Scientific Documentation

P1166, Poloxamer 407, NF

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.

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P1166, Poloxamer 407, NF

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Specification for Poloxamer 407, NF (P1166)

Item Number	P1166
Item	Poloxamer 407, NF
CAS Number	9003-11-6
Molecular Formula	$HO(C_2H_4O)_a(C_3H_6O)_b(C_2H_4O)_aH$
Molecular Weight	AV. M.W. 12,500
MDL Number	
Synonyms	Pluronic F127 ; Polyethylene-Polypropylene Glycol

Test	Specification	
	Min	Max
AVERAGE MOLECULAR WEIGHT	9,840	14,600
WEIGHT PERCENT OXYETHYLENE	73.2 +/-1.7 %	
pH OF A 1 IN 40 SOLUTION	5.0	7.5
ELEMENTAL IMPURITIES		AS REPORTED
UNSATURATION		0.065 mEq/g
FREE ETHYLENE OXIDE		1 µg/g
FREE PROPYLENE OXIDE		5 µg/g
FREE 1,4-DIOXANE		5 µg/g
IDENTIFICATION	SPECTRUM MATCHES REFERENCE	
CERTIFIED HALAL		
EXPIRATION DATE		
DATE OF MANUFACTURE		
APPEARANCE		
RESIDUAL SOLVENTS		AS REPORTED

Spectrum Chemical Mfg Corp

Corporate Headquarters:	*West Coast Facility:*
769 Jersey Ave.	14422 S. San Pedro St.
New Brunswick, NJ 08901	Gardena, CA 90248
732.214.1300	310.516.8000

Certificate Of Analysis

Item Number	P1166	Lot Number	1KI0752
Item	Poloxamer 407, NF	CAS Number	9003-11-6
Molecular Formula	$HO(C_2H_4O)_a(C_3H_6O)_b(C_2H_4O)_aH$	Molecular Weight	AV. M.W. 12,500

TEST	SPECIFICATION		RESULT
	MIN	MAX	
AVERAGE MOLECULAR WEIGHT	9,840	14,600	11,936
WEIGHT PERCENT OXYETHYLENE	73.2 +/-1.7 %		72.5 %
UNSATURATION	0.048 +/- 0.017 mEq/g		0.0043 mEq/g
pH OF A 1 IN 40 SOLUTION	5.0	7.5	6.5
ELEMENTAL IMPURITIES		AS REPORTED	NO ELEMENTAL IMPURITIES PRESENT
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	<1 µg/g
IDENTIFICATION	SPECTRUM MATCHES REFERENCE		SPECTRUM MATCHES REFERENCE
CERTIFIED HALAL			CERTIFIED HALAL
EXPIRATION DATE			05-APR-2024
DATE OF MANUFACTURE			06-APR-2021
APPEARANCE			WHITE GRANULES
RESIDUAL SOLVENTS		AS REPORTED	.

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

Certificate of Analysis Results Certified By:

Jigisha Patel
VP Regulatory Compliance & Technical Services, Regulatory

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

Read and understand label and SDS before handling any chemicals. All Spectrum's chemicals are for manufacturing, processing, repacking or research purposes by experienced personnel only. It is the customer's responsibility to provide adequate hazardous material training and ensure that appropriate Personal Protective Equipment (PPE) is used before handling any chemical.

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

SAFETY DATA SHEET

Preparation Date: 6/29/2015 **Revision Date:** 10/11/2018 **Revision Number:** G3

1. IDENTIFICATION

Product identifier

Product code: P1166
Product Name: POLOXAMER 407, NF

Other means of identification
Synonyms: Polyethylene-polypropylene glycol; Polyoxyethylene-Polyoxypropylene Block Copolymer; Poly(Ethyleneoxide-co-Polypropylene oxide), Block; Block Copolymer of Ethylene Oxide and Propylene Oxide; Ethylene oxide/Polypropylene oxide copolymer; Methyl-oxirane polymer with oxirane
CAS #: 9003-11-6
RTECS # TP6328666
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 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 not considered hazardous according to the 2012 OSHA Hazard Communication Standard (29 CFR 1910.1200)

Not a dangerous substance or mixture according to the Globally Harmonized System (GHS)

Label elements

Not classified

Hazards not otherwise classified (HNOC)
Not Applicable

Other hazards
Not available

3. COMPOSITION/INFORMATION ON INGREDIENTS

Components	CAS-No.	Weight %
Poloxamer 407	9003-11-6	100
Propylene oxide	75-56-9	0.0005
1,4-Dioxane	123-91-1	0.0005
Ethylene oxide	75-21-8	0.0001

4. FIRST AID MEASURES

First aid measures

General Advice: National Capital Poison Center in the United States can provide assistance if you have a poison emergency and need to talk to a poison specialist. Call 1-800-222-1222.

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

Eye Contact: Flush eyes with water for 15 minutes. Get medical attention if irritation occurs. If symptoms persist, call a physician.

Inhalation: Move to fresh air. If not breathing, give artificial respiration. If breathing is difficult, give oxygen. Get medical attention.

Ingestion: Do not induce vomiting without medical advice. Never give anything by mouth to an unconscious person. Consult a physician if necessary.

Most important symptoms and effects, both acute and delayed

Symptoms May cause eye/skin irritation
May cause gastrointestinal disturbances
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 (CO2). Dry chemical. Water spray mist or foam.

Unsuitable Extinguishing Media: No information available.

Specific hazards arising from the chemical

Hazardous Combustion Products: Carbon Monoxide, Carbon Dioxide.

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. Keep people away from and upwind of spill/leak. Do not touch damaged containers or spilled material unless wearing appropriate protective clothing. Remove all sources of ignition.

Environmental precautions Prevent further leakage or spillage if safe to do so. Prevent product from entering drains.

Methods and material for containment and cleaning up

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

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

7. HANDLING AND STORAGE

Precautions for safe handling

Technical Measures/Precautions:
Provide sufficient air exchange and/or exhaust in work rooms. Keep away from incompatible materials.

Safe Handling Advice
Wear personal protective equipment. Avoid contact with skin, eyes and clothing. Keep away from heat and sources of ignition. Do not ingest. Do not breathe dust. Handle in accordance with good industrial hygiene and safety practice.

Conditions for safe storage, including any incompatibilities

Technical Measures/Storage Conditions:
Keep container tightly closed in a dry and well-ventilated place. Store at room temperature in the original container. Store away from incompatible materials.

Incompatible Materials:
Oxidizing agents
Strong acids
Strong bases

8. EXPOSURE CONTROLS/PERSONAL PROTECTION

Control parameters

National occupational exposure limits

United States

Components	CAS-No.	OSHA	NIOSH	ACGIH	AIHA WEEL
Poloxamer 407	9003-11-6	None	None	None	None
Propylene oxide	75-56-9	100 ppm TWA 240 mg/m³ TWA	None	2 ppm TWA	None
1,4-Dioxane	123-91-1	100 ppm TWA 360 mg/m³ TWA	1 ppm Ceiling 30 min 3.6 mg/m³ Ceiling 30 min	20 ppm TWA	None
Ethylene oxide	75-21-8	1 ppm TWA 5 ppm STEL	0.1 ppm TWA 0.18 mg/m³ TWA 5 ppm Ceiling 10 min/day 9 mg/m³ Ceiling 10 min/day	1 ppm TWA	None

Canada

Components	CAS-No.	Canada - Alberta	Canada - British Columbia	Canada - Ontario	Canada - Quebec
Poloxamer 407	9003-11-6	None	None	None	None
Propylene oxide	75-56-9	2 ppm TWA 4.7 mg/m³ TWA	2 ppm TWA	None	None
1,4-Dioxane	123-91-1	20 ppm TWA 72 mg/m³ TWA	20 ppm TWA	None	None
Ethylene oxide	75-21-8	1 ppm TWA 1.8 mg/m³ TWA	0.1 ppm TWA 1 ppm STEL	1 ppm TWA 1.8 mg/m³ TWA 10 ppm STEL 18 mg/m³ STEL	1 ppm TWAEV 1.8 mg/m³ TWAEV

Australia and Mexico

Components	CAS-No.	Australia	Mexico
Poloxamer 407	9003-11-6	None	None
Propylene oxide	75-56-9	20 ppm TWA 48 mg/m³ TWA	20 ppm TWA 50 mg/m³ TWA
1,4-Dioxane	123-91-1	10 ppm TWA 36 mg/m³ tWA	25 ppm TWA 90 mg/m³ TWA 100 ppm STEL 360 mg/m³ STEL
Ethylene oxide	75-21-8	1 ppm TWA 1.8 mg/m³ TWA	1 ppm TWA 2 mg/m³ TWA

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 with side-shields. or Goggles

Skin and body protection: Long sleeved clothing
Chemical resistant apron
Gloves

Respiratory protection: Effective dust mask. or. Wear respirator with dust filter. Use a dust respirator under conditions where exposure to the substance is apparent (e.g. generation of

high concentration of dust (dust clouds) , inadequate ventilation, development of respiratory tract irritation), and engineering controls are not feasible. Be sure to use an approved/certified respirator or equivalent.

Hygiene measures: Avoid contact with skin, eyes and clothing. Wash hands before breaks and immediately after handling the product. When using, do not eat, drink or smoke.

9. PHYSICAL AND CHEMICAL PROPERTIES

Physical state: Solid	**Appearance:** Waxy. Granular. Coarse pariticles.	**Color:** White.
Odor: No information available.	**Taste** No information available.	**Formula:** HO(C2H4O)a(C3H6O)b(C2H4O)aH
Molecular/Formula weight (g/mole): Avg. 12,500	**Flammability:** No information available	**Flash point (°C):** >150
Flashpoint (°C/°F): >150°C/302°F	**Flash Point Tested according to:** Closed cup	**Autoignition Temperature (°C/°F):** >250°C(482°F)
Lower Explosion Limit (%): No information available	**Upper Explosion Limit (%):** No information available	**Melting point/range(°C/°F):** 53°C(127.4°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):** No information available
Viscosity: No information available	**Miscibility:** No information available	**Solubility:** Soluble in cold water Solubility in Water: 175 g/l at 25 °C

10. STABILITY AND REACTIVITY

Reactivity
Reactive with oxidizing agents
Reacts with strong bases
Reactive with strong acids

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: Oxidizing agents
Strong acids
Strong bases

Hazardous decomposition products: Carbon oxides.

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 407	
CAS-No.	9003-11-6

LD50/oral/rat = 5700 mg/kg Oral LD50 Rat
16 g/kg
LD50/oral/mouse = 3 gm/kg
LD50/dermal/rabbit = >5000 mg/kg
LD50/dermal/rat = No information available
LC50/inhalation/rat = 320 mg/m^3 Inhalation LC50 Rat 4 h
LC50/inhalation/mouse = No information available
Other LD50 or LC50information = No information available

Propylene oxide	
CAS-No.	75-56-9

LD50/oral/rat = = 520 mg/kg Oral LD50 Rat
LD50/oral/mouse = No information available
LD50/dermal/rabbit = 1244 mg/kg Dermal LD50 Rabbit
LD50/dermal/rat = No information available
LC50/inhalation/rat = 4000 ppm Inhalation LC50 Rat 4 h; 0.948 mg/L Inhalation LC50 Rat 4 h
LC50/inhalation/mouse = No information available
Other LD50 or LC50information = No information available

1,4-Dioxane	
CAS-No.	123-91-1

LD50/oral/rat = 5170 mg/kg Oral LD50 Rat; 4200 mg/kg Oral LD50 Rat
LD50/oral/mouse = No information available
LD50/dermal/rabbit = 7600 mg/kg Dermal LD50Rabbit
LD50/dermal/rat = No information available
LC50/inhalation/rat = 46 mg/l Inhalation LC50 Rat 2 h
LC50/inhalation/mouse = No information available
Other LD50 or LC50information = No information available

Ethylene oxide	
CAS-No.	75-21-8

LD50/oral/rat = 72 mg/kg Oral LD50 Rat
LD50/oral/mouse = No information available
LD50/dermal/rabbit = No information available
LD50/dermal/rat = No information available
LC50/inhalation/rat = 800 ppm Inhalation LC50 Rat 4 h
LC50/inhalation/mouse = No information available
Other LD50 or LC50information = No information available

Product Information

LD50/oral/rat =
VALUE- Acute Tox Oral = 5700 mg/kg

LD50/oral/mouse =
Value - Acute Tox Oral = 3000 mg/kg

LD50/dermal/rabbit
VALUE-Acute Tox Dermal = > 5000 mg/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 = 320 mg/m^3 (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: May cause eye irritation.

Inhalation May cause irritation of respiratory tract.

Ingestion May cause gastrointestinal disturbances. May cause hypermotility, diarrhea. May affect behavior/central nervous system (somnolence).

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
Poloxamer 407	9003-11-6	Not listed	Not listed	Not listed	Not listed	Not listed	Not listed
Propylene oxide	75-56-9	Group 2B - Possibly Carcinogenic to Humans - Monograph 60 [1994] Supplement 7	A3 Confirmed Animal Carcinogen with Unknown Relevance to Humans	Reasonably Anticipated To Be A Human Carcinogen	Present	Not listed	Not listed

		[1987]					
1,4-Dioxane	123-91-1	Group 2B - Possibly Carcinogenic to Humans - Monograph 71 [1999] Supplement 7 [1987] Monograph 11 [1976]	A3 Confirmed Animal Carcinogen with Unknown Relevance to Humans	Reasonably Anticipated To Be A Human Carcinogen	Present	Not listed	Not listed
Ethylene oxide	75-21-8	Group 1 - Carcinogenic to Humans - Monograph 100F [2012] Monograph 97 [2008] Monograph 60 [1994] overall evaluation upgraded from Group 2A to Group 1 based on mechanistic and other relevant data	A2 Suspected Human Carcinogen	Known Human Carcinogen	Present see 29 CFR 1910.1047	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: Aquatic environment.

Poloxamer 407 - 9003-11-6
Freshwater Algae Data: >970 mg/l 72 h EC50 algae
Freshwater Fish Species Data: >10,000 mg/l 96 h LC50 Brachydanio rerio
Propylene oxide - 75-56-9
Freshwater Algae Data: 240 mg/L EC50 Pseudokirchneriella subcapitata 96 h
Freshwater Fish Species Data: 215 mg/L LC50 Lepomis macrochirus 96 h static 1
Water Flea Data: 350 mg/L EC50 Daphnia magna 48 h
1,4-Dioxane - 123-91-1
Freshwater Fish Species Data: 10000 mg/L LC50 Lepomis macrochirus 96 h static 1 10000 mg/L LC50 Lepomis macrochirus 96 h semi-static 1 9850 mg/L LC50 Pimephales promelas 96 h

flow-through 1 10306 - 14742 mg/L LC50 Pimephales promelas 96 h static 1 9850 mg/L LC50 Pimephales promelas 96 h 1

Water Flea Data: 163 mg/L EC50 water flea 48 h

Ethylene oxide - 75-21-8

Freshwater Fish Species Data: 73 - 96 mg/L LC50 Pimephales promelas 96 h 1

Water Flea Data: 137 - 300 mg/L LC50 Daphnia magna 48 h

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
Poloxamer 407	9003-11-6	None	None	None	None
Propylene oxide	75-56-9	None	None	None	None
1,4-Dioxane	123-91-1	None	None	None	U108
Ethylene oxide	75-21-8	None	None	None	U115 ignitable waste, toxic waste

14. TRANSPORT INFORMATION

DOT

UN-No: Not Regulated
Proper Shipping Name: No information available
Hazard Class: No information available
Subsidiary Class No information available
Packing group: No information available
Emergency Response Guide Number No information available
Marine Pollutant No data available
DOT RQ (lbs): No information available
Special Provisions No Information available
Symbol(s): No information available
Description: No information available

TDG (Canada)

UN-No: Not Regulated
Proper Shipping Name: No information available
Hazard Class: No information available
Subsidiary Risk: No information available
Packing Group: No information available
Marine Pollutant No Information available
Description: No information available

ADR

UN-No: Not Regulated
Proper Shipping Name: No information available
Hazard Class: No information available
Packing Group: No information available
Subsidiary Risk: 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
Marine Pollutant 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

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

IATA
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
ERG Code: No information available
Special Provisions No information available

15. REGULATORY INFORMATION

International Inventories

Components	CAS-No.	U.S. TSCA	KOREA KECL	Philippines (PICCS)	Japan ENCS	CHINA	Australia (AICS)	EINECS-No.
Poloxamer 407	9003-11-6	Present XU(ACTIVE)	Present KE-24574	Present	Present (7)-1246	Present	Present	Not present
Propylene oxide	75-56-9	PresentACTIVE	Present KE-24565	Present	Present (2)-219	Present	Present	Present 200-879-2
1,4-Dioxane	123-91-1	PresentACTIVE	Present KE-10463	Present	Present (5)-839	Present	Present	Present 204-661-8
Ethylene oxide	75-21-8	PresentACTIVE	Present KE-27537	Present	Present (2)-218	Present	Present	Present 200-849-9

U.S. Regulations

Poloxamer 407
FDA - Direct Food Additives 21 CFR 172.808 (condensates); 21 CFR 173.340
FDA - 21 CFR - Total Food Additives - List Sourced from EAFUS 172.808, 173.340, 176.210, 177.1210, 177.1680, 178.1010, 178.3570; Present (average molecular weight 14000; not regulated under 21 CFR); Present (average molecular weight 9760-13200; not regulated under 21 CFR); 172.810 (average molecular weight 3500-4125);

178.1010 (min average molecular weight1900)

Propylene oxide

Massachusetts RTK: Present
Massachusetts EHS: carcinogen; extraordinarily hazardous
New Jersey RTK Hazardous Substance List: 1615
New Jersey (EHS) List: 1615 500 lb TPQ
New Jersey - Discharge Prevention - List of Hazardous Substances: Present
New Jersey TCPA - EHS: 7700lbTQ
Pennsylvania RTK: Environmental hazard
Special hazardous substance
Pennsylvania RTK - Environmental Hazard List Present
Pennsylvania RTK - Special Hazardous Substances Present
Minnesota - Hazardous Substance List: Present
New York Release Reporting - List of Hazardous Substances:
100 lb RQ
Louisana Reportable Quantity List for Pollutants: Listed
California Directors List of Hazardous Substances: Present

FDA - Direct Food Additives 21 CFR 172.892 (<=25%)
FDA - 21 CFR - Total Food Additives 172.892, 175.105, 176.210
- List Sourced from EAFUS

1,4-Dioxane

Massachusetts RTK: Present
Massachusetts EHS: carcinogen; extraordinarily hazardous
New Jersey RTK Hazardous Substance List: 0789
New Jersey (EHS) List: 0789 500 lb TPQ
New Jersey - Discharge Prevention - List of Hazardous Substances: Present
Pennsylvania RTK: Environmental hazard
Special hazardous substance
Pennsylvania RTK - Environmental Hazard List Present
Pennsylvania RTK - Special Hazardous Substances Present
Minnesota - Hazardous Substance List: Present
New York Release Reporting - List of Hazardous Substances:
100 lb RQ
1 lb RQ
Louisana Reportable Quantity List for Pollutants: 100lbfinal RQ
45.4kgfinal RQ
California Directors List of Hazardous Substances: Present

Ethylene oxide

Massachusetts RTK: Present
Massachusetts EHS: carcinogen; extraordinarily hazardous
New Jersey RTK Hazardous Substance List: 0882
New Jersey (EHS) List: 0882 500 lb TPQ
New Jersey - Discharge Prevention - List of Hazardous Substances: Present
New Jersey TCPA - EHS: 2700lbTQ
Pennsylvania RTK: Environmental hazard
Special hazardous substance
Pennsylvania RTK - Environmental Hazard List Present
Pennsylvania RTK - Special Hazardous Substances Present
Michigan PSM HHC: = 5000 lb TQ
Minnesota - Hazardous Substance List: Present
New York Release Reporting - List of Hazardous Substances:
10 lb RQ
Louisana Reportable Quantity List for Pollutants: Listed
California Directors List of Hazardous Substances: Present

FDA - 21 CFR - Total Food Additives 172.710, 172.808, 175.105, 176.180, 176.210, 177.2470, 178.3520
- List Sourced from EAFUS

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

Chemicals Known to the State of California to Cause Cancer:

⚠WARNING: This product can expose you to chemicals including (see table below) which is (are) known to the State of California to cause cancer. For more information go to www.p65warnings.ca.gov.

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

⚠WARNING: This product can expose you to chemicals including (see table below) which is (are) known to the State of California to cause birth defects or other reproductive harm. For more information go to www.p65warnings.ca.gov.

Components	CAS-No.	Carcinogen	Developmental Toxicity	Male Reproductive Toxicity	Female Reproductive Toxicity:
Poloxamer 407	9003-11-6	Not Listed	Not Listed	Not Listed	Ethylene oxide
Propylene oxide	75-56-9	carcinogen	Not Listed	Not Listed	Not Listed
1,4-Dioxane	123-91-1	carcinogen	Not Listed	Not Listed	Not Listed
Ethylene oxide	75-21-8	carcinogen	Developmental toxicity	Male reproductive toxicity	female reproductive toxicity

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
Poloxamer 407	9003-11-6	None	None	None	None	None
Propylene oxide	75-56-9	100 lb final RQ 45.4 kg final RQ	100 lb EPCRA RQ	None	None	0.1 % de minimis concentration
1,4-Dioxane	123-91-1	100 lb final RQ 45.4 kg final RQ	None	None	None	0.1 % de minimis concentration
Ethylene oxide	75-21-8	10 lb final RQ 4.54 kg final RQ	1000 lb TPQ 10 lb EPCRA RQ	None	None	0.1 % de minimis concentration

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
Poloxamer 407	9003-11-6	Not Applicable	Not Applicable
Propylene oxide	75-56-9	Not Applicable	Not Applicable
1,4-Dioxane	123-91-1	Not Applicable	Not Applicable
Ethylene oxide	75-21-8	Not Applicable	10/04/1982 10/04/1992

Canada

WHIMIS 2015 - GHS Classifications

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

Component	WHMIS 2015 Hazard Classification
Propylene oxide 75-56-9 (0.0005)	Flammable liquids - Category 1: H224 Extremely flammable liquid and vapour.; Acute toxicity - Oral - Category 4: H302 Harmful if swallowed.; Acute toxicity - Dermal - Category 4: H312 Harmful in contact with skin.; Acute toxicity - Inhalation - Category 3: H331 Toxic if inhaled.; Serious Eye Damage/Eye Irritation - Category 2: H319 Causes serious eye irritation.; Carcinogenicity - Category 2: H351 Suspected of causing cancer.; Specific target organ toxicity - Single exposure - Category 3: H335 May cause respiratory irritation.
1,4-Dioxane 123-91-1 (0.0005)	Flammable liquids - Category 2: H225 Highly flammable liquid and vapour.; Serious Eye Damage/Eye Irritation - Category 2: H319 Causes serious eye irritation.; Carcinogenicity - Category 2: H351 Suspected of causing cancer.
Ethylene oxide 75-21-8 (0.0001)	Flammable gases - Category 1: H220 Extremely flammable gas.; Gases under pressure - Liquefied gas: H280 Contains gas under pressure, may explode when heated.; Acute toxicity - Inhalation - Category 3: H331 Toxic if inhaled.; Skin corrosion/irritation - Category 2: H315 Causes skin irritation.; Serious Eye Damage/Eye Irritation - Category 2: H319 Causes serious eye irritation.; Respiratory sensitizers - Category 1B: H334 May cause allergic or asthmatic symptoms or breathing difficulties if inhaled.; Skin sensitizers - Category 1B: H317 May cause allergic skin reaction.; Germ cell mutagenicity - Category 1B: H340 May cause genetic defects.; Carcinogenicity - Category 1B: H350 May cause

cancer.; Reproductive Toxicity - Category 1: H360 May damage fertility or the unborn child.; Specific target organ toxicity - Single exposure - Category 3: H335 May cause respiratory irritation.; Specific target organ toxicity - Repeated exposure - Category 1: H372 Causes damage to organs through prolonged or repeated exposure.

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

Components	**WHMIS Ingredient Disclosure List -**
Propylene oxide	1 %
1,4-Dioxane	0.1 %
Ethylene oxide	0.1 %

Inventory

Components	CAS-No.	Canada (DSL)	Canada (NDSL)
Poloxamer 407	9003-11-6	Present	Not Listed
Propylene oxide	75-56-9	Present	Not Listed
1,4-Dioxane	123-91-1	Present	Not Listed
Ethylene oxide	75-21-8	Present	Not Listed

Components	CAS-No.	CEPA Schedule I - Toxic Substances
Poloxamer 407	9003-11-6	Not listed
Propylene oxide	75-56-9	Present
1,4-Dioxane	123-91-1	Not listed
Ethylene oxide	75-21-8	Present
Components	CAS-No.	CEPA - 2010 Greenhouse Gases Subject to Mandatory Reporting
Poloxamer 407	9003-11-6	Not listed
Propylene oxide	75-56-9	Not listed
1,4-Dioxane	123-91-1	Not listed
Ethylene oxide	75-21-8	Not listed

EU Classification

EU GHS - SV - CLP 1272/2008

Components	CAS-No.	EU GHS - SV - CLP (1272/2008)
Poloxamer 407	9003-11-6	
Propylene oxide	75-56-9	Flammable liquids - Flam. Liq. 1: H224 Extremely flammable liquid and vapour.; Acute toxicity - Oral - Acute Tox. 4: H302 Harmful if swallowed.; Acute toxicity - Dermal - Acute Tox. 3: H311 Toxic in contact with skin.; Acute toxicity - Inhalation - Acute Tox. 3: H331 Toxic if inhaled.; Skin corrosion/irritation - Skin Irrit. 2: H315 Causes skin irritation.; Serious Eye Damage/Eye Irritation - Eye Irrit. 2: H319 Causes serious eye irritation.; Germ cell mutagenicity - Muta. 1B: H340 May cause genetic defects.; Carcinogenicity - Carc. 1B: H350 May cause cancer.; Specific target organ toxicity - Single exposure - STOT SE 3: H335 May cause respiratory irritation.603-055-00-4
1,4-Dioxane	123-91-1	Flammable liquids - Flam. Liq. 2: H225 Highly flammable liquid and vapour.; Serious Eye Damage/Eye Irritation -

		Eye Irrit. 2: H319 Causes serious eye irritation.; Carcinogenicity - Carc. 2: H351 Suspected of causing cancer.; Specific target organ toxicity - Single exposure - STOT SE 3: H335 May cause respiratory irritation.; Supplemental Hazards: EUH019 May form explosive peroxides.; Supplemental Hazards: EUH066 Repeated exposure may cause skin dryness or cracking.603-024-00-5
Ethylene oxide	75-21-8	Flammable gases - Flam. Gas 1: H220 Extremely flammable gas.; Gases under pressure: H280 Contains gas under pressure, may explode when heated.; Acute toxicity - Inhalation - Acute Tox. 3: H331 Toxic if inhaled. (Minimum classification); Skin corrosion/irritation - Skin Irrit. 2: H315 Causes skin irritation.; Serious Eye Damage/Eye Irritation - Eye Irrit. 2: H319 Causes serious eye irritation.; Germ cell mutagenicity - Muta. 1B: H340 May cause genetic defects.; Carcinogenicity - Carc. 1B: H350 May cause cancer.; Specific target organ toxicity - Single exposure - STOT SE 3: H335 May cause respiratory irritation.603-023-00-X

EU - CLP (1272/2008)

R-phrase(s)
not determined (not applicable)

S -phrase(s)
none

Components	CAS-No.	**Classification**	**Concentration Limits:**	**Safety Phrases**
Poloxamer 407	9003-11-6		No information	
Propylene oxide	75-56-9	F+; R12 Xn; R20/21/22 Xi; R36/37/38 Carc.Cat.2; R45 Muta.Cat.2; R46	No information	
1,4-Dioxane	123-91-1	F; R11-19 Xi; R36/37 Carc.Cat.3; R40 R66	No information	S: (2)-9-16-36/37-46
Ethylene oxide	75-21-8	F+; R12 T; R23 Xi; R36/37/38 Carc.Cat.2; R45 Muta.Cat.2; R46 R6	No information	S: 53-45

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

Indication of danger:
None.

16. OTHER INFORMATION

Preparation Date: 6/29/2015
Revision Date: 10/11/2018
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

spectrum®

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
P1166	Poloxamer 407, 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

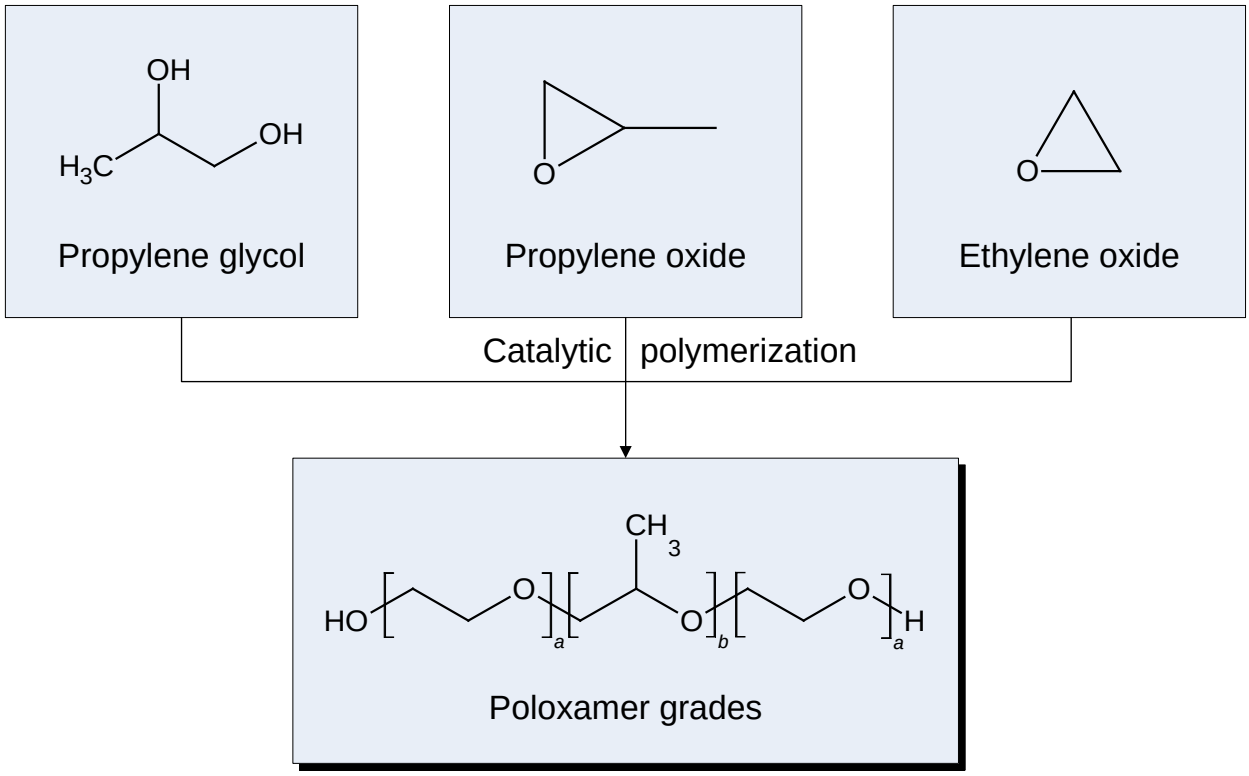
Thank you for your interest in Spectrum products. If we may be of further assistance, please feel free to contact the Quality Assurance department at 310-516-8000 or via email at qualityassurance@spectrumchemical.com

Sincerely,

Oralia Chavez
Quality Assurance Specialist

Manufacturing Process Flowchart

Poloxamer 407, NF - P1166



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

P1166, Poloxamer 407, NF

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 following chemical 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.

Organic Compliance Statement

The above mentioned catalog item has not been produced using GMOs.

Shelf Life Statement

The above mentioned catalog item is typically assigned a shelf life of 36 months from the date of manufacture. The actual assigned shelf life for any specific lot should be referenced on the Certificate of Analysis.

Other Chemicals Statement

Spectrum does not have any reason to suspect the above mentioned catalog item contains any of the following chemicals. This product does not come into contact with these chemicals during packaging or storage:

- Aflatoxins
- Phthalates

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RE: Elemental Impurities - Poloxamer 407, NF (Cat# P1166)

To Whom It May Concern:

Thank you for your interest in Spectrum high quality chemicals.

The above mentioned material complies with the USP<232>, <233> Elemental Impurities and the ICH Q3D Elemental Impurities Guideline. No Class 1, Class 2A, Class 2B or Class 3 elemental impurities are likely to be present. These substances are not used in the production process, are not intentionally added or known to be present in the above mentioned material.

This information is subject to change and is intended for risk assessment only. It is responsibility of the end user to evaluate suitability of any chemical for the intended use as well as to assess compound-specific limits of daily intake of metal impurities. For lot-specific information, please refer to the respective Certificate of Analysis.

If you have any further questions, please contact us by telephone at 1(800)772-8786 Option 2, or by email at TechServices@spectrumchemical.com.

Sincerely,

Technical Services
Spectrum Chemical Mfg. Corp.

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

CORPORATE HEADQUARTERS
769 Jersey Avenue
New Brunswick, NJ 08901
PHONE 732.214.1300
FAX 732.246.7132

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

spectrum®

RE: Residual Solvents - Poloxamer 407, NF (Cat# P1166)

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
1,4-Dioxane	2	< 5 ppm

No Class 1, Class 3 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.

Sincerely,

Technical Services
Spectrum Chemical Mfg. Corp.

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

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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.

Exp. Date: 00-00-0000

49452P1166

USE CARE: This material has been evaluated per GHS/OSHA criteria and is not classified as hazardous. All chemicals may pose unknown hazards and must be used with caution. Use personal protection and safe handling methods consistent with proper workplace safety practices. Consult SDS for additional properties and precautions. If adverse reaction occurs seek medical attention.

KEEP FROM CHILDREN

P1166 **SIZ SY**

Poloxamer 407

(Pluronic® F127;
Polyethylene–Polypropylene Glycol)

NF

CAS 9003-11-6

IFANCA CERTIFIED M HALAL حلال

CAUTION: For manufacturing, processing or repacking. Not for pesticide use.

Read and understand the label and Safety Data Sheet (SDS) prior to use.

Chemical Emergency: (800)424-9300

www.SpectrumChemical.com

$HO(C_2H_4O)_a(C_3H_6O)_b(C_2H_4O)_aH$

Av. M.W. 12,500

Block copolymer of ethylene oxide and propylene oxide. Stabilized with 100 ppm BHT. Pluronic® is a registered trademark of BASF Corporation.

Average Molecular Weight	9,840-14,600
Weight Percent Oxyethylene	73.2 ±1.7%
pH of a 1 in 40 Solution	5.0-7.5

MAXIMUM LIMITS

Elemental Impurities	As reported
Unsaturation	0.065 mEq/g
Free Ethylene Oxide	1 µg/g
Free Propylene Oxide	5 µg/g
Free 1,4-Dioxane	5 µg/g
Residual Solvents	To pass test

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

G 15/K12GHS ? Lot No. XQ####

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Gardena, CA 90248
310.516.8000

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RE: Lot Numbering System

Dear Valued Customer:

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

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

Example: ZI0928 = The 928th material produced in California in September 2010

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

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

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

Example: 2AA0706 = The 706th material produced in New Jersey in January 2011

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

Sincerely,

Oralia Chavez,
Quality Assurance Specialist

CORPORATE HEADQUARTERS
769 Jersey Avenue
New Brunswick, NJ 08901
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FAX 732.246.7132

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

المجلس الإسلامي الأمريكي للغذاء و التغذية

THE ISLAMIC FOOD AND NUTRITION COUNCIL OF AMERICA

IFANCA HALAL PRODUCT CERTIFICATE شهادة حلال

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

Date: **November 02, 2021**

Document #: **11205.11206.II214223**

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

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

	ProductName	Product Code	Halal-ID	Product Certificate #
1.	Poloxamer 407, NF	P1166	C90914	HC-21SPIT67

Muhammad Munir Chaudry, Ph.D.
President

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

MEMBER

WWW.IFANCA.ORG • IFANCA Head Office • 777 Busse Highway • Park Ridge, Illinois 60068 USA • Tel: (847) 993-0034 • Fax (847) 993-0038