



# Scientific Documentation

P1169, Poloxamer 188, NF

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

Ver4.04 19.September.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 blue ink, appearing to read "Michael Dang", with a long horizontal flourish extending to the right.

Michael Dang  
Director, Quality Systems & GMP Compliance  
[mdang@spectrumchemical.com](mailto:mdang@spectrumchemical.com)

**P1169**, Poloxamer 188, NF

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**spectrum**<sup>®</sup>  
CHEMICAL MFG CORP



## Specification for Poloxamer 188, NF (P1169)

Item Number	P1169
Item	Poloxamer 188, NF
CAS Number	9003-11-6
Molecular Formula	$\text{HO}(\text{C}_2\text{H}_4\text{O})_a(\text{C}_3\text{H}_6\text{O})_b(\text{C}_2\text{H}_4\text{O})_a\text{H}$
Molecular Weight	APPROX. AV. M.W. 8400
MDL Number	
Synonyms	Pluronic F68 ; Polyethylene-Polypropylene Glycol

Test	Specification	
	Min	Max
AVERAGE MOLECULAR WEIGHT	7,680	9,510
WEIGHT PERCENT OXYETHYLENE	81.8 +/-1.9 %	
pH OF A 1 IN 40 SOLUTION	5.0	7.5
UNSATURATION	0.026+/-0.008meq	
ELEMENTAL IMPURITIES	AS REPORTED	
FREE ETHYLENE OXIDE		1 µg/g
FREE PROPYLENE OXIDE		5 µg/g
FREE 1,4-DIOXANE		5 µg/g
IDENTIFICATION	SPECTRUM	
EXPIRATION DATE		
DATE OF MANUFACTURE		
APPEARANCE		
RESIDUAL SOLVENTS:	AS REPORTED	

### *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: 6/30/2014

Revision Date: 6/30/2014

Revision Number: G1

## 1. IDENTIFICATION

### Product identifier

**Product code:** P1169  
**Product Name:** POLOXAMER 188, NF

### Other means of identification

**Synonyms:** Pluronic F68; Polyethylene-polypropylene glycol; Polyoxyethylene-Polyoxypropylene Block Copolymer; Poly(Ethylene oxide-co-Polypropylene oxide), Block; Block Copolymer of Ethylene Oxide and Propylene Oxide; Ethylene oxide/Polypropylene oxide copolymer; Methyl-oxirane polymer with oxirane; Oxirane, methyl-,polymer with oxirane, block

**CAS #:** 9003-11-6  
**RTECS #** MD0911050  
**CI#:** Not available

### Recommended use of the chemical and restrictions on use

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

**Supplier:** Spectrum Chemicals and Laboratory Products, Inc.  
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:** Regina Wachenheim (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**

Components	CAS-No.	Weight %	Trade Secret
Poloxamer 188 9003-11-6	9003-11-6	100	*

**4. FIRST AID MEASURES****First aid measures****General Advice:**

Poison information centres in each State capital city can provide additional assistance for scheduled poisons (13 1126)

**Skin Contact:**

Wash off immediately with soap and plenty of water removing all contaminated clothes and shoes. Get medical attention if irritation develops. Consult a physician if necessary.

**Eye Contact:**

Flush eye 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. May cause hypermotility, diarrhea.

**Indication of any immediate medical attention and special treatment needed****Notes to Physician:**

Treat symptomatically

**Protection of first-aiders**

First-Aid Providers: Avoid exposure to blood or body fluids. Wear gloves and other necessary protective clothing. Dispose of contaminated clothing and equipment as bio-hazardous waste

**5. FIRE-FIGHTING MEASURES****Extinguishing Media****Suitable Extinguishing Media:**

Carbon dioxide (CO<sub>2</sub>). Dry chemical. Water spray mist or foam.

**Unsuitable Extinguishing Media:**

No information available.

**Specific hazards arising from the chemical****Hazardous Combustion Products:**

Carbon monoxide; Carbon dioxide

**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. Avoid dust formation. Remove all sources of ignition.

**Environmental precautions** No information available.

### 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. Keep away from heat and sources of ignition. Avoid dust formation. Do not ingest. Do not breathe vapours/dust. Handle in accordance with good industrial hygiene and safety practice.

### Conditions for safe storage, including any incompatibilities

**Technical Measures/Storage Conditions:**

Keep containers tightly closed in a dry, cool and well-ventilated place. Store away from incompatible materials.

**Incompatible Materials:**

Strong oxidizing agents.

## 8. EXPOSURE CONTROLS/PERSONAL PROTECTION

### Control parameters

#### National occupational exposure limits

U.S Occupational Exposure Limits: Not determined

**United States**

Components	OSHA	NIOSH	ACGIH	AIHA WHEEL
Poloxamer 188 - 9003-11-6	None	None	None	None

**Canada**

Canada Occupational Exposure Limits: Not determined

Components	Alberta	British Columbia	Ontario	Quebec
Poloxamer 188 - 9003-11-6	None	None	None	None

## Australia and Mexico

Occupational Exposure Limits for Australia and Mexico: Not determined

Components	Australia	Mexico
Poloxamer 188 9003-11-6	None	None

### Appropriate engineering controls

#### Engineering measures to reduce exposure:

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

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

#### Personal Protective Equipment

- Eye protection:** Safety glasses. Safety glasses with side-shields.
- Skin and body protection:** Long sleeved clothing. Chemical resistant apron. Gloves.
- Respiratory protection:** Effective dust mask. Wear respirator with dust filter..
- Hygiene measures:** Avoid contact with skin, eyes and clothing. Wash hands before breaks and immediately after handling the product. When using, do not eat, drink or smoke.

## 9. PHYSICAL AND CHEMICAL PROPERTIES



## 9. PHYSICAL AND CHEMICAL PROPERTIES

<b>Physical state:</b> Solid.	<b>Appearance:</b> Prills.	<b>Color:</b> White.
<b>Odor:</b> No information available	<b>Taste</b> No information available	<b>Formula:</b> Polymer or (C3-H6-O.C2-H4-O)x
<b>Molecular/Formula weight:</b> Av. M.W. 7680-9510	<b>Flash point (°C):</b> No data available	<b>Flashpoint (°C/°F):</b> No information available.
<b>Flash Point Tested according to:</b> Not available	<b>Lower Explosion Limit (%):</b> No information available	<b>Upper Explosion Limit (%):</b> No information available
<b>Autoignition Temperature (°C/°F):</b> No information available	<b>pH:</b> No information available	<b>Melting point/range(°C/°F):</b> 52 °C/125.6 °F
<b>Boiling point/range(°C/°F):</b> No information available	<b>Decomposition temperature(°C/°F):</b> No information available	<b>Specific gravity:</b> No information available
<b>Density (g/cm3):</b> No information available	<b>Bulk density:</b> No information available	<b>Vapor pressure @ 20°C (kPa):</b> No information available
<b>Evaporation rate:</b> No information available	<b>Vapor density:</b> No information available	<b>VOC content (g/L):</b> No information available
<b>Odor threshold (ppm):</b> No information available	<b>Partition coefficient (n-octanol/water):</b> No information available	<b>Viscosity:</b> No information available
<b>Miscibility:</b> Miscible with water	<b>Solubility:</b> No information available	

## 10. STABILITY AND REACTIVITY

### Reactivity

Reactive with oxidizing agents

### Chemical stability

**Stability:** Stable at normal conditions

**Possibility of Hazardous Reactions:** Hazardous polymerization does not occur

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

**Incompatible Materials:** Strong oxidizing agents.

**Hazardous decomposition products:** Carbon monoxide. Carbon dioxide.

### Other Information

**Corrosivity:** No information available

**Special Remarks on Corrosivity:** No information available

## 11. TOXICOLOGICAL INFORMATION

### Information on likely routes of exposure

#### **Principal Routes of Exposure:**

Ingestion. Inhalation.

## Acute Toxicity

### Component Information

*Poloxamer 188 - 9003-11-6*

**LD50/oral/rat** = > 5000 mg/kg  
**LD50/oral/mouse** = No information available  
**LD50/dermal/rabbit** = > 2000 mg/kg  
**LD50/dermal/rat** = No information available  
**LC50/inhalation/rat** = 320 mg/m<sup>3</sup> Inhalation LC50 Rat 4 h  
**LC50/inhalation/mouse** = No information available  
**Other LD50 or LC50 information** = No information available

### Product Information

**LD50/oral/rat** =  
**VALUE- Acute Tox Oral** = >5000mg/kg

**LD50/oral/mouse** =  
**Value - Acute Tox Oral** = No information available

**LD50/dermal/rabbit**  
**VALUE-Acute Tox Dermal** = >2000mg/kg

**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** = 320mg/m<sup>3</sup> (4-hr.)

**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:** Contact with eyes may cause irritation.

**Inhalation**  
**Ingestion** This material is in the form of prills and is unlikely to cause respiratory tract irritation.  
May cause hypermotility, diarrhea. May affect behavior/central nervous system (somnolence). May cause muscle weakness.

**Aspiration hazard** No information available

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

**Chronic Toxicity**  
**Sensitization:** No information available.  
No information available

**Mutagenic Effects:** No information available

**Carcinogenic effects:** No information available.

Components	ACGIH - Carcinogens	IARC	NTP	OSHA HCS - Carcinogens	Australia - Prohibited Carcinogenic Substances	Australia - Notifiable Carcinogenic Substances
Poloxamer 188	Not listed	Not listed	Not listed	Not listed	Not listed	Not listed

**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:**                        Aquatic environment.

*Poloxamer 188 - 9003-11-6*

**Freshwater Fish Species Data:**                      Oncorhynchus mykiss LC50 96 h: >120 mg/kg

**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	RCRA - F Series Wastes	RCRA - K Series Wastes	RCRA - P Series Wastes	RCRA - U Series Wastes
Poloxamer 188	None	None	None	None

**14. TRANSPORT INFORMATION**

**DOT**

**UN-No:**    Not regulated  
**Proper Shipping Name:**                      No information available

## 14. TRANSPORT INFORMATION

**Hazard Class:** No information available  
**Subsidiary Risk:** Not applicable  
**Packing Group:** None  
**Marine Pollutant:** No data available  
**ERG No:** No information available  
**DOT RQ (lbs):** 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  
**Description:** No information available

### ADR

**UN-No:** Not Regulated  
**Proper Shipping Name:** No information available  
**Hazard Class:** No information available  
**Packing Group:** No information available  
**Subsidiary Risk:** No information available  
**Classification Code:** No information available  
**Description:** No information available  
**CEFIC Tremcard No:** No information available

### IMO / 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  
**Description:** No information available  
**IMDG Page:** No information available  
**Marine Pollutant:** No information available  
**MFAG:** No information available  
**Maximum Quantity:** No information available

### RID

**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  
**Classification Code:** No information available  
**Description:** No information available

### ICAO

**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  
**Description:** No information available

### IATA

**UN-No:** Not Regulated  
**Proper Shipping Name:** No information available

**14. TRANSPORT INFORMATION**

**Hazard Class:** No information available  
**Subsidiary Risk:** No information available  
**Packing Group:** No information available  
**Description:** No information available

**15. REGULATORY INFORMATION****International Inventories**

Components	U.S. TSCA	KOREA KECL	Philippines (PICCS)	Japan ENCS	CHINA	Australia (AICS)	EINECS-No.
Poloxamer 188	Present XU	Present KE-24574	Present	Present (7)-1246	Present	Present	Not present

**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	Carcinogen	Developmental Toxicity	Male Reproductive Toxicity	Female Reproductive Toxicity:
Poloxamer 188	Not Listed	Not Listed	Not Listed	Not Listed

**CERCLA/SARA**

Components	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 <i>de minimis</i>
Poloxamer 188	None	None	None	None	None

**U.S. TSCA**

Components	TSCA Section 5(a)2 - Chemicals With Significant New Use Rules (SNURS)	TSCA 8(d) -Health and Safety Reporting
Poloxamer 188	Not Applicable	Not Applicable

**Canada****WHMIS hazard class:**

Non-controlled

**Canada Controlled Products Regulation:**

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

**Inventory**

Components	Canada (DSL)	Canada (NDSL)
Poloxamer 188	Present	Not Listed

<b>Components</b>	<b>CEPA Schedule I - Toxic Substances</b>	<b>CEPA - 2010 Greenhouse Gases Subject to Mandatory Reporting</b>
Poloxamer 188	Not listed	Not listed

**EU Classification**

**R-phrase(s)**

not determined

**S -phrase(s)**

none

<b>Components</b>	<b>Classification</b>	<b>Concentration Limits:</b>	<b>Safety Phrases</b>
Poloxamer 188		No information	

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

**Indication of danger:**

Not dangerous

**16. OTHER INFORMATION**

**16. OTHER INFORMATION**

NFPA	HMIS	Personal Protective Equipment
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Health Hazard	1
Fire Hazard	1
Reactivity	0



See Section 8.

Preparation Date: 6/30/2014  
Revision Date: 6/30/2014  
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 Material Safety Data Sheet**



## **Manufacturer**

Product Covered: P1169, Poloxamer 188, NF

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 blue ink, appearing to read "Michael Dang", with a long horizontal flourish extending to the right.

Michael Dang  
Director, Quality Systems & GMP  
Compliance  
[mdang@spectrumchemical.com](mailto:mdang@spectrumchemical.com)

19.September.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](mailto:qualityassurance@spectrumchemical.com)

Sincerely,



Oralia Chavez  
Quality Assurance Specialist

September 19, 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.

<b>Catalog Number</b>	<b>Product Name</b>
P1169	Poloxamer 188, NF

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](mailto:qualityassurance@spectrumchemical.com)

Sincerely,



Oralia Chavez  
Quality Assurance Specialist



May 3, 2016

Re: Poloxamer 188, NF- P1169

To Whom It May Concern:

Thank you for your interest in Spectrum high quality chemicals.

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

Poloxamer 188, NF- P1169

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](mailto:techservices@spectrumchemical.com).

Sincerely,

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

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



May 3, 2016

Re: Poloxamer 188, NF- P1169

To Whom It May Concern:

Thank you for your interest in Spectrum high quality chemicals.

We at Spectrum Chemical Mfr. Corp. understand the concern regarding the presence of allergens in raw materials. Please be assured that the following chemical does not contain (Milk; Egg; Fish; Shellfish; Sulfur dioxide and sulfites at concentrations of more than 10 mg/kg or 10 mg/liter expressed as SO<sub>2</sub>; Lupin; Tree nuts; Mollusks; Wheat; Peanuts; Soy; Cereals containing Gluten; Celery; Mustard; Sesame Seed).

Poloxamer 188, NF- P1169

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

Sincerely,

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

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





May 3, 2016

Re: Poloxamer 188, NF- P1169

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 Aflatoxins in raw materials. To the best of our knowledge, the product listed below is not contaminated with Aflatoxins. Aflatoxins are not used in production. The following product does not come in contact with Aflatoxins at any stage of production.

Poloxamer 188, NF- P1169

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

Sincerely,

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

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

Item Number	P1169	Lot Number	1HB0789
Item	Poloxamer 188, NF		
CAS Number	9003-11-6		
Molecular Formula	$\text{HO}(\text{C}_2\text{H}_4\text{O})_a(\text{C}_3\text{H}_6\text{O})_b(\text{C}_2\text{H}_4\text{O})_c\text{H}$	Molecular Weight	APPROX. AV.

Test	Specification		Result
	min	max	
AVERAGE MOLECULAR WEIGHT	7,680	9,510	8,577
WEIGHT PERCENT OXYETHYLENE	81.8 +/-1.9 %		81.0 %
pH OF A 1 IN 40 SOLUTION	5.0	7.5	6.4
UNSATURATION	0.026+/-0.008 mEq/g		0.025 meq/g
ELEMENTAL IMPURITIES	AS REPORTED		COMPLIES WITH STANDARD
FREE ETHYLENE OXIDE		1 µg/g	1 µg/g
FREE PROPYLENE OXIDE		5 µg/g	1 µg/g
FREE 1,4-DIOXANE		5 µg/g	0 µg/g
IDENTIFICATION	TO PASS TEST		PASSES TEST
EXPIRATION DATE			14-SEP-2019
DATE OF MANUFACTURE			14-SEP-2016
APPEARANCE			WHITE GRANULES
RESIDUAL SOLVENTS:	TO PASS TEST		PASSES TEST

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 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.

## 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.

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

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

June 15, 2018

**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:** Z10928 = The 928<sup>th</sup> material produced in California in September 2010

The lot numbering system utilized for 2011 and forward, is a sequence of **seven characters**. The first character, a number, represents the production facility:

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

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

**Example:** 2AA0706 = The 706<sup>th</sup> material produced in New Jersey in January 2011

Thank you for your interest with Spectrum products. Please feel free to contact us at 310-516-8000 or via email at [qualityassurance@spectrumchemical.com](mailto:qualityassurance@spectrumchemical.com) if we may be of further assistance.

Sincerely,



Michael Dang  
Director, Quality Systems & GMP Compliance  
[mdang@spectrumchemical.com](mailto:mdang@spectrumchemical.com)



## Stability – Shelf Life Guidance

Product Covered: P1169, Poloxamer 188, NF

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

The product, P1169, Poloxamer 188, NF, 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", is positioned above the printed name and title.

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