



Scientific Documentation

I3003, Ivermectin, 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

Ver4.04 8.February.2018



Dear Customer,

Thank you for your interest in Spectrum's quality products and services.

Spectrum has been proudly serving the scientific community for over 45 years. It is our mission to manufacture and distribute fine chemicals and laboratory products with Quality and delivery you can count on every time.

To accomplish our mission, Spectrum utilizes our sourcing leverage and supplier qualification expertise in offering one of the industry's most comprehensive line of fine chemical products under one brand, in packaging configurations designed to meet your research and production requirements. Our product grades include: USP, NF, BP, EP, JP, FCC, ACS, KSA, Reagent grade, as well as DEA controlled substances. We operate facilities in the United States on the East Coast, West Coast, as well as in Shanghai, China in order to provide the best logistical support for our customers.

At Spectrum, Quality is priority number one. Suppliers with the best qualifications are preferred and we employ full-functioning in-house analytical laboratories at each of our facilities. Our facilities and systems are USFDA registered and ISO certified. We frequently host customer audits and cherish opportunities for improvements. Quality is engrained into our culture. Quality is priority number one.

In the following pages, we have designed and prepared documented scientific information to aid you in your initial qualification or your continual use of our products. Please do not hesitate to contact us if further information or the most up-to-date documentation is desired from any of the covered areas.

We appreciate your business and we look forward to hearing from you.

Sincerely,

A handwritten signature in black ink, appearing to read "Alan Wang", is written over a light gray rectangular background.

Alan Wang, MSQA, CQA
Director, Global Supplier Quality Assurance
awang@spectrumchemical.com

I3003, Ivermectin, USP

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spectrum[®]
PHARMACEUTICAL MFG CORP



Specification for Ivermectin, USP (I3003)

Item Number	I3003
Item	Ivermectin, USP
CAS Number	70288-86-7
Molecular Formula	
Molecular Weight	
MDL Number	
Synonyms	

Test	Specification	
	Min	Max
ASSAY (H_2B_{1a})	90 %	
ASSAY (SUM OF H_2B_{1a} and H_2B_{1b} ; DRIED BASIS)	95.0	102.0 %
SPECIFIC ROTATION	-17° to -20°	
RESIDUE ON IGNITION		0.1 %
ELEMENTAL IMPURITIES	AS REPORTED	
WATER DETERMINATION		1.0 %
ALCOHOL AND FORMAMIDE	TO PASS TEST	
RELATED COMPOUNDS	TO PASS TEST	
IDENTIFICATION	TO PASS TEST	
EXPIRATION DATE		
DATE OF MANUFACTURE		
APPEARANCE		
RESIDUAL SOLVENTS	TO PASS TEST	

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

SAFETY DATA SHEET

Preparation Date: 2/5/2018

Revision Date: 2/5/2018

Revision Number: G1

1. IDENTIFICATION

Product identifier

Product code: I3003
Product Name: IVERMECTIN, USP

Other means of identification

Synonyms: Ivermectin is a mixture of avermectin A1a (component H2B1a (CAS no. 71827-03-7)) and avermectin A1a (component H2B1b (CAS no. 70209-81-3))
CAS #: 70288-86-7
RTECS # IH7891500
CI#: Not available

Recommended use of the chemical and restrictions on use

Recommended use: Medication.
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: Martin LaBenz (West Coast)
Contact Person: Ibad Tirmiz (East Coast)

2. HAZARDS IDENTIFICATION

Classification

This chemical is considered hazardous according to the 2012 OSHA Hazard Communication Standard (29 CFR 1910.1200)

Considered a dangerous substance or mixture according to the Globally Harmonized System (GHS)

Acute toxicity - Oral	Category 2
Acute toxicity - Dermal	Category 3
Acute toxicity - Inhalation (Dusts/Mists)	Category 2

Label elements

Danger

Hazard statements
 Fatal if swallowed
 Fatal if inhaled
 Toxic in contact with skin



Hazards not otherwise classified (HNOC)

Not Applicable

Other hazards

Not available

Precautionary Statements - Prevention

Wash face, hands and any exposed skin thoroughly after handling
Do not eat, drink or smoke when using this product
Do not breathe dust/fume/gas/mist/vapors/spray
Use only outdoors or in a well-ventilated area
Wear respiratory protection
Wear protective gloves
Wear protective clothing

Precautionary Statements - Response

IF ON SKIN: Wash with plenty of water
Call a POISON CENTER or doctor/physician if you feel unwell
Remove/Take off immediately all contaminated clothing
Wash contaminated clothing before reuse
IF INHALED: Remove person to fresh air and keep comfortable for breathing. Immediately call a POISON CENTER or doctor/physician.
IF SWALLOWED: Immediately call a POISON CENTER or doctor/physician
Rinse mouth

Precautionary Statements - Storage

Store locked up
Store in a well-ventilated place. Keep container tightly closed

Precautionary Statements - Disposal

Dispose of contents/container to an approved waste disposal plant

3. COMPOSITION/INFORMATION ON INGREDIENTS

Components	CAS-No.	Weight %
Ivermectin	70288-86-7	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. Ensure that medical personnel are aware of the material(s) involved and take precautions to protect themselves. First aider needs to protect himself.

Skin Contact: Wash off immediately with soap and plenty of water removing all contaminated clothing and shoes. Get medical attention.

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

Inhalation: Move to fresh air. If breathing is difficult, give oxygen. If not breathing, give artificial respiration. **WARNING!** It may be hazardous to the person providing aid to give mouth-to-mouth resuscitation when the inhaled or ingested material is toxic, infectious or corrosive. Do not use mouth-to-mouth resuscitation if victim ingested or inhaled the substance; induce artificial respiration with the aid of a pocket mask equipped with a one-way valve or other proper respiratory medical device. Immediate medical attention is required.

Ingestion: Do not induce vomiting without medical advice. Never give anything by mouth to an unconscious person. Fatal if swallowed. Immediate medical attention is required. Call a physician or Poison Control Center immediately.

Most important symptoms and effects, both acute and delayed

Symptoms May cause headache
May cause dizziness
tiredness
Seizures
May cause incoordination
May cause nausea and vomiting
Abdominal pain
May cause diarrhea
May affect eyes/vision
Joint pain
Weakness

Indication of any immediate medical attention and special treatment needed

Notes to Physician: Antidote: Always have a Cyanide Antidote Kit (Package) when working with cyanide compounds. Get medical advice on how to use it and when it should be used. If cyanide gas is inhaled, break an Amyl nitrate pearl in a cloth and hold it lightly under the nose for 15 seconds. Repeat 5 times at about 15 second intervals. Use artificial respiration if breathing has stopped. If cyanide is swallowed, use Amyl nitrate as previously stated for 15 seconds. Nithidote Kit or Hydroxocobalamin (Cyanokit) are alternate approved treatments. Oxygen therapy may be useful in combination with the above.

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 chemical. 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.

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. Keep people away from and upwind of spill/leak. Avoid contact with skin, eyes and clothing. Use personal protective equipment. Do not touch damaged containers or spilled material unless wearing appropriate protective clothing. Avoid breathing dust. Remove all sources of ignition.

Environmental precautions Prevent further leakage or spillage if safe to do so. Do not let product enter drains. Prevent from entering into soil, ditches, sewers, waterways, and/or ground water.

Methods and material for containment and cleaning up

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

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

7. HANDLING AND STORAGE

Precautions for safe handling

Technical Measures/Precautions:

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

Safe Handling Advice

Wear personal protective equipment. Avoid contact with skin, eyes and clothing. Use only in well-ventilated areas. 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. Store in cool place. Keep refrigerated. Keep at temperatures between 2 and 8 °C. Store away from incompatible materials. Store in a segregated and approved area.

Incompatible Materials:

Strong oxidizing agents
Alkalis
Acids
Bases
Ammonia
Peroxides

8. EXPOSURE CONTROLS/PERSONAL PROTECTION

Control parameters

National occupational exposure limits

United States

Components	CAS-No.	OSHA	NIOSH	ACGIH	AIHA WEEL
Ivermectin	70288-86-7	None	None	None	None

Canada

Components	CAS-No.	Canada - Alberta	Canada - British Columbia	Canada - Ontario	Canada - Quebec
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Ivermectin	70288-86-7	None	None	None	None
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Australia and Mexico

Components	CAS-No.	Australia	Mexico
Ivermectin	70288-86-7	None	None

Appropriate engineering controls

Engineering measures to reduce exposure:

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

Individual protection measures, such as personal protective equipment

Personal Protective Equipment

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

9. PHYSICAL AND CHEMICAL PROPERTIES

Physical state: Solid	Appearance: Needles. Crystalline powder.	Color: White.
Odor: No information available.	Taste No information available.	Formula: No information available
Molecular/Formula weight: No information available	Flammability: No information 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): 150-157°C/302-314.6°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):**
3.94

Viscosity:
No information available

Miscibility:
No information available

Solubility:
Practically insoluble in water

10. STABILITY AND REACTIVITY

Reactivity

No information available

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.

Incompatible Materials: Strong oxidizing agents
Alkalis
Acids
Bases
Ammonia
Peroxides

Hazardous decomposition products: No information available.

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:

Skin. Ingestion. Inhalation.

Acute Toxicity

Component Information

Ivermectin

CAS-No. 70288-86-7

LD50/oral/rat = 10 mg/kg Oral LD50 Rat (LOLI); 2 mg/kg (RTECS)

LD50/oral/mouse = 25 mg/kg

LD50/dermal/rabbit = No information available

LD50/dermal/rat = No information available

LC50/inhalation/rat = No information available

LC50/inhalation/mouse = No information available

Other LD50 or LC50 information = No information available

Product Information

LD50/oral/rat =
VALUE- Acute Tox Oral = 10 mg/kg

LD50/oral/mouse =
Value - Acute Tox Oral = 25 mg/kg

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: Toxic in contact with skin. May cause skin irritation.

Eye Contact: May cause eye irritation.

Inhalation Fatal if inhaled. May cause irritation of respiratory tract.

Ingestion Fatal if swallowed. May affect behavior/central nervous system (dizziness, headache). May affect behavior/central nervous system (ataxia). May affect behavior/central nervous system (tiredness). May affect behavior/central nervous system (convulsions/seizures). Ingestion may cause nausea, vomiting. May cause diarrhea. May cause abdominal pain. May cause joint pain. May cause weakness. May cause vision disturbances. May affect the cardiovascular system (tachycardia). May cause difficulty breathing. May cause skin rash, redness or itching.

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.

Components	CAS-No.	IARC	ACGIH - Carcinogens	NTP	OSHA HCS - Carcinogens	Australia - Notifiable Carcinogenic Substances	Australia - Prohibited Carcinogenic Substances
Ivermectin	70288-86-7	Not listed	Not listed	Not listed	Not listed	Not listed	Not listed

ACGIH (American Conference of Governmental Industrial Hygienists)

IARC (International Agency for Research on Cancer)

NTP (National Toxicology Program)

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

Reproductive toxicity No data is available
Reproductive Effects: No information available
Developmental Effects: No information available
Teratogenic Effects: No information available

Specific Target Organ Toxicity

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

12. ECOLOGICAL INFORMATION

Ecotoxicity

Ecotoxicity effects: No data available.
Persistence and degradability: No information available
Bioaccumulative potential: No information available.
Mobility: 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
Ivermectin	70288-86-7	None	None	None	None

14. TRANSPORT INFORMATION

DOT

UN-No: UN2811
Proper Shipping Name: Toxic solids, organic, n.o.s. (ivermectin)
Hazard Class: 6.1
Subsidiary Class No information available
Packing group: II
Emergency Response Guide Number 154
Marine Pollutant No data available

DOT RQ (lbs): No information available
Special Provisions IB8, IP2, IP4, T3, TP33
Symbol(s): [DOT]: (G) - Identifies proper shipping names for which one or more technical names of the hazardous material must be entered in parentheses, in association with the basic description.
Description: UN2811, Toxic solids, organic, n.o.s., 6.1, II

TDG (Canada)
UN-No: UN2811
Proper Shipping Name: Toxic solid, organic, n.o.s.
Hazard Class: 6.1
Subsidiary Risk: No information available
Packing Group: II
Marine Pollutant No Information available
Description: UN2811, Toxic solid, organic, n.o.s., 6.1, II

ADR
UN-No: UN2811
Proper Shipping Name: Toxic solid, organic, n.o.s.
Hazard Class: 6.1
Packing Group: II
Subsidiary Risk: No information available
Special Provisions 274, 614
Description: UN2811, Toxic solid, organic, n.o.s., 6.1, II

IMO / IMDG
UN-No: UN2811
Proper Shipping Name: Toxic solids, organic, n.o.s. (ivermectin)
Hazard Class: 6.1
Subsidiary Risk: No information available
Packing Group: II
Marine Pollutant No information available
EMS: F-A
Special Provisions 274
Description UN2811, Toxic solid, organic, n.o.s. (IVERMECTIN), 6.1, II

RID
UN-No: UN2811
Proper Shipping Name: Toxic solid, organic, n.o.s.
Hazard Class: 6.1
Subsidiary Risk: No information available
Packing Group: II
Special Provisions 274, 614
Description: UN2811, Toxic solid, organic, n.o.s., 6.1, II

ICAO
UN-No: UN2811
Proper Shipping Name: Toxic solid, organic, n.o.s.
Hazard Class: 6.1
Subsidiary Risk: No information available
Packing Group: II
Description: UN2811, Toxic solid, organic, n.o.s., 6.1, II
Special Provisions A3, A5

IATA
UN-No: UN2811
Proper Shipping Name: Toxic solid, organic, n.o.s.
Hazard Class: 6.1
Subsidiary Risk: No information available
Packing Group: II

ERG Code: 6L
Special Provisions No information available
Description: UN2811, Toxic solid, organic, n.o.s., 6.1, II

15. REGULATORY INFORMATION

International Inventories

Components	CAS-No.	U.S. TSCA	KOREA KECL	Philippines (PICCS)	Japan ENCS	CHINA	Australia (AICS)	EINECS-No.
Ivermectin	70288-86-7	Not Listed	Not present	Not present	Not present	Not present	Not present	Present 274-536-0

U.S. Regulations

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

Chemicals Known to the State of California to Cause Cancer:

This product does not contain a chemical requiring a warning under California Prop. 65. (See table below)

Chemicals Known to the State of California to Cause Reproductive Toxicity:

This product does not contain a chemical requiring a warning under California Prop. 65. (See table below)

Components	CAS-No.	Carcinogen	Developmental Toxicity	Male Reproductive Toxicity	Female Reproductive Toxicity:
Ivermectin	70288-86-7	Not Listed	Not Listed	Not Listed	Not Listed

CERCLA/SARA

Components	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
Ivermectin	70288-86-7	None	None	None	None	None

U.S. TSCA

Components	CAS-No.	TSCA Section 5(a)2 - Chemicals With Significant New Use Rules (SNURS)	TSCA 8(d) -Health and Safety Reporting
Ivermectin	70288-86-7	Not Applicable	Not Applicable

Canada

WHMIS 2015 - GHS Classifications

WHMIS 2015 Hazard Classification Information: The WHMIS 2015 classification of this product has not been validated or reviewed yet.

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

D1A Very toxic materials

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)
Ivermectin	70288-86-7	Present	Not Listed

Components	CAS-No.	CEPA Schedule I - Toxic Substances
Ivermectin	70288-86-7	Not listed
Components	CAS-No.	CEPA - 2010 Greenhouse Gases Subject to Mandatory Reporting
Ivermectin	70288-86-7	Not listed

EU Classification

EU GHS - SV - CLP 1272/2008

Components	CAS-No.	EU GHS - SV - CLP (1272/2008)
Ivermectin	70288-86-7	No information

EU - CLP (1272/2008)

R-phrase(s)

R28 - Very toxic if swallowed.

R26 - Very toxic by inhalation.

R24 - Toxic in contact with skin.

S -phrase(s)

S45 - In case of accident or if you feel unwell, seek medical advice immediately (show the label where possible).

S36/37/39 - Wear suitable protective clothing, gloves and eye/face protection.

Components	CAS-No.	Classification	Concentration Limits:	Safety Phrases
Ivermectin	70288-86-7		No information	

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

Indication of danger:

T+ - Very toxic.

T - Toxic



16. OTHER INFORMATION

Preparation Date: 2/5/2018
Revision Date: 2/5/2018
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



Manufacturer

Product Covered: I3003, Ivermectin, USP

Spectrum takes ownership as the manufacturer for the Spectrum product listed above and provides full quality assurance, customer service, and technical product support.

While information concerning the raw material manufacturer of our starting materials is considered proprietary, such information can be made available upon request contingent on demonstration of business volume justification and successful execution of confidential disclosure agreement (CDA).

Requests for disclosure of proprietary raw material manufacturer information may be submitted to the assigned account representative for consideration.

Sincerely,

A handwritten signature in black ink, appearing to read "Alan Wang", is written over a light gray rectangular background.

Alan Wang, MSQA, CQA
Director, Global Supplier Quality Assurance
awang@spectrumchemical.com

8.February.2018

CERTIFICATE OF REGISTRATION

This is to certify that the quality management system of:

Spectrum Chemicals and Laboratory Products, Inc.

Main Site: 14422 South San Pedro Street, Gardena, California, 90248,
USA,

Additional sites: 13915 South Main Street, Los Angeles, California,
90061, USA

769 Jersey Avenue, New Brunswick, New Jersey, 08901, USA

755 Jersey Avenue, New Brunswick, New Jersey, 08901, USA

777 Jersey Avenue, New Brunswick, New Jersey, 08901, USA

400 N. Oracle, Suite 221, Tucson, Arizona, 85704, USA, USA

has been assessed and registered by Intertek as conforming to the
requirements of:

ISO 9001:2015

The quality management system is applicable to:

Main Site: The manufacture and distribution of specialty fine
chemicals, solutions, equipment, supplies and products for the
laboratory, pharmaceutical, food, healthcare, cosmetic, fragrance,
biotechnology, environmental and process industries.

Certificate Number:

94-316m-03

Initial Certification Date:

27 December 1994

Certificate Issue Date:

31 July 2017

Certificate Expiry Date:

28 January 2019



A handwritten signature in black ink, appearing to read 'Calin Moldovean', written over a horizontal line.

Authorized Signature

Calin Moldovean

President Business Assurance

Intertek Testing Services NA, Inc. dba Intertek
900 Chelmsford Street, Lowell, MA, USA



APPENDIX TO CERTIFICATE OF REGISTRATION

This appendix identifies the locations by the management system of

Spectrum Chemicals and Laboratory Products, Inc.

755 and 769 Jersey Avenue: The manufacture and distribution of specialty fine chemicals, solutions, equipment, supplies and products for the laboratory, pharmaceutical, food, healthcare, cosmetic, fragrance, biotechnology, environmental and process industries.

777 Jersey Avenue: The manufacture and distribution of specialty fine chemicals, solutions, equipment, supplies and products for Compounding Pharmacies.

7400 N. Oracle: The manufacture and distribution of specialty fine chemicals, solutions, equipment, supplies and products for the laboratory, pharmaceutical, food, healthcare, cosmetic, fragrance, biotechnology, environmental and process industries.



管理体系认证 注册证书

兹证明，以下组织：

斯百全化学（上海） 有限公司

上海市松江区申港路3802弄A20

的管理体系，符合以下标准要求并予以注册：

ISO 9001:2015

此管理体系适用于：

药用辅料销售，化学品销售

统一社会信用代码：

91310000777627048K

证书编号：

111310001

首次认证日期：

2015年11月17日

认证决定日期：

2017年12月26日

签发日期：

2017年12月26日

有效期至：

2018年11月10日



014

Calin Moldovean

President, Business Assurance

Intertek Certification Limited, 10A Victory
Park, Victory Road, Derby DE24 8ZF, United
Kingdom

Intertek Certification Limited
是 UKAS 认可的认证机构，
注册号为 014



CERTIFICATE OF REGISTRATION

This is to certify that the management system of:

Spectrum China Ltd.

Building A20, No. 3802, Shengang Road, Songjiang District, Shanghai, China

has been registered by Intertek as conforming to the requirements of:

ISO 9001:2015

The management system is applicable to:

Sales for Pharmaceutical Excipients, Sales for Chemicals

Unified Social Credit Identifier:

91310000777627048K

Certificate Number:

111310001

Initial Certification Date:

17 November 2015

Date of Certification Decision:

26 December 2017

Issuing Date:

26 December 2017

Valid Until:

10 November 2018



014

A handwritten signature in black ink, appearing to read 'Calin Moldovean'.

Calin Moldovean

President, Business Assurance

Intertek Certification Limited, 10A Victory Park, Victory Road, Derby DE24 8ZF, United Kingdom

Intertek Certification Limited is a UKAS accredited body under schedule of accreditation no. 014.



July 13, 2017

Certification of Compliance with current Good Manufacturing Practices

Dear Valued Customer:

Spectrum Chemical Mfg Corp certifies that our USP, NF, FCC, EP, BP, JP and food grade products are 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.

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:	<u>2020632</u>
Spectrum-New Brunswick, NJ:	<u>2246824</u>
Spectrum-Shanghai, China:	<u>3006174778</u>

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

February 8, 2018

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
I3003	Ivermectin, 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
Spectrum-Shanghai, China: 03006174778

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



Oct. 5, 2017

Re: Ivermectin, USP-I3003

To Whom It May Concern:

Thank you for your interest in Spectrum high quality chemicals.

We at Spectrum Chemical Mfg. Corp. understand the concern regarding Bovine Spongiform Encephalopathy (BSE). Please be assured that the chemical

Ivermectin, USP-I3003

is BSE/TSE free.

If you have any further questions, please contact Tech Services at (310) 516-8000 Extension 5471, or by email at techservices@spectrumchemical.com.

Sincerely,

Darlene Dagdag-Lyudmirskiy
Technical Services
Spectrum Chemical Mfg. Corp.

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

Item Number	I3003	Lot Number	1EE0406
Item	Ivermectin, USP		
CAS Number	70288-86-7		
Molecular Formula		Molecular Weight	

Test	Specification		Result
	min	max	
ASSAY (H ₂ B _{1a})	90 %		96.9 %
ASSAY (H ₂ B _{1a} + H ₂ B _{1b})	95.0 - 102.0 %		95.72 %
SPECIFIC ROTATION [α] _D	-17° to -20°		-17.9
WATER		1.0 %	0.59 %
RESIDUE ON IGNITION		0.1 %	0.08 %
HEAVY METALS		0.002 %	<0.002 %
ALCOHOL AND FORMAMIDE	TO PASS TEST		PASSES TEST
RELATED COMPOUNDS	TO PASS TEST		PASSES TEST
IDENTIFICATION	TO PASS TEST		PASSES TEST
EXPIRATION DATE			12-MAR-2018
RESIDUAL SOLVENTS	TO PASS TEST		.
CLASS 1 (solvent) / BENZENE			< 2 ppm
DATE OF MANUFACTURE			13-MAR-2015
APPEARANCE			WHITE CRYSTALS

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

Certificate of Analysis Results Certified By:



Adan Hernandez
 Quality Control Manager
 Spectrum Chemicals & Laboratory Products



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

Read and understand label and MSDS/SDS before handling any chemicals. All Spectrum's chemicals are for manufacturing, processing, repacking or research purposes by experienced personal only. The customer must ensure to provide its users adequate hazardous material training and appropriate protective gears before handling our chemicals.

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.

A **DANGER**

B

C • **Fatal if swallowed or if inhaled** •
• **Toxic in contact with skin.**

D I3003

E Ivermectin

F 1 KG

G U.S.P.

H CAS 70288-86-7

I DOT: UN2811, Toxic solid, organic, n.o.s. (ivermectin), 6.1, PG II

J **KEEP FROM CHILDREN**

K **REFRIGERATE**

A mixture of Ivermectin components B_{1a}, C₄₈H₇₄O₁₄ and B_{1b}, C₄₇H₇₂O₁₄.

Components:

H₂B_{1a}:CAS 70161-11-4
H₂B_{1b}:CAS 70209-81-3

Assay (H₂B_{1a}) Min. 90%
Assay (Sum of H₂B_{1a} and H₂B_{1b}; Dried Basis) 95.0-102.0%
Specific Rotation -17° to -20°

L Exp. Date: 03-31-2025

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

N **WARNING:** This product contains a chemical known to the State of California to cause birth defects or other reproductive harm. Keep tightly closed.

O Lot No. 062233

P B 3/E5GHS

Q **SPECTRUM CHEMICAL MFG. CORP.** Gardena, CA 90248 • New Brunswick, NJ 08901

- A** Bar Code
- B** GHS Hazard Pictograms
- C** Warning, Safety Data and Precautionary Information
- D** Product Catalog Number
- E** Item Name, Form, Grade
- O** Storage Color Band
- F** Size/Quantity
- G** Chemical Abstracts Service (CAS) Registry Number
- H** Caution Information
- I** DOT Shipping Information
- J** Toll-Free 24-Hour Chemical Emergency Telephone Number
- K** Empirical Formula, Formula Weight and Technical Specifications Panel
- L** Expiration Information
- M** Lot Number
- N** Kosher Certified by Kosher Supervision of America (KSA).

This color-coded band indicates the hazard most likely to be posed by that material under storage conditions. The criteria used to assign band colors have been established by the Storage Code working group of the Society for Chemical Hazard Communication (SCHC). It is recommended that like colors be stored together, unless otherwise stated, based on the color codes indicated to the right. However, it is the responsibility of the customer to check with their local fire department for possible conflicts with our recommendations when storing hazardous chemicals.

- YELLOW:** Oxidizer
- RED:** Flammable
- GREEN:** General Storage
- BLUE:** Health Hazard
- WHITE:** Corrosive

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

January 26, 2016

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

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 qualityassurance@spectrumchemical.com if we may be of further assistance.

Sincerely,



Michael Dang
Manager, GMP Compliance



Stability – Shelf Life Guidance

Product Covered: I3003, Ivermectin, USP

Spectrum Chemical's manufacturing partner has assigned the following shelf life guidance for the product listed above.

The product, I3003, Ivermectin, USP, is assigned a 36 months shelf life from date of manufacturing. The quality and integrity of the chemical depends on the handling and storage conditions. Please refer to the Safety Data Sheet for proper storage and handling procedures.

Adan R. Hernandez
Quality Control Manager

A handwritten signature in black ink, appearing to read "Adan R. Hernandez".

Corporate Headquarters
769 Jersey Avenue
New Brunswick, NJ 08901-3605

8.February.2018