

# Scientific Documentation

## Leucovorin Calcium, USP

Not appropriate for regulatory submission.

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

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



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## Specification for Leucovorin Calcium, USP (LE117)

Item Number	LE117
Item	Leucovorin Calcium, USP
CAS Number	1492-18-8
Molecular Formula	C <sub>20</sub> H <sub>21</sub> CaN <sub>7</sub> O <sub>7</sub>
Molecular Weight	511.50
MDL Number	
Synonyms	Folinic Acid Calcium Salt

Test	Specification	
	Min	Max
ASSAY (ANHYDROUS BASIS)	95.0	105.0 %
WATER DETERMINATION		17.0 %
ORGANIC IMPURITIES:		
5-FORMYL-5,6,7,8-TETRAHYDROPTEROIC ACID		0.5 %
4-AMINOBENZOYLGLUTAMIC ACID		1.5 %
10-FORMYLDIHYDROFOLIC ACID		1.0 %
5,10-DIFORMYLTETRAHYDROFOLIC ACID		1.5 %
7,8-DIHYDROFOLIC ACID		0.5 %
10-FORMYLFOLIC ACID		0.5 %
FOLIC ACID		1.5 %
INDIVIDUAL UNSPECIFIED IMPURITY		0.3 %
TOTAL IMPURITIES		2.5 %
5-(γ-FOLINOYL)TETRAHYDROFOLATE		0.3 %
ELEMENTAL IMPURITIES		AS REPORTED
IDENTIFICATION		TO PASS TEST
RETEST 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

## Certificate Of Analysis

Item Number	LE117	Lot Number	4MG0056
Item	Leucovorin Calcium, USP	Manufacturer Lot	100-22-6
CAS Number	1492-18-8	Manufacturer Code	15093
Molecular Formula	C <sub>20</sub> H <sub>21</sub> CaN <sub>7</sub> O <sub>7</sub>	Molecular Weight	511.50

TEST	SPECIFICATION		RESULT
	MIN	MAX	
ASSAY (ANHYDROUS BASIS)	95.0	105.0 %	96.0 %
WATER DETERMINATION		17.0 %	12.4 %
ORGANIC IMPURITIES:			.
5-FORMYL-5,6,7,8-TETRAHYDROPTEROIC ACID		0.5 %	0.0 %
4-AMINOBENZOYLGLUTAMIC ACID		1.5 %	0.0 %
10-FORMYLDIHYDROFOLIC ACID		1.0 %	0.0 %
5,10-DIFORMYLTETRAHYDROFOLIC ACID		1.5 %	0.0 %
7,8-DIHYDROFOLIC ACID		0.5 %	0.0 %
10-FORMYLFOLIC ACID		0.5 %	0.0 %
FOLIC ACID		1.5 %	0.0 %
INDIVIDUAL UNSPECIFIED IMPURITY		0.3 %	0.0 %
TOTAL IMPURITIES		2.5 %	0.0 %
5-(γ-FOLINOYL)TETRAHYDROFOLATE		0.3 %	0.0 %
ELEMENTAL IMPURITIES		AS REPORTED	COMPLIES WITH STANDARD
IDENTIFICATION		TO PASS TEST	PASSES TEST
RETEST DATE			09-DEC-2025
DATE OF MANUFACTURE			09-DEC-2022
APPEARANCE			LIGHT YELLOW POWDER
RESIDUAL SOLVENTS		AS REPORTED	.
CLASS 3 (solvent) / ETHANOL			<5000 ppm

Certificate of Analysis Results Entered By:

GHERRERA  
Genaro Herrera  
25-OCT-23 13:20:43

Certificate of Analysis Results Approved By:

MCAMACHO  
Matheu Camacho  
25-OCT-23 13:35:27

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.**

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.

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 GMT Fine Chemicals SA at Rue des îles 6, Couvet, 2108, Switzerland (CHE). Copies of the original Certificate of Analysis are available upon request from your Spectrum Sales Representative or by calling Spectrum's Quality Department at 1-800-772-8786.

# SAFETY DATA SHEET

# spectrum®



Revision date 13-March-2024

Revision Number 4

## 1. Identification

### Product identifier

Product Name LEUCOVORIN CALCIUM, USP

### Other means of identification

Product Code(s) LE117

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  
(310) 516-8000

### Emergency telephone number

Emergency Telephone Chemtrec 1-800-424-9300

## 2. Hazard(s) identification

### Classification

Skin corrosion/irritation	Category 2
Serious eye damage/eye irritation	Category 2A
Specific target organ toxicity (single exposure)	Category 3

### Hazards not otherwise classified (HNOC)

Not applicable

### Label elements

#### **Warning**

#### **Hazard statements**

Causes skin irritation  
Causes serious eye irritation  
May cause respiratory irritation



**Appearance** Powder

**Physical state** Solid

**Odor** Odorless

**Precautionary Statements - Prevention**

Wash face, hands and any exposed skin thoroughly after handling  
Avoid breathing dust/fume/gas/mist/vapors/spray  
Use only outdoors or in a well-ventilated area  
Wear protective gloves/eye protection/face protection

**Precautionary Statements - Response**

Specific treatment (see .? on this label)  
IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing  
If eye irritation persists: Get medical advice/attention  
IF ON SKIN: Wash with plenty of water and soap  
If skin irritation occurs: Get medical advice/attention  
Take off contaminated clothing and wash it before reuse  
IF INHALED: Remove person to fresh air and keep comfortable for breathing  
Call a POISON CENTER or doctor if you feel unwell

**Precautionary Statements - Storage**

Store in a well-ventilated place. Keep container tightly closed  
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-%
Leucovorin Calcium	1492-18-8	100

### 4. First-aid measures

**Description of first aid measures**

<b>General advice</b>	Show this safety data sheet to the doctor in attendance.
<b>Inhalation</b>	Remove to fresh air. IF exposed or concerned: Get medical advice/attention. Get medical attention immediately if symptoms occur.
<b>Eye contact</b>	Rinse immediately with plenty of water, also under the eyelids, for at least 15 minutes. Keep eye wide open while rinsing. Remove contact lenses, if present and easy to do. Continue rinsing. Get medical attention if irritation develops and persists. Do not rub affected area.
<b>Skin contact</b>	Wash off immediately with soap and plenty of water for at least 15 minutes. Get medical attention if irritation develops and persists.
<b>Ingestion</b>	Do NOT induce vomiting. Clean mouth with water and drink afterwards plenty of water. Never give anything by mouth to an unconscious person. Call a physician.

**Self-protection of the first aider**      Avoid contact with skin, eyes or clothing. Wear personal protective clothing (see section 8).

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

**Symptoms**      May cause redness and tearing of the eyes. Burning sensation.

**Indication of any immediate medical attention and special treatment needed**

**Note to physicians**      Treat symptomatically.

## **5. Fire-fighting measures**

**Suitable Extinguishing Media**      Use extinguishing measures that are appropriate to local circumstances and the surrounding environment.

**Large Fire**      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 oxides. Nitrogen oxides (NOx). Calcium oxides.

**Explosion data**

**Sensitivity to mechanical impact**      none.

**Sensitivity to static discharge**      none.

**Special protective equipment for fire-fighters**      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. Use personal protective equipment as required. Evacuate personnel to safe areas. Avoid contact with skin, eyes or clothing.

**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. Do not eat, drink or smoke when using this product. Take off contaminated clothing and wash before reuse. Ensure adequate ventilation. Avoid breathing vapors or mists. In case of insufficient ventilation, wear suitable respiratory equipment.

**Conditions for safe storage, including any incompatibilities**

**Storage Conditions**      Sensitive to light. Store in light-resistant containers. Keep containers tightly closed in a dry, cool 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** If splashes are likely to occur, wear safety glasses with side-shields.

**Hand protection** Wear suitable gloves. Impervious gloves.

**Skin and body protection** Wear suitable protective clothing. Long sleeved 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** Wear suitable gloves and eye/face protection. Do not eat, drink or smoke when using this product. Avoid contact with skin, eyes or clothing.

## 9. Physical and chemical properties

### Information on basic physical and chemical properties

<b>Physical state</b>	Solid
<b>Appearance</b>	Powder
<b>Color</b>	White to yellowish
<b>Odor</b>	Odorless
<b>Odor threshold</b>	No information available

<u>Property</u>	<u>Values</u>	<u>Remarks • Method</u>
<b>pH</b>	6.8-8.0 (2.5%)	None known
<b>Melting point / freezing point</b>	no data available	None known
<b>Boiling point / boiling range</b>	no data available	None known
<b>Flash point</b>	no data available	None known
<b>Evaporation rate</b>	no data available	None known
<b>Flammability (solid, gas)</b>	no data available	None known
<b>Flammability Limit in Air</b>		None known
<b>Upper flammability or explosive limits</b>	No data available	
<b>Lower flammability or explosive limits</b>	No data available	
<b>Vapor pressure</b>	No data available	None known
<b>Vapor density</b>	no data available	None known
<b>Relative density</b>	1.5	None known
<b>Water solubility</b>	Soluble in water	None known
<b>Solubility(ies)</b>	Practically insoluble in Acetone Practically insoluble in alcohol	None known
<b>Partition coefficient</b>	No data available	None known

Autoignition temperature	no data available	None known
Decomposition temperature	240 - 250 °C 464 482 °F	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	511.50
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	Strong acids. Strong bases. Strong oxidizing agents.
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. May cause irritation of respiratory tract.
Eye contact	Specific test data for the substance or mixture is not available. Irritating to eyes. (based on components). Causes serious eye irritation.
Skin contact	Specific test data for the substance or mixture is not available. Causes skin irritation. (based on components).
Ingestion	Specific test data for the substance or mixture is not available. Ingestion may cause gastrointestinal irritation, nausea, vomiting and diarrhea.

### Symptoms related to the physical, chemical and toxicological characteristics

Symptoms	Redness. May cause redness and tearing of the eyes.
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### Acute toxicity

#### Numerical measures of toxicity

Chemical name	Oral LD50	Dermal LD50	Inhalation LC50
Leucovorin Calcium 1492-18-8	> 8 g/kg ( Rat )	-	-

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

<b>Skin corrosion/irritation</b>	Classification based on data available for ingredients. Irritating to skin.
<b>Serious eye damage/eye irritation</b>	Classification based on data available for ingredients. Causes serious eye irritation.
<b>Respiratory or skin sensitization</b>	No information available.
<b>Germ cell mutagenicity</b>	No information available.
<b>Carcinogenicity</b>	No information available.
<b>Reproductive toxicity</b>	No information available.
<b>STOT - single exposure</b>	May cause respiratory irritation.
<b>STOT - repeated exposure</b>	No information available.
<b>Aspiration hazard</b>	No information available.
<b>Other adverse effects</b>	No information available.
<b>Interactive effects</b>	No information available.

## 12. Ecological information

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

## 13. Disposal considerations

### Waste treatment methods

<b>Waste from residues/unused products</b>	Dispose of in accordance with local regulations. Dispose of waste in accordance with environmental legislation.
<b>Contaminated packaging</b>	Do not reuse empty containers.

## 14. Transport information

<b><u>DOT</u></b>	not regulated
<b><u>TDG</u></b>	not regulated
<b><u>MEX</u></b>	not regulated
<b><u>ICAO (air)</u></b>	not regulated
<b><u>IATA</u></b>	not regulated
<b><u>IMDG</u></b>	not regulated
<b><u>RID</u></b>	not regulated

**ADR** not regulated

**ADN** not regulated

## 15. Regulatory information

### International Inventories

**TSCA** Not listed

**Note** \*Contact supplier for details. One or more substances in this product are either not listed on the US TSCA inventory, listed on the confidential US TSCA inventory or are otherwise exempted from inventory listing requirements

**DSL/NDSL** Does not Comply

**EINECS/ELINCS** Complies

**ENCS** This product complies with ENCS:

**IECSC** This product does not comply with china:

**KECL** Complies

**PICCS** Does not Comply

**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 does not contain any chemicals which are subject to the reporting requirements of the Act and Title 40 of the Code of Federal Regulations, Part 372.

#### **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 2

Flammability 0

Instability 0

Physical and chemical properties -

### HMIS

Health hazards 2

Flammability 0

Physical hazards 0

Personal protection X

### Key or legend to abbreviations and acronyms used in the safety data sheet

#### **Legend Section 8: EXPOSURE CONTROLS/PERSONAL PROTECTION**

TWA TWA (time-weighted average)

STEL

STEL (Short Term Exposure Limit)

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** 13-March-2024

**Revision Note** 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
LE117	Leucovorin Calcium, 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

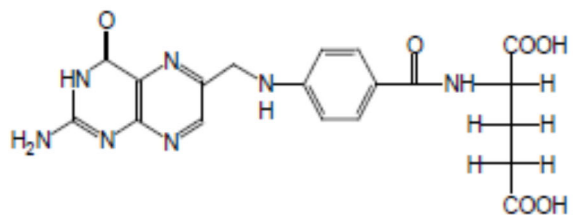
Thank you for your interest in Spectrum products. If we may be of further assistance, please feel free to contact the Quality Assurance department at 310-516-8000 or via email at [qualityassurance@spectrumchemical.com](mailto:qualityassurance@spectrumchemical.com)

Sincerely,

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

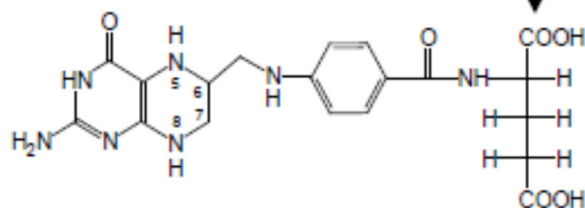
Oralia Chavez  
Quality Assurance Specialist

## Manufacturing Process Flowchart Leucovorin Calcium, USP (Cat# LE117)



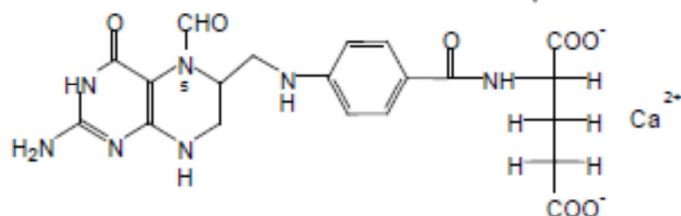
*Folic Acid*

Reduction



*Tetrahydrofolic Acid*

Formylation  
Salification



*Raw Leucovorin Calcium*

Crystallization

**Leucovorin Calcium**

### CORPORATE HEADQUARTERS

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### WEST COAST FACILITY

14422 South San Pedro Street  
Gardena, California 90248  
PHONE 310.516.8000  
FAX 310.516.9843

## LE117, Leucovorin Calcium, 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

### EU Fragrance Allergen Statement

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

### GMO Statement

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

### Melamine Statement

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

## Nitrosamine Statement

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

## Animal Testing Statement

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

## Organic Compliance Statement

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

## Shelf Life Statement

The above mentioned catalog item is typically assigned a shelf life of 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        | • Parabens      |
| • Antibiotics       | • Pesticides    |
| • Bisphenol A (BPA) | • Phthalates    |
| • CMR Substances    | • Preservatives |



**RE: Elemental Impurities - Leucovorin Calcium, USP (Cat# LE117)**

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
Tin	Sn	3	< 2 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 [TechServices@spectrumchemical.com](mailto:TechServices@spectrumchemical.com).

Sincerely,

Technical Services  
Spectrum Chemical Mfg. Corp.

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

**CORPORATE HEADQUARTERS**

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New Brunswick, NJ 08901

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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 - Leucovorin Calcium, USP (Cat# LE117)**

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
Ethanol	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 [TechServices@spectrumchemical.com](mailto:TechServices@spectrumchemical.com).

Sincerely,

Technical Services  
Spectrum Chemical Mfg. Corp.

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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.

**WARNING**

- Causes serious eye irritation • Causes skin irritation • May cause respiratory irritation.
- Wear protective gloves, eye protection, face protection • Avoid breathing dust • Use only outdoors or in a well-ventilated area • Wash face, hands and any exposed skin thoroughly after handling.

**FIRST AID:** IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing. If eye irritation persists: Get medical attention. IF ON SKIN: Wash with plenty of water. Take off contaminated clothing and wash it before reuse. If skin irritation occurs: Get medical attention. IF INHALED: Remove person to fresh air and keep comfortable for breathing. Call a POISON CENTER or physician if you feel unwell.

**KEEP FROM CHILDREN**



**LE117                      SIZ SY**

**Leucovorin Calcium**

**(Folinic Acid Calcium Salt)**

**USP**

CAS 1492-18-8

**CAUTION:** For manufacturing, processing, repacking, or for prescription compounding. Rx only.  
**Read and understand the label and Safety Data Sheet (SDS) prior to use.**

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

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

$C_{20}H_{21}CaN_7O_7$                       F.W. 511.50

Manufacturer/Supplier Code ..... ?  
 Manufacturer Lot Number ..... ?  
 Assay (Anhydrous Basis) ..... 95.0-105.0%

**MAXIMUM LIMITS**

Water Determination ..... 17.0%  
 Organic Impurities:  
   5-Formyl-5,6,7,8-tetrahydropteroic Acid ..... 0.5%  
   4-Aminobenzoylglutamic Acid ..... 1.5%  
   10-Formyldihydrofolic Acid ..... 1.0%  
   5,10-Diformyltetrahydrofolic Acid ..... 1.5%  
   7,8-Dihydrofolic Acid ..... 0.5%  
   10-Formylfolic Acid ..... 0.5%  
   Folic Acid ..... 1.5%  
   Individual Unspecified Impurity ..... 0.3%  
   Total Impurities ..... 2.5%  
   5-(γ-Folinoyl)tetrahydrofolate ..... 0.3%  
   Elemental Impurities ..... As reported  
   Residual Solvents ..... To pass test

**WARNING:** Cancer and Reproductive Harm-  
[www.P65Warnings.ca.gov](http://www.P65Warnings.ca.gov)

Repackaged by Spectrum as:  
 Lot No. XQ####

Retest Date: 00-00-0000



### Spectrum Chemical Mfg Corp

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