters:	West Coast Facility:
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	CY901	Lot Number	4LJ0002
Item	Cyanocobalamin, USP, bioCERTIFIED (TM)	Manufacturer Lot	CNN-152207
CAS Number	68-19-9	Manufacturer Code	13524
Molecular Formula	C <sub>63</sub> H <sub>88</sub> CoN <sub>14</sub> O <sub>14</sub> P	Molecular Weight	1355.37

TECT	SPECIFICATION		DECULT
TEST	MIN	MAX	RESULT
ASSAY (DRIED BASIS)	96.0	102.0 %	97.4 %
LOSS ON DRYING		12.0 %	3.1 %
RELATED COMPOUNDS:			
7B,8B-LACTOCYANOCOBALAMIN		1.0 %	0.0 %
50-CARBOXYCYANOCOBALAMIN		0.5 %	0.0 %
34-METHYLCYANOCOBALAMIN		2.0 %	0.0 %
32-CARBOXYCYANOCOBALAMIN		1.0 %	0.0 %
8-EPI-CYANOCOBALAMIN		1.0 %	0.0 %
ANY OTHER UNIDENTIFIED IMPURITY		0.5 %	0.0 %
TOTAL IMPURITIES		3.0 %	0.0 %
ELEMENTAL IMPURITIES		AS REPORTED	COMPLIES WITH STANDARD
MICROBIAL LIMITS:			
BACTERIAL ENDOTOXIN		0.4 USP EU/ug	<0.4 USP EU/ug
TOTAL AEROBIC MICROBIAL COUNT		10³cfu/g	<10 <sup>3</sup> cfu/g
TOTAL YEASTS AND MOLDS COUNT		10²cfu/g	<10²cfu/g
IDENTIFICATION	TO PASS TEST		PASSES TEST
EXPIRATION DATE			31-JUL-2025
DATE OF MANUFACTURE			01-JUL-2022
APPEARANCE			DARK RED CRYSTALS
RESIDUAL SOLVENTS		TO PASS TEST	
CLASS 3 (solvent) / ACETONE			<5000 ppm

Certificate of Analysis Results Entered By:

SVANGOOR Swetha Vangoor 17-NOV-22 08:34:15

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 Interquim, S.A. de C.V. at Guillermo Marconi No. 16, Fracc. Parque Industrial Cuamatla, Cuautitlan Izcalli, Estado de Mexico 54730, Mexico (MEX). 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.

Certificate of Analysis Results Approved By:

AWILLIAMS Allison Williams 17-NOV-22 08:34:27

# SAFETY DATA SHEET

Revision date 04-October-2022

Product identifierProduct NameCYANOCOBALAMIN, USP, bioCERTIFIED™Droduct Code(s)CY901Product Code(s)NoneSynonymsNoneRecommended use of the chemicatory testrictions on useRecommended useNo information availableRestrictions on useNo information availableDetaits of the supplier of the safet estrectSupplier Address Spectrum Chemical Mfg. Corp. Stardena, CA 990248 (30) 516-8000	1. Identification	
Other means of identification   CY901     Product Code(s)   CY901     Synonyms   None     Recommended use of the chemical and restrictions on use     Recommended use   No information available     Restrictions on use   No information available     Details of the supplier of the safety data sheet     Supplier Address   Spectrum Chemical Mfg. Corp.     14422 South San Pedro St.   Gardena, CA 90248	Product identifier	
Product Code(s)CY901SynonymsNoneRecommended use of the chemical restrictions on useRecommended useNo information availableRestrictions on useNo information availableDetails of the supplier of the safet sheetSupplier Address Spectrum Chemical Mfg. Corp. 14422 South San Pedro St. Gardena, CA 90248	Product Name	CYANOCOBALAMIN, USP, bioCERTIFIED™
SynonymsNoneRecommended use of the chemical and restrictions on useRecommended useNo information availableRestrictions on useNo information availableDetails of the supplier of the safety data sheetSupplier Address Spectrum Chemical Mfg. Corp. 14422 South San Pedro St. Gardena, CA 90248	Other means of identification	
Recommended use of the chemical and restrictions on use     Recommended use   No information available     Restrictions on use   No information available     Details of the supplier of the safety data sheet     Supplier Address     Spectrum Chemical Mfg. Corp.     14422 South San Pedro St.     Gardena, CA 90248	Product Code(s)	CY901
Recommended use   No information available     Restrictions on use   No information available     Details of the supplier of the safety data sheet.     Supplier Address     Spectrum Chemical Mfg. Corp.     14422 South San Pedro St.     Gardena, CA 90248	Synonyms	None
Restrictions on use No information available   Details of the supplier of the safety data sheet.   Supplier Address   Spectrum Chemical Mfg. Corp.   14422 South San Pedro St.   Gardena, CA 90248	Recommended use of the chemical	and restrictions on use
Details of the supplier of the safety data sheet       Supplier Address       Spectrum Chemical Mfg. Corp.       14422 South San Pedro St.       Gardena, CA 90248	Recommended use	No information available
Supplier Address Spectrum Chemical Mfg. Corp. 14422 South San Pedro St. Gardena, CA 90248	Restrictions on use	No information available
Spectrum Chemical Mfg. Corp. 14422 South San Pedro St. Gardena, CA 90248	Details of the supplier of the safety	data sheet
	Spectrum Chemical Mfg. Corp. 14422 South San Pedro St. Gardena, CA 90248 (310) 516-8000	
Emergency telephone number	Emergency telephone number	

**Emergency Telephone** 

Chemtrec 1-800-424-9300

#### 2. Hazard(s) identification

#### **Classification**

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

#### Hazards not otherwise classified (HNOC)

Not applicable

#### Label elements

#### Hazard statements

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

Physical state Solid

Odor No information available



**Revision Number** 1

#### **Precautionary Statements - Storage**

Store locked up.

#### **Precautionary Statements - Disposal**

Dispose of contents/container to an approved waste disposal plant

#### Other information

No information available.

#### 3. Composition/information on ingredients

#### Substance

Chemical name	CAS No	Weight-%
Cyanocobalamin	68-19-9	100

#### 4. First-aid measures

#### **Description of first aid measures**

General advice	IF exposed or concerned: Get medical advice/attention.	
Inhalation	Remove to fresh air.	
Eye contact	Rinse thoroughly with plenty of water for at least 15 minutes, lifting lower and upper eyelids. Consult a physician.	
Skin contact	Wash skin with soap and water.	
Ingestion	Clean mouth with water and drink afterwards plenty of water.	
Most important symptoms and effe	cts, both acute and delayed	
Symptoms	No information available.	
Indication of any immediate medica	al attention and special treatment needed	
Note to physicians	Treat symptomatically.	

#### 5. Fire-fighting measures

Suitable Extinguishing Media Large Fire	Use extinguishing measures that are appropriate to local circumstances and the surrounding environment. CAUTION: Use of water spray when fighting fire may be inefficient.
Unsuitable extinguishing media	Do not scatter spilled material with high pressure water streams.
Specific hazards arising from the chemical	No information available.
Hazardous combustion products	Carbon Monoxide, Carbon Dioxide. Nitrogen oxides (NOx). Phosphorus oxides. Cobalt oxides.
Explosion data Sensitivity to mechanical impac	ct none.
Sensitivity to static discharge	none.

Firefighters should wear self-contained breathing apparatus and full firefighting turnout gear. Use personal protection equipment.

#### 6. Accidental release measures

Personal precautions, protective equipment and emergency procedures		
Personal precautions	Ensure adequate ventilation.	
Other information	Refer to protective measures listed in Sections 7 and 8.	
Methods and material for containment and cleaning up		
Methods for containment	Prevent further leakage or spillage if safe to do so.	
Methods for cleaning up	Pick up and transfer to properly labeled containers.	

7. Handling and storage		
Precautions for safe handling		
Advice on safe handling	Handle in accordance with good industrial hygiene and safety practice. Avoid contact with skin, eyes or clothing.	
Conditions for safe storage, including any incompatibilities		
Storage Conditions	Keep container tightly closed in a dry and well-ventilated place.	

#### 8. Exposure controls/personal protection

Control parameters		
Exposure Limits	The following ingredients are the only ingredients of the product above the cut-off level (or level that contributes to the hazard classification of the mixture) which have an exposure limit applicable in the region for which this safety data sheet is intended or other recommended limit. At this time, the other relevant constituents have no known exposure limits from the sources listed here.	
Appropriate engineering controls		
Engineering controls	Showers Eyewash stations Ventilation systems.	
Individual protection measures, such as personal protective equipment		
Eye/face protection	No special protective equipment required.	
Hand protection	Wear suitable gloves.	
Skin and body protection	Wear suitable protective clothing.	
Respiratory protection	No protective equipment is needed under normal use conditions. If exposure limits are exceeded or irritation is experienced, ventilation and evacuation may be required.	
General hygiene considerations	Do not eat, drink or smoke when using this product. Wash hands before breaks and	

# 9. Physical and chemical properties

Information on basic physical and	chemical properties	
Physical state	Solid	
Appearance	Powder or Crystalline powder	
Color	dark red	
Odor	No information available	
Odor threshold	No information available	
Property_	Values	Remarks • Method
рН	Slightly Acidic	None known
Melting point / freezing point	> 300 °C / 572 °F	None known
Boiling point / boiling range	no data available	None known
Flash point	no data available	None known
Evaporation rate	no data available	None known
Flammability (solid, gas)	no data available	None known
Flammability Limit in Air		None known
Upper flammability or explosive limits	No data available	
Lower flammability or explosive limits	No data available	
Vapor pressure	No data available	None known
Vapor density	no data available	None known
Relative density	no data available	None known
Water solubility	Slightly soluble in water	None known
Solubility(ies)	Soluble in hot alcohol	None known
	Insoluble in Acetone	
	Insoluble in Chloroform	
Partition coefficient	No data available	None known
Autoignition temperature	no data available	None known
Decomposition temperature		None known
Kinematic viscosity	no data available	None known
Dynamic viscosity	No data available	None known
Other information		
Explosive properties	No information available	
Oxidizing properties	No information available	
Softening point	No information available	
Molecular weight	No information available	
VOC Content (%)	No information available	
Liquid Density	No information available	
Bulk density	No information available	

# 10. Stability and reactivity

Reactivity	No information available.
Chemical stability	Stable under normal conditions.
Possibility of hazardous reactions	None under normal processing.
Conditions to avoid	None known based on information supplied.
Incompatible materials	None known based on information supplied.
llessed and de service stitle a une de ste	New design has a day information associated

#### Hazardous decomposition products None known based on information supplied.

#### 11. Toxicological information

Information on likely routes of exposure

Product Information	
Inhalation	Specific test data for the substance or mixture is not available.
Eye contact	Specific test data for the substance or mixture is not available.
Skin contact	Specific test data for the substance or mixture is not available.
Ingestion	Specific test data for the substance or mixture is not available.
Symptoms related to the physical, or	chemical and toxicological characteristics
Symptoms	No information available.

#### Acute toxicity

#### Numerical measures of toxicity No information available

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

Skin corrosion/irritation Serious eye damage/eye irritation Respiratory or skin sensitization Germ cell mutagenicity	No information available. No information available. No information available. No information available.
Reproductive toxicity	No information available.
STOT - single exposure STOT - repeated exposure Aspiration hazard	No information available. No information available. No information available.
Other adverse effects	No information available.
Interactive effects	No information available.

# 12. Ecological information

Ecotoxicity	The environmental impact of this product has not been fully investigated.
Persistence and degradability Bioaccumulation	No information available. Inherently biodegradable.
Other adverse effects	No information available.

13. Disposal consideration	ons
Waste treatment methods	
Waste from residues/unused products	Dispose of in accordance with local regulations. Dispose of waste in accordance with environmental legislation.
Contaminated packaging	Do not reuse empty containers.

14. Transport information	

DOT	not regulated
TDG	not regulated
MEX	not regulated
ICAO (air)	not regulated
IATA	not regulated
IMDG_	not regulated
RID	not regulated
ADR	not regulated
ADN	not regulated

#### 15. Regulatory information

International Inventories

TSCA	Complies
DSL/NDSL	Complies
EINECS/ELINCS	Complies
ENCS	This product complies with ENCS:
IECSC	This product complies with China:
KECL	Complies
PICCS	Complies
AICS	All the constituents of this material are listed on the Australian Inventory of Chemical Substances (AICS).

Legend:

**TSCA** - United States Toxic Substances Control Act Section 8(b) Inventory

DSL/NDSL - Canadian Domestic Substances List/Non-Domestic Substances List

**EINECS/ELINCS** - European Inventory of Existing Chemical Substances/European List of Notified Chemical Substances **ENCS** - Japan Existing and New Chemical Substances

**IECSC** - China Inventory of Existing Chemical Substances

KECL - Korean Existing and Evaluated Chemical Substances

**PICCS** - Philippines Inventory of Chemicals and Chemical Substances

#### US Federal Regulations

#### SARA 313

Section 313 of Title III of the Superfund Amendments and Reauthorization Act of 1986 (SARA). This product contains a chemical or chemicals which are subject to the reporting requirements of the Act and Title 40 of the Code of Federal Regulations, Part 372.

Chemical name	SARA 313 - Threshold Values %
Cyanocobalamin - 68-19-9	1.0

#### SARA 311/312 Hazard Categories

Should this product meet EPCRA 311/312 Tier reporting criteria at 40 CFR 370, refer to Section 2 of this SDS for appropriate classifications.

#### **CWA (Clean Water Act)**

This product does not contain any substances regulated as pollutants pursuant to the Clean Water Act (40 CFR 122.21 and 40 CFR 122.42).

#### **CERCLA**

This material, as supplied, does not contain any substances regulated as hazardous substances under the Comprehensive Environmental Response Compensation and Liability Act (CERCLA) (40 CFR 302) or the Superfund Amendments and Reauthorization Act (SARA) (40 CFR 355). There may be specific reporting requirements at the local, regional, or state level pertaining to releases of this material.

#### US State Regulations

#### California Proposition 65

This product does not contain any Proposition 65 chemicals.

#### U.S. State Right-to-Know Regulations

This product does not contain any substances regulated under applicable state right-to-know regulations

#### U.S. EPA Label Information

EPA Pesticide Registration Number Not applicable

#### 16. Other information

NFPA Health hazards 0 Flammability 0 Instability 0 Physical and chemical properties -HMIS Health hazards 1\* Flammability 0 Physical hazards 0 Personal protection X Chronic Hazard Star Legend \* = Chronic Health Hazard Key or legend to abbreviations and acronyms used in the safety data sheet Legend Section 8: EXPOSURE CONTROLS/PERSONAL PROTECTION STEL (Short Term Exposure Limit) TWA TWA (time-weighted average) STEL Ceiling Maximum limit value Key literature references and sources for data used to compile the SDS Agency for Toxic Substances and Disease Registry (ATSDR) U.S. Environmental Protection Agency ChemView Database European Food Safety Authority (EFSA) EPA (Environmental Protection Agency) Acute Exposure Guideline Level(s) (AEGL(s)) U.S. Environmental Protection Agency Federal Insecticide, Fungicide, and Rodenticide Act U.S. Environmental Protection Agency High Production Volume Chemicals Food Research Journal Hazardous Substance Database International Uniform Chemical Information Database (IUCLID) Japan GHS Classification Australia National Industrial Chemicals Notification and Assessment Scheme (NICNAS) NIOSH (National Institute for Occupational Safety and Health) National Library of Medicine's ChemID Plus (NLM CIP) National Library of Medicine's PubMed database (NLM PUBMED) National Toxicology Program (NTP) New Zealand's Chemical Classification and Information Database (CCID) Organization for Economic Co-operation and Development Environment, Health, and Safety Publications Organization for Economic Co-operation and Development High Production Volume Chemicals Program Organization for Economic Co-operation and Development Screening Information Data Set World Health Organization

Revision date Revision Note 04-October-2022 No information available.

Disclaimer The information provided in this Safety Data Sheet is correct to the best of our knowledge, information and belief at the date of its publication. The information given is designed only as a guidance for safe handling, use, processing, storage, transportation, disposal and release and is not to be considered a warranty or quality specification. The information relates only to the specific material designated and may not be valid for such material used in combination with any other materials or in any process, unless specified in the text.

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
CY901	Cyanocobalamin, USP, bioCERTIFIED ™

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:2020632Spectrum-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 <u>qualityassurance@spectrumchemical.com</u>

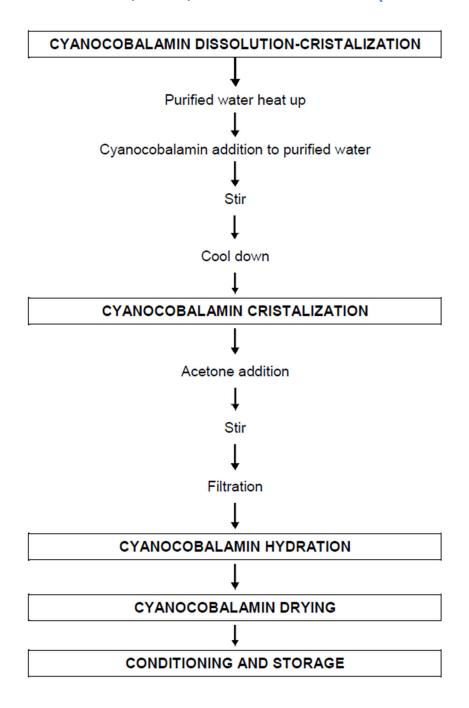
Sincerely,

Oulu Clamy

Oralia Chavez Quality Assurance Specialist



# Manufacturing Process Flowchart Cyanocobalamin, USP, bioCERTIFIED ™ (Cat# CY901)



#### 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

# **Spectrum**<sup>®</sup> **CY901**, Cyanocobalamin, USP, bioCERTIFIED <sup>™</sup>

### **Source Statement**

The above mentioned catalog item is manufactured by fermentation and purification.

### **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 following chemical 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 36 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
- Antibiotics
- Bisphenol A (BPA)
- CMR Substances

- Parabens
- Pesticides
- Phthalates
- Preservatives

#### RE: Elemental Impurities - Cyanocobalamin, USP, bioCERTIFIED ™ (Cat# CY901)

To Whom It May Concern:

Thank you for your interest in Spectrum high quality chemicals.

The above material complies with the USP<232>, <233> Elemental Impurities and the ICH Q3D Elemental Impurities Guideline. The following elemental impurities are likely to be present:

<b>Elemental Impurity</b>		Class	Expected Concentration
Cadmium	Cd	1	< 0.5 ppm
Lead	Pb	1	< 0.5 ppm
Arsenic	As	1	< 1.5 ppm
Mercury	Hg	1	< 3 ppm
Cobalt	Co	2A	< 5 ppm
Vanadium	V	2A	< 10 ppm
Nickel	Ni	2A	< 20 ppm
Thallium	TI	2B	Not tested
Gold	Au	2B	Not tested
Palladium	Pd	2B	Not tested
Iridium	lr	2B	Not tested
Osmium	Os	2B	Not tested
Rhodium	Rh	2B	Not tested
Ruthenium	Ru	2B	Not tested
Selenium	Se	2B	Not tested
Silver	Ag	2B	Not tested
Platinum	Pt	2B	Not tested
Lithium	Li	3	Not tested
Antimony	Sb	3	Not tested
Barium	Ba	3	Not tested
Molybdenum	Мо	3	Not tested
Copper	Cu	3	Not tested
Tin	Sn	3	Not tested
Chromium	Cr	3	Not tested

Elements indicated as "Not tested" are not intentionally added to the manufacturing process.

Other elemental impurities considered by USP <232>, <233> and ICH Q3D which are not addressed in the above mentioned table are not likely to be present. These

CORPORATE HEADQUARTERS

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AN ISO 9001:2015 REGISTERED COMPANY

substances are not used in the production process, are not intentionally added or known to be present in the above mentioned material.

This information is subject to change and is intended for risk assessment only. It is responsibility of the end user to evaluate suitability of any chemical for the intended use as well as to assess compound-specific limits of daily intake of metal impurities. 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 <u>TechServices@spectrumchemical.com</u>.

Sincerely,

Technical Services Spectrum Chemical Mfg. Corp.

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

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AN ISO 9001:2015 REGISTERED COMPANY

www.spectrumchemical.com

#### RE: Residual Solvents - Cyanocobalamin, USP, bioCERTIFIED ™ (Cat# CY901)

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
Acetone	3	< 5000 ppm

No Class 1, Class 2 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 <u>TechServices@spectrumchemical.com</u>.

Sincerely,

Technical Services Spectrum Chemical Mfg. Corp.

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

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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

AN ISO 9001:2015 REGISTERED COMPANY

www.spectrumchemical.com

# **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.

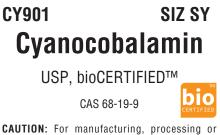


**USE CARE:** This material has been evaluated per GHS/OSHA criteria and is not classified as hazardous. All chemicals may pose unknown hazards and must be used with caution. Use personal protection and safe handling methods consistent with proper workplace safety practices. Consult SDS for additional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

**KEEP FROM CHILDREN** 

#### WARNING:

Cancer and Reproductive Harmwww.P65Warnings.ca.gov



repacking. Rx only. Further processing and testing required for use in parenteral applications. Read and understand the label and Safety Data Sheet (SDS) prior to use.

> Chemical Emergency: (800)424-9300 www.SpectrumChemical.com

$C_{63}H_{88}CON_{14}O_{14}P$	F.W. 1355.37
Not sterile.	
Manufacturer/Supplier Code Manufacturer Lot Number	
	00.0.100.000

Assay (Dried Basis)	96.0-102.0%			
MAXIMUM LIMITS				
Loss on Drying				
Related Compounds:				
76,86-Lactocyanocobalamin				
50-Carboxycyanocobalamin	0.5%			
34-Methylcyanocobalamin				
32-Carboxycyanocobalamin				
8-Epi-Cyanocobalamin				
Any Other Unidentified Impurity				
Total Impurities				
Elemental İmpurities	As reported			
Residual Solvents	To pass test			
Microbial Limits:				
Bacterial Endotoxins	0.4 USP EU/ua			
Total Aerobic Microbial Count				
Total Yeasts and Molds				

LIGHT SENSITIVE, HYGROSCOPIC: Keep tightly closed in light-resistant containers. Repackaged by Spectrum as:

G 1/I10GHS-A	?	Lot No. XQ####

#### Spectrum Chemical Mfg Corp

#### Corporate Headquarters:

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