



Scientific Documentation

FO105, Folic Acid, Powder, USP

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

Ver4.06 10.August.2022

FO105, Folic Acid, Powder, USP

Table of Contents

- Product Specification
- Certificate of Analysis Sample(s)
- Safety Data Sheet (SDS)
- Certification of Current Good Manufacturing Practices (cGMP)
- Manufacturing Process Flowchart
- Source Statement
- BSE/TSE Statement
- Allergen Statement
- GMO Statement
- Melamine Statement
- Nitrosamine Statement
- Animal Testing Statement
- Organic Compliance Statement
- Shelf Life Statement
- Other Chemicals Statement
- Elemental Impurities Statement
- Residual Solvents Statement
- General Label Information – Sample Label
- General Lot Numbering System Guidance

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- Halal Certificate

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Item Number	FO105
Item	Folic Acid, Powder, USP
CAS Number	59-30-3
Molecular Formula	C ₁₉ H ₁₉ N ₇ O ₆
Molecular Weight	441.40
MDL Number	
Synonyms	N-[4-(2-Amino-4-hydroxypteridin-6-ylmethylamino)benzoyl]-L(+)-glutamic Acid ; Folacin ; Pteroylglutamic Acid

Test	Specification	
	Min	Max
ASSAY (ANHYDROUS BASIS)	97.0	102.0 %
WATER DETERMINATION		8.5 %
RESIDUE ON IGNITION		0.3 %
RELATED COMPOUNDS		2.0 %
ELEMENTAL IMPURITIES:		
CADMIUM (Cd)	AS REPORTED	
LEAD (Pb)	AS REPORTED	
ARSENIC (As)	AS REPORTED	
MERCURY (Hg)	AS REPORTED	
IDENTIFICATION A . ULTRAVIOLET ABSORPTION	The ratio A256 / A365 is 2.80 - 3.00	
CERTIFIED HALAL		
EXPIRATION DATE		
DATE OF MANUFACTURE		
APPEARANCE		
RESIDUAL SOLVENTS:	AS REPORTED	

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

Item Number	FO105	Lot Number	2KH0349
Item	Folic Acid, Powder, USP	CAS Number	59-30-3
Molecular Formula	C ₁₉ H ₁₉ N ₇ O ₆	Molecular Weight	441.40

TEST	SPECIFICATION		RESULT
	MIN	MAX	
ASSAY (ANHYDROUS BASIS)	97.0	102.0 %	99.2 %
WATER DETERMINATION		8.5 %	8.0 %
RESIDUE ON IGNITION		0.3 %	0.08 %
RELATED COMPOUNDS		2.0 %	< 2.0 %
ELEMENTAL IMPURITIES:			COMPLIES WITH STANDARD
CADMIUM (Cd)	AS REPORTED		< 0.5 ppm
LEAD (Pb)	AS REPORTED		< 0.5 ppm
ARSENIC (As)	AS REPORTED		< 0.5 ppm
MERCURY (Hg)	AS REPORTED		< 0.1 ppm
IDENTIFICATION A . ULTRAVIOLET ABSORPTION	The ratio A256 / A365 is 2.80 - 3.00		2.90
CERTIFIED HALAL			CERTIFIED HALAL
EXPIRATION DATE			18-MAY-2023
DATE OF MANUFACTURE			19-MAY-2021
APPEARANCE			ORANGE POWDER
RESIDUAL SOLVENTS:	AS REPORTED		NO RESIDUAL SOLVENTS USED
MONOGRAPH EDITION			(USP) 2021

Spectrum Chemical Mfg Corp
755 Jersey Avenue
New Brunswick 08901 NJ



Certificate of Analysis Results Certified By:

Jigisha Patel

Jigisha Patel
VP Regulatory Compliance & Technical Services,
Regulatory

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: 7/2/15

Revision date 1/10/2019

Revision Number: G2

1. Identification

Product identifier

Product code: FO105
Product Name: FOLIC ACID, POWDER, USP

Other means of identification

Synonyms: N-(4-(((2-Amino-1,4-dihydro-4-oxo-6-pteridiny)l)methyl)amino)benzoyl)-L-glutamic acid
 4-Pteridinol, 2-amino-6-(p-((1,3-dicarboxypropyl)carbamo)l)anilino)methyl)-
 Acifolic
 Folacid
 Folacin
 Folate
 Folbal
 Folcidin
 Folcysteine
 Folettes
 Foliamin
 Folicet
 Folipac
 Folsan
 Folsaure
 Folsav
 Folvite
 Glutamic acid, N-(p-(((2-amino-4-hydroxy-6-pteridiny)l)methyl)amino)benzoyl)-, L-
 Glutamic acid,
 N-(p-(((2-amino-4-hydroxypyrimido(4,5-b)pyrazin-6-yl)methyl)amino)benzoyl)-, L-
 Glutamic acid, pteroyl-, L-
 Incafolic
 L-Glutamic acid,
 N-(4-(((2-amino-1,4-dihydro-4-oxo-6-pteridiny)l)methyl)amino)benzoyl)-
 N-(p-(((2-Amino-4-hydroxy-6-pteridiny)l)methyl)amino)benzoyl)-L-glutamic acid
 Pteroyl-L-glutamic acid
 Pteroyl-L-monoglutamic acid
 Pteroylglutamic acid
 Pteroylmonoglutamate
 Pteroylmonoglutamic acid
 Vitamin B9
 Vitamin M
 L-Glutamic acid,
 N-(4-(((2-amino-3,4-dihydro-4-oxo-6-pteridiny)l)methyl)amino)benzoyl)-

CAS #: 59-30-3
RTECS # LP5425000
CI#: Not available

Recommended use of the chemical and restrictions on use

Product code: FO105

Product name: FOLIC ACID,
 POWDER, USP

Page

Recommended use: Vitamin.
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-%
Folic Acid	59-30-3	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 May cause eye/skin irritation
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: Dry powder. Carbon dioxide (CO₂). 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 (NO_x).

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

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. Avoid dust formation. Avoid dispersal of dust in the air.

Environmental precautions Prevent further leakage or spillage if safe to do so.

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

Product code: FO105

Product name: FOLIC ACID,
POWDER, USP

Page

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. Avoid dust formation. 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. Store away from incompatible materials. Protect from light. Sensitive to light. Store in light-resistant containers.

Incompatible Materials:

Oxidizing agents
Reducing agents

8. EXPOSURE CONTROLS/PERSONAL PROTECTION

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

Component	CAS No	OSHA	NIOSH	ACGIH	AIHA WEEL
Folic Acid	59-30-3	None	None	None	None

Canada

Component	CAS No	Canada - Alberta	Canada - British Columbia	Canada - Ontario	Canada - Quebec
Folic Acid	59-30-3	None	None	None	None

Australia and Mexico

Component	CAS No	Australia	Mexico
Folic Acid	59-30-3	None	None

Appropriate engineering controls

Engineering measures to reduce exposure: Ensure adequate ventilation, especially in confined areas.

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 and face before breaks and immediately after handling the product When using, do not eat, drink or smoke.

9. PHYSICAL AND CHEMICAL PROPERTIES

Physical state: Solid	Appearance: Powder.	Color: Yellow. Yellow Brown. Yellow-orange.
Odor: Odorless.	Taste Tasteless.	Formula C19H19N7O6
Molecular/Formula weight (g/mole): 441.4 g/mole	Flammability (solid, gas) no data available	Flashpoint (°C/°F): No information available
Flash Point Tested according to: Not available	Autoignition Temperature (°C/°F): No information available	Lower Explosion Limit (%): No information available
Upper Explosion Limit (%): No information available	Melting point/range(°C/°F): >285°C/>545°F	Decomposition temperature(°C/°F): No information available
Boiling point/range(°C/°F): No information available	Bulk density: No information available	Density (g/cm3): No information available
Specific gravity: No information available	pH No information available	Vapor pressure @ 20°C (kPa): 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): -2.81	Viscosity: No information available
Miscibility: No information available	Solubility: Very slightly soluble in cold water Very slightly soluble in hot water Very soluble in Methanol Insoluble in diethyl ether, acetone. Insoluble in Chloroform Insoluble in Benzene Very slightly soluble in Ethanol Very slightly soluble in Butanol Relatively soluble in Acetic Acid, Phenol, Pyridine, and in solutions of alkali hydroxides and carbonates. Solubility in water: 0.0016 mg/ml water @25 deg C, 1% in boiling water	

10. STABILITY AND REACTIVITY

Reactivity

Reactive with oxidizing agents

Reactive with reducing agents

Chemical stability

Stability: Sensitive to light. Exposure to light accelerates decomposition. Stable under recommended storage conditions.

Possibility of Hazardous Reactions: Hazardous polymerization does not occur

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

Incompatible Materials: Oxidizing agents
Reducing agents

Hazardous decomposition products: Carbon monoxide. Carbon dioxide. 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:
Inhalation. Ingestion.

Acute Toxicity

Component Information

Folic Acid	
CAS No	59-30-3

- LD50/oral/rat =** No information available
- LD50/oral/mouse =** 10000 mg/kg Oral LD50 Mouse
- 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 = No information available

LD50/oral/mouse =
Value - Acute Tox Oral = 10000 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 No information available. 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
Folic Acid	59-30-3	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.

Product code: FO105

Product name: FOLIC ACID,
POWDER, USP

Page

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
Folic Acid	59-30-3	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.
<i>Folic Acid</i>	59-30-3	PresentACTIVE	Present KE-01305	Present	Not present	Present	Present	Present 200-419-0

U.S. Regulations*Folic Acid*

FDA - Direct Food Additives 21 CFR 172.345
FDA - 21 CFR - Total Food Additives 101.79, 101.9, 107.100, 137.165, 137.185, 137.235, 137.260, 137.305, 137.350, 139.115,
- List Sourced from EAFUS 139.122, 139.155, 172.345, 172.896

California Prop. 65: Safe Drinking Water and Toxic Enforcement Act of 1986.**Chemicals Known to the State of California to Cause Cancer:****Product code:** FO105**Product name:** FOLIC ACID,
POWDER, USP**Page**

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:
Folic Acid	59-30-3	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
Folic Acid	59-30-3	None	None	None	None	None

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
Folic Acid	59-30-3	Not Applicable	Not Applicable

Canada

WHMIS 2015 - GHS Classifications

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

Component Folic Acid 59-30-3 (100)	WHMIS 2015 Hazard Classification 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)
Folic Acid	59-30-3	Present	Not Listed

Component	CAS No	CEPA Schedule I - Toxic Substances
Folic Acid	59-30-3	Not listed
Component	CAS No	CEPA - 2010 Greenhouse Gases Subject to Mandatory Reporting
Folic Acid	59-30-3	Not listed

EU Classification

EU GHS - SV - CLP 1272/2008

Component	CAS No	EU GHS - SV - CLP (1272/2008)
Folic Acid	59-30-3	

EU - CLP (1272/2008)

Product code: FO105

Product name: FOLIC ACID,
POWDER, USP

Page

R-phrase(s)

not determined (not applicable)

S -phrase(s)

none

Component	CAS No	Classification	Concentration Limits:	Safety Phrases
Folic Acid	59-30-3		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: 7/2/15
Revision date 1/10/2019
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
FO105	Folic Acid, Powder, 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

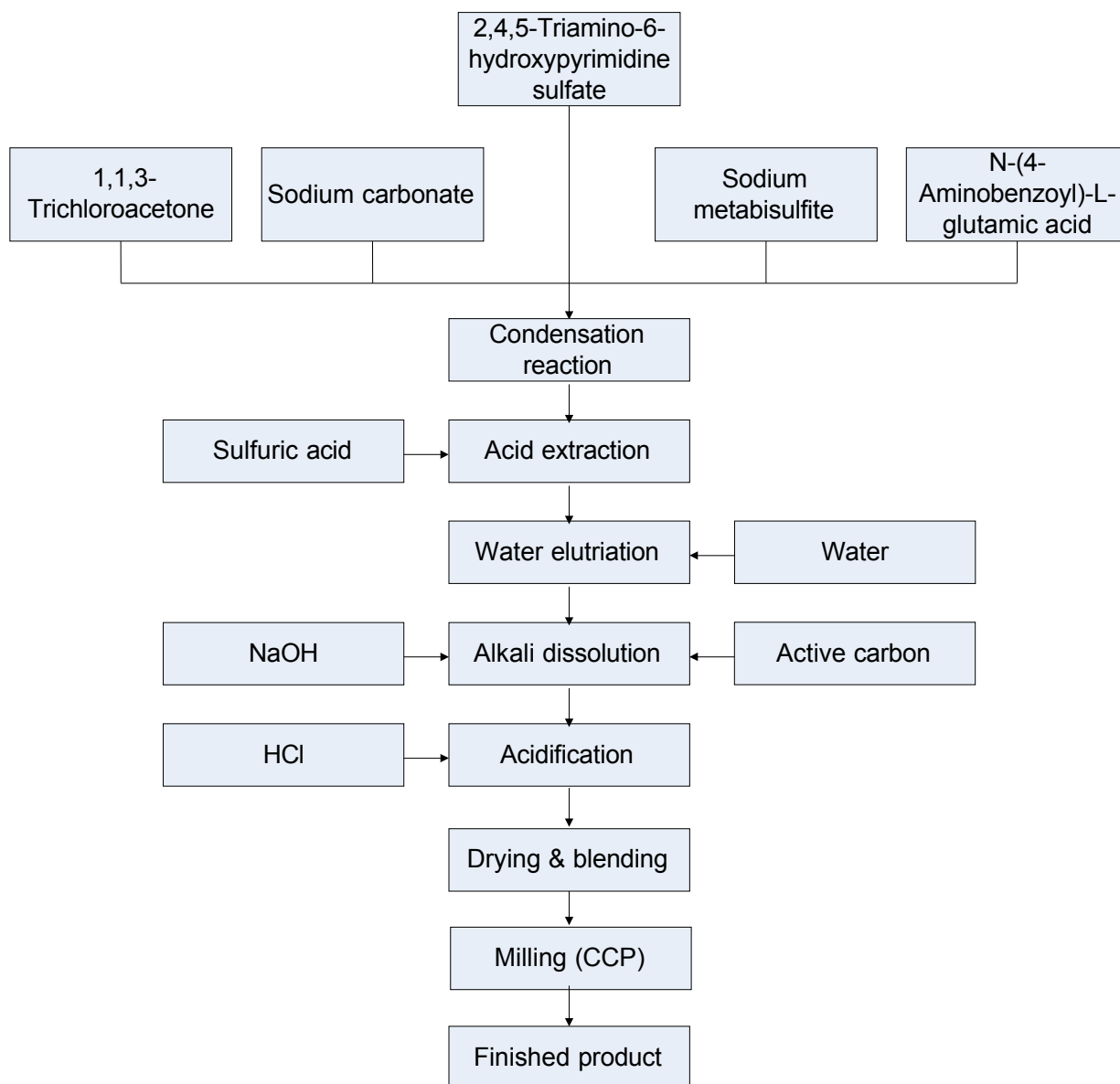
Thank you for your interest in Spectrum products. If we may be of further assistance, please feel free to contact the Quality Assurance department at 310-516-8000 or via email at qualityassurance@spectrumchemical.com

Sincerely,

Oralia Chavez
Quality Assurance Specialist

Manufacturing Process Flowchart

Folic Acid, Powder, USP - FO105



Spectrum Chemical Mfg Corp

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West Coast Facility:

14422 S. San Pedro St.
Gardena, CA 90248

310.516.8000

FO105, Folic Acid, Powder, USP

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

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 24 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)
- Pesticides
- Phthalates



RE: Elemental Impurities - Folic Acid, Powder, USP (Cat# FO105)

To Whom It May Concern:

Thank you for your interest in Spectrum high quality chemicals.

The above mentioned material complies with the USP<232>, <233> Elemental Impurities and the ICH Q3D Elemental Impurities Guideline. No Class 1, Class 2A, Class 2B or Class 3 elemental impurities are 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 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
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



RE: Residual Solvents - Folic Acid, Powder, USP (Cat# FO105)

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 TechServices@spectrumchemical.com.

Sincerely,

Technical Services
Spectrum Chemical Mfg. Corp.

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CORPORATE HEADQUARTERS

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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

F0105

SIZ SY

Folic Acid

Powder

USP

CAS 59-30-3



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

$C_{19}H_{19}N_7O_6$ F.W. 441.40

Assay (Anhydrous Basis) 97.0-102.0%
MAXIMUM LIMITS
 Water Determination 8.5%
 Residue on Ignition 0.3%
 Related Compounds 2.0%
 Elemental Impurities As reported
 Residual Solvents To pass test

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

WARNING: Cancer and Reproductive Harm-
www.P65Warnings.ca.gov

G 14/18GHS

?

Lot No. XQ####

Spectrum Chemical Mfg Corp

Corporate Headquarters:

769 Jersey Ave.
 New Brunswick, NJ 08901

732.214.1300

West Coast Facility:

14422 S. San Pedro St.
 Gardena, CA 90248

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: ZI0928 = The 928th 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 706th 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

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



المجلس الإسلامي الأمريكي للغذاء و التغذية
THE ISLAMIC FOOD AND NUTRITION COUNCIL OF AMERICA

IFANCA HALAL PRODUCT CERTIFICATE شهادة حلال

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.II214072

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

ProductName	Product Code	Halal-ID	Product Certificate #
1. Folic Acid, Powder, USP	FO105	B94115	HC-21SPSA04


Muhammad Munir Chaudry, Ph.D.
President



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



Page 1 of 1