

# **Scientific Documentation**

RI103, Riboflavin, USP

Not appropriate for regulatory submission. Please visit <a href="www.spectrumchemical.com">www.spectrumchemical.com</a> 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

### RI103, Riboflavin, USP

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# Spectrum®



Item Number	RI103
Item	Riboflavin, USP
CAS Number	83-88-5
Molecular Formula	$C_{17}H_{20}N_4O_6$
Molecular Weight	376.36
MDL Number	
Synonyms	Vitamin B2; 7,8-Dimethyl-10-(1-D-ribityl)isoalloxazine

Test	Specification		
	Min	Max	
ASSAY (C <sub>17</sub> H <sub>20</sub> N <sub>4</sub> O <sub>6</sub> )	98.0%	102.0 %	
SPECIFIC ROTATION [a] <sub>D</sub>	-115° to -135°		
LOSS ON DRYING		1.5 %	
RESIDUE ON IGNITION		0.3 %	
LUMIFLAVIN		0.025	
ELEMENTAL IMPURITIES:			
CADMIUM (Cd)	AS REPORTED		
LEAD (Pb)	AS REPORTED		
ARSENIC (As)	AS REPORTED		
MERCURY (Hg)	AS REPORTED		
IDENTIFICATION	PALE GREENISH YELLOW WITH YELLOWISH-GREEN FLUORESCENCE		
CERTIFIED KOSHER			
CERTIFIED HALAL			
APPEARANCE			
EXPIRATION DATE			
DATE OF MANUFACTURE			
RESIDUAL SOLVENTS	AS REPORTED		
MONOGRAPH EDITION			

### 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	RI103	Lot Number	1KJ0921
Item	Riboflavin, USP	CAS Number	83-88-5
Molecular Formula	$C_{17}H_{20}N_4O_6$	Molecular Weight	376.36

TECT	SPECIFI	CATION	DECILIT.
TEST	MIN	MAX	RESULT
ASSAY (C <sub>17</sub> H <sub>20</sub> N <sub>4</sub> O <sub>6</sub> )	98.0%	102.0 %	98.6 %
SPECIFIC ROTATION [a] <sub>D</sub>	-115° to -135°		-120.0°
LOSS ON DRYING		1.5 %	0.3 %
RESIDUE ON IGNITION		0.3 %	0.1 %
LUMIFLAVIN		0.025	0.004
ELEMENTAL IMPURITIES:			COMPLIES WITH STANDARD
IDENTIFICATION	PALE GREENISH YELLOW WITH YELLOWISH- GREEN FLUORESCENCE		PALE GREENISH YELLOW WITH YELLOWISH-GREEN FLUORESCENCE
CERTIFIED KOSHER			CERTIFIED KOSHER
CERTIFIED HALAL			CERTIFIED HALAL
APPEARANCE			YELLOW-ORANGE CRYSTALLINE POWDER
EXPIRATION DATE			26-MAR-2024
DATE OF MANUFACTURE			27-MAR-2021
RESIDUAL SOLVENTS	AS REPORTED		NO RESIDUAL SOLVENTS USED
MONOGRAPH EDITION			(USP) 43

Spectrum Chemical Mfg Corp 14422 South San Pedro Street Gardena 90248 CA



Certificate of Analysis Results Certified By:

Jigisha Patel

VP Regulatory Compliance & Technical Services, Regulatory

igisha Patel.

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.

The Elemental Impurities standards implemented by USP and other Pharmaceutical Compendia reflect a growing understanding of the toxicology of trace levels of elemental impurities that can remain in drug substances originating from either raw materials or manufacturing processes. Identifying and quantifying impurities can be critical to predicting the best possible patient outcomes. Elemental Impurities has been a requirement of all products meeting USP/NF, EP and BP monographs since January 1, 2018. More information can be found in USP sections <232> Elemental Impurities – Limits and <233> Elemental Impurities – Procedures. Data for drug substances furnished by Spectrum Chemical Mfg. Corp can be used to ensure that patient daily exposures by oral administration to the selected elements are not exceeded in the formulation of pharmaceutical products.





# SAFETY DATA SHEET

Preparation Date: 02/16/2015 Revision Date: 6/13/2018 Revision Number: G3

### 1. IDENTIFICATION

Product identifier

Product code: RI103

Product Name: RIBOFLAVIN, USP

Other means of identification

Synonyms: Vitamin B2; 7,8-Dimethyl-10-(D-ribo-2,3,4,5-tetrahydroxypentyl)isoalloxazine

CAS #: 83-88-5
RTECS # VJ1400000
CI#: Not available

Recommended use of the chemical and restrictions on use

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

Supplier: Spectrum Chemical Mfg. Corp

14422 South San Pedro St. Gardena, CA 90248

(310) 516-8000

Order Online At: <a href="https://www.spectrumchemical.com">https://www.spectrumchemical.com</a>

Emergency telephone numberChemtrec 1-800-424-9300Contact Person:Martin LaBenz (West Coast)Contact Person:Ibad Tirmiz (East Coast)

### 2. HAZARDS IDENTIFICATION

### Classification

This chemical is not considered hazardous according to 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

Product code: RI103 Product name: RIBOFLAVIN, USP 1/10

Components	CAS-No.	Weight %
Riboflavin	83-88-5	100

### 4. FIRST AID MEASURES

First aid measures

General Advice: 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.

**Skin Contact:** 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.

Eye Contact: Flush eyes with water for 15 minutes. Get medical attention if irritation occurs. If symptoms

persist, call a physician.

**Inhalation:** Move to fresh air. If not breathing, give artificial respiration. If breathing is difficult, give

oxygen. Get medical attention.

**Ingestion:** 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

Symptoms Health injuries are not known or expected under normal use

Indication of any immediate medical attention and special treatment needed

Notes to Physician: Treat symptomatically.

**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** 

Suitable Extinguishing Media: Carbon dioxide (CO2). Dry chemical. Water spray mist or

foam.

Unsuitable Extinguishing Media: No information available.

Specific hazards arising from the chemical

Hazardous Combustion Products: Carbon Monoxide, Carbon Dioxide. Nitrogen Oxides.

**Specific hazards:** May be combustible at high temperatures.

**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

Product code: RI103 Product name: RIBOFLAVIN, USP 2 / 10

### 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. 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. All equipment used when handling the product must be grounded. 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 container tightly closed in a dry and well-ventilated place. Store at room temperature in the original container. Protect from light. Sensitive to light. Store in light-resistant containers. Store away from incompatible materials.

### **Incompatible Materials:**

Strong oxidizing agents

### 8. EXPOSURE CONTROLS/PERSONAL PROTECTION

### Control parameters

### National occupational exposure limits

### **United States**

Components	CAS-No.	OSHA	NIOSH	ACGIH	AIHA WEEL
Riboflavin	83-88-5	None	None	None	None

### Canada

Components	CAS-No.	Canada - Alberta	Canada - British Columbia	Canada - Ontario	Canada - Quebec
Riboflavin	83-88-5	None	None	None	None

### **Australia and Mexico**

_				
	Components	CAS-No.	Australia	Mexico

Product code: RI103 Product name: RIBOFLAVIN, USP 3 / 10

Riboflavin	83-88-5	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

Vapor pressure @ 20°C (kPa):

below the exposure limit.

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

### **Personal Protective Equipment**

**Eye protection:** Goggles or Safety glasses with side-shields

**Skin and body protection:** Chemical resistant apron

Gloves

Long sleeved clothing

**Respiratory protection:** 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.

**Hygiene measures:** 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

Physical state: Appearance: Color:

Solid Crystalline powder. Yellow. Orange to Red-Brown.

Odor:TasteFormula:No information available.Bitter.C17H20N4O6

Molecular/Formula weight: Flammability: Flashpoint (°C/°F):
376.36 Flammability: Flashpoint (°C/°F):
No information available.

Flash Point Tested according to: Autoignition Temperature (°C/°F): Lower Explosion Limit (%): Not available

No information available

No information available

Upper Explosion Limit (%): Melting point/range(°C/°F): Decomposition temperature(°C/°F):

No information available No information available 280°C/536°F

:Ha

Boiling point/range(°C/°F): Bulk density: Density (g/cm3):
No information available No information available

No information available No information available No information available

**Evaporation rate:** Vapor density: VOC content (g/L):
No information available
No information available

Odor threshold (ppm): Partition coefficient
No information available (n-octanol/water):

Specific gravity:

Product code: RI103 Product name: RIBOFLAVIN, USP 4/10

No information available

Viscosity:

No information available

Miscibility:

Solubility:

No information available

Very slightly soluble in cold water

Insoluble in Ether Insoluble in acids Insoluble in Chloroform Slightly soluble in Ethanol

### **10. STABILITY AND REACTIVITY**

Reactivity

Reactive with oxidizing agents

**Chemical stability** 

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

Possibility of Hazardous Reactions: Hazardous polymerization does not occur

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

Incompatible Materials: Strong oxidizing agents

Hazardous decomposition

products:

Carbon oxides. Nitrogen oxides (NOx).

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.

### **Acute Toxicity**

### **Component Information**

Riboflavin
CAS-No. 83-88-5

LD50/oral/rat = > 10 g/kg Oral LD50 Rat

**LD50/oral/mouse** = No information available

**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 LC50information = No information available

### **Product Information**

LD50/oral/rat =

VALUE- Acute Tox Oral = > 10 g/kg

Product code: RI103 Product name: RIBOFLAVIN, USP 5/10

LD50/oral/mouse =

Value - Acute Tox Oral = No information available

LD50/dermal/rabbit

VALUE-Acute Tox Dermal = 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** Not expected to be a health hazard. 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: Mutations in microorganisms

Experiments with bacteria and/or yeast have shown mutagenic effects

Carcinogenic effects: Not considered carcinogenic.

Components	CAS-No.	IARC	ACGIH - Carcinogens	NTP	OSHA HCS - Carcinogens	Australia - Notifiable Carcinogenic Substances	Australia - Prohibited Carcinogenic Substances
Riboflavin	83-88-5	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

Product code: RI103 Product name: RIBOFLAVIN, USP 6 / 10

Teratogenic Effects: No information available

**Specific Target Organ Toxicity** 

STOT - single exposure STOT - repeated exposure Target Organs:

No information available. No information available.

No information available.

### 12. ECOLOGICAL INFORMATION

**Ecotoxicity** 

**Ecotoxicity effects:** No data available.

Persistence and degradability: No information available

**Bioaccumulative potential:** No information available.

**Mobility:** 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

Components	CAS-No.	RCRA - F Series Wastes	RCRA - K Series Wastes	RCRA - P Series Wastes	RCRA - U Series Wastes
Riboflavin	83-88-5	None	None	None	None

### 14. TRANSPORT INFORMATION

DOT

UN-No: Not Regulated

Proper Shipping Name:
Hazard Class:
Subsidiary Class
Packing group:
No information available

Number

Marine PollutantNo data availableDOT RQ (lbs):No information availableSpecial ProvisionsNo Information availableSymbol(s):No information availableDescription:No information available

TDG (Canada)

UN-No: Not Regulated

Proper Shipping Name:
Hazard Class:
Subsidiary Risk:
No information available
No information available
No information available
No information available

Product code: RI103 Product name: RIBOFLAVIN, USP 7/10

Marine PollutantNo Information availableDescription:No information available

**ADR** 

UN-No: Not Regulated

Proper Shipping Name:
Hazard Class:
No information available

IMO / IMDG

UN-No: Not Regulated

Proper Shipping Name:
Hazard Class:
Subsidiary Risk:
Packing Group:
Marine Pollutant

No information available
No information available
No information available
No information available

RID

UN-No: Not Regulated

Proper Shipping Name:
Hazard Class:
Subsidiary Risk:
No information available
No information available
No information available
No information available

**ICAO** 

UN-No: Not Regulated

Proper Shipping Name:
Hazard Class:
Subsidiary Risk:
No information available
No information available
No information available
No information available

**IATA** 

UN-No: Not Regulated

Proper Shipping Name:
Hazard Class:
Subsidiary Risk:
Packing Group:
ERG Code:
No information available

### 15. REGULATORY INFORMATION

### **International Inventories**

Components	CAS-No.	U.S. TSCA	KOREA KECL	Philippines (PICCS)	Japan ENCS	CHINA	Australia (AICS)	EINECS-No.
Riboflavin	83-88-5	Present(ACTI VE)	Present KE-11845	Present	Present (5)-3909 (9)-2282	Present	Present	Present 201-507-1

### **U.S. Regulations**

Riboflavin

FDA - Food Additives Generally Recognized as Safe (GRAS): 21 CFR 184.1695

FDA - 21 CFR - Total Food Additives 101.9 107.100 136.115 137.165 137.185 137.260 137.305 137.350 139.115 139.122 139.155 184.1695 73.450

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

Product code: RI103 Product name: RIBOFLAVIN, USP 8 / 10

### 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)

Components	CAS-No.	Carcinogen	Developmental Toxicity	Male	Female
			,	Reproductive	Reproductive
				Toxicity	Toxicity:
Riboflavin	83-88-5	Not Listed	Not Listed	Not Listed	Not Listed

### **CERCLA/SARA**

Components	CAS-No.	CERCLA -	Section 302	Section 302	Section 313 -	Section 313 -
		Hazardous	Extremely	Extremely	Chemical Category	Reporting
		Substances and	Hazardous	Hazardous		de minimis
		their Reportable	Substances	Substances and		
		Quantities	and TPQs	RQs		
Riboflavin	83-88-5	None	None	None	None	None

### U.S. TSCA

Components		TSCA Section 5(a)2 - Chemicals With Significant New Use Rules (SNURS)	TSCA 8(d) -Health and Safety Reporting
Riboflavin	83-88-5	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

### WHMIS 1988 Hazard Class

Non-controlled

### **Canada Controlled Products Regulation:**

This product has been classified according to the hazard criteria of the CPR (Controlled Products Regulation) and the MSDS contains all of the information required by the CPR.

### Inventory

Components	CAS-No.	Canada (DSL)	Canada (NDSL)
Riboflavin	83-88-5	Present	Not Listed

Components	CAS-No.	CEPA Schedule I - Toxic Substances
Riboflavin	83-88-5	Not listed
Components	CAS-No.	CEPA - 2010 Greenhouse Gases Subject
		to Mandatory Reporting
Riboflavin	83-88-5	Not listed

### **EU Classification**

### EU GHS - SV - CLP 1272/2008

Components	CAS-No.	EU GHS - SV - CLP (1272/2008)
Riboflavin	83-88-5	

Product code: RI103 Product name: RIBOFLAVIN, USP 9 / 10

### EU - CLP (1272/2008)

### R-phrase(s)

not determined (not applicable)

### S -phrase(s)

none

Components	CAS-No.	Concentration Limits:	Safety Phrases
Riboflavin	83-88-5	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: 02/16/2015
Revision Date: 6/13/2018
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**

Product code: RI103 Product name: RIBOFLAVIN, USP 10 / 10



### 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
RI103	Riboflavin, USP

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 <a href="mailto:qualityassurance@spectrumchemical.com">qualityassurance@spectrumchemical.com</a>

Sincerely,

Oralia Chavez

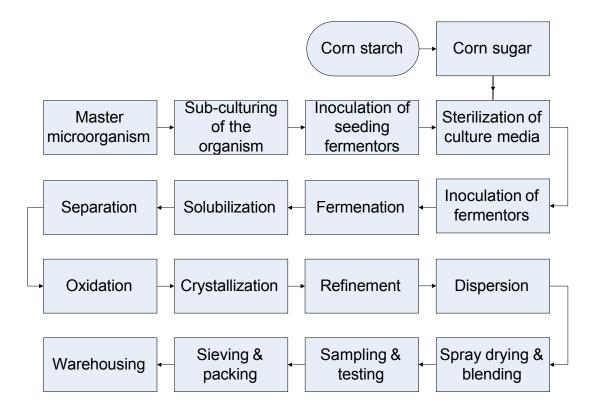
**Quality Assurance Specialist** 

Order Clony



# **Manufacturing Process Flowchart**

# Riboflavin, USP - RI103



### Spectrum Chemical Mfg Corp



# RI103, Riboflavin, USP

### **Source Statement**

The above mentioned catalog item is manufactured by derived plant product: corn starch fermentation. No animal 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 following chemical and therefore are not expected to be present.

### **GMO Statement**

The above mentioned catalog item is manufactured with the use of genetically modified organisms: corn starch.

### **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 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 - Riboflavin, USP (Cat# RI103)

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:

Elemental Impurity		Class	Expected Concentration
Cadmium	Cd	1	< 1 ppm
Lead	Pb	1	< 0.5 ppm
Arsenic	As	1	< 1 ppm
Mercury	Hg	1	< 0.1 ppm
Cobalt	Со	2A	< 1 ppm
Vanadium	V	2A	< 1 ppm
Nickel	Ni	2A	< 1 ppm

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 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 <a href="mailto:TechServices@spectrumchemical.com">TechServices@spectrumchemical.com</a>.

Sincerely,

Technical Services
Spectrum Chemical Mfg. Corp.

CORPORATE HEADQUARTERS

769 Jersey Avenue New Brunswick, NJ 08901 PHONE 732.214.1300 FAX 732.246.7132 WEST COAST FACILITY

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

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Gardena, California 90248
PHONE 310.516.8000
FAX 310.516.9843



### RE: Residual Solvents - Riboflavin, USP (Cat# RI103)

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 the USP <467> Residual Solvents and the ICH Q3C Residual Solvents Guideline. No Class 1, Class 2, Class 3 or other solvents are used or produced in the manufacture of this product.

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 <a href="mailto:TechServices@spectrumchemical.com">TechServices@spectrumchemical.com</a>.

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 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



### **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** 

**RI103** 

SIZ SY

### Assay (Dried Basis) ...... 98.0-102.0% Specific Rotation, $[\alpha]_{n}^{25}$ ......-115° to -135°

 $C_{17}H_{20}N_4O_6$  F.W. 376.36

### MAXIMUM LIMITS

Loss on Drying ......1.5% Residue on Ignition ......0.3% Lumiflavin ......To pass test Elemental Impurities ......As reported Residual Solvents ......To pass test

LIGHT SENSITIVE: Keep tightly closed in lightresistant containers.

FLUSHED WITH NITROGEN

Lot No. XO#### G 10/18GHS

# Riboflavin

(Vitamin B<sub>2</sub>)

KSA

USP

CAS 83-88-5



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

### Spectrum Chemical Mfg Corp

Corporate Headquarters: 769 Jersey Ave. New Brunswick, NJ 08901 West Coast Facility: 14422 S. San Pedro St. Gardena, CA 90248

732.214.1300 310.516.8000



### **RE: Lot Numbering System**

**Dear Valued Customer:** 

This letter is to inform you of Spectrum Chemicals and Laboratory Products' Lot Numbering System. The system is based on an alpha-numerical sequence which provides the month, year and location of production.

The lot numbering system utilized until 2010 is a sequence of **six characters**, two letters followed by four numbers. The first letter represents the year, for example, Y denotes 2009 and Z denotes 2010. The second letter represents the month and site, for example, A-L denotes January through December at Spectrum's Gardena, CA facility, while M-X denotes January through December at the New Brunswick, NJ facility. The following four numbers are sequentially assigned.

**Example**: Zl0928 = The 928<sup>th</sup> material produced in California in September 2010 The lot numbering system utilized for 2011 and forward, is a sequence of **seven characters**. The first character, a number, represents the production facility:

- 1 = Gardena, CA Facility
- 2 = New Brunswick, NJ Facility
- 3 = China Facility
- 4 = Pharmacy, NJ Facility

The second character, a letter, represents the year. For example, A denotes 2011 and B denotes 2012. The third character, a letter, represents the month, with A denoting January and L denoting December. The following four numbers are sequentially assigned.

**Example**: 2AA0706 = The 706<sup>th</sup> material produced in New Jersey in January 2011
Thank you for your interest with Spectrum products. Please feel free to contact us at 310-516-8000 or via email at quality\_assurance@spectrumchemical.com if we may be of further assistance.

Sincerely,

Oralia Chavez,

**Quality Assurance Specialist** 

Ordu Anny

CORPORATEHEADQUARTERS

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



The following product(s) prepared by the named company are certified kosher with the stated requirements:

### **Spectrum Laboratory Products, Inc.**

S-0032

14422 South San Pedro Street Gardena CA 90248 USA

Product Name RI103, Riboflavin, USP

**Brand** Spectrum

UKD-ID KSAV3-B6B2K75

D/P/M P

Symbol Required KSA

This certificate expires on Feb 01, 2023

**Special Conditions** 

Rabbi Binyomin Lisbon Kashrus Administrator

Placing the KSA logo on products not listed above constitutes an un-authorized use of the KSA symbol, which is a federally registered trademark.



# شهادة حلال FANCA HALAL PRODUCT CERTIFICATE

This is to certify that the following product(s) have been produced under the supervision of the Islamic Food and Nutrition Council of America(IFANCA). The production facility as well as component ingredients have been reviewed and approved. The product(s) are in compliance with the halal requirements under Islamic laws.

**Date: November 02, 2021** 

Document #: 11205.11206.II214312

Company Name & Address: Spectrum Laboratory Products, Inc. 755-769 Jersey Ave New Brunswick, New Jersey 08901 USA

Plant Name & Address: Spectrum Laboratory Products, Inc. 769-Jersey Ave New Brunswick, New Jersey 08901 USA

ProductNameProduct CodeHalal-IDProduct Certificate #1. Riboflavin, USPRI103C43355HC-21SP5344

Muhammad Munir Chaudry, Ph.D. President





This Certificate is valid until August 31, 2022 and subject to renewal at that time.



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