

Scientific Documentation G1016, Glycerin, Natural, USP, EP, BP

Not appropriate for regulatory submission. Please visit <u>www.spectrumchemical.com</u> 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,

1 Jan

Michael Dang Director, Quality Systems & GMP Compliance mdang@spectrumchemical.com

G1016, Glycerin, Natural, USP, EP, BP

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Item Number	<u>G1016</u>	
Item	Glycerin, Natural, USP, EP, BP	
CAS Number	56-81-5	
Molecular Formula	C ₃ H ₈ O ₃	
Molecular Weight	92.10	
MDL Number		
Synonyms	Glycerol ; 1,2,3-Propanetriol	

Test	Specification		
	Min	Max	
ASSAY (ANHYDROUS BASIS)	99.0	101.0%	
SPECIFIC GRAVITY @ 25°C	1.249		
APPEARANCE OF SOLUTION	TO PASS TEST		
REFRACTIVE INDEX	1.470	1.475	
COLOR	TO PASS TEST		
RESIDUE ON IGNITION (SULPHATED ASH)		0.01%	
CHLORIDE (Cl)		10 ppm	
SULFATE (SO ₄)		20 ppm	
ELEMENTAL IMPURITIES	AS REPORTED		
CHLORINATED COMPOUNDS (HALOGENATED COMPOUNDS as CI)		30 ppm	
WATER		2.0%	
FATTY ACIDS AND ESTERS	TO PASS TEST		
RELATED COMPOUNDS (USP)	TO PASS TEST		
IMPURITY A AND RELATED SUBSTANCES	TO PASS TEST		
ACIDITY OR ALKALINITY	TO PASS TEST		
ALDEHYDES		10 ppm	
SUGARS	TO PASS TEST		
ESTERS	TO PASS TEST		
IDENTIFICATION:			
IDENTIFICATION: A (USP)	TO PASS TEST		
IDENTIFICATION: B (USP)	TO PASS TEST		
IDENTIFICATION: C (USP)	TO PASS TEST		
CERTIFIED KOSHER			
CERTIFIED HALAL			
EXPIRATION DATE			
DATE OF MANUFACTURE			
APPEARANCE			
RESIDUAL SOLVENTS	TO PASS TEST		

spectrum®



SAFETY DATA SHEET

Preparation Date: 1/22/2014	Revision Date: 7/5/2018	Revision Number: G3
	1. IDENTIFICATION	
Product identifier		
Product code: Product Name:	G1016 GLYCERIN, NATURAL, USP, EP, BP, JP	
Other means of identification 1,2,3-Propanetriol Synonyms: 1,2,3-Trihydroxypropane Glycerin mist Glycerin mist Glycerin, anhydrous Glycerin, synthetic Glycerine Glyceritol Glycyl alcohol Grocolene Osmoglyn Synthetic glycerin Trihydroxypropane glycérine (French) Glycérina (Spanish) glycérine (French) CAS #: 56-81-5 RTECS # MA8050000 Cl#: Not available		
Recommended use of the chem Recommended use:	lical and restrictions on use Solvent. Cosmetics. Lubricant. Soaps. In Foods.	
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: Emergency telephone number Contact Person: Contact Person:	https://www.spectrumchemical.com Chemtrec 1-800-424-9300 Martin LaBenz (West Coast) 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)

Serious eye damage/eye irritation	Category 2B

Label elements

Warning

Hazard statements Causes eye irritation

Hazards not otherwise classified (HNOC) Not Applicable

Other hazards

Causes mild skin irritation

Precautionary Statements - Prevention

Wash face, hands and any exposed skin thoroughly after handling

Precautionary Statements - Response

IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing. If eye irritation persists: Get medical advice/attention.

3. COMPOSITION/INFORMATION ON INGREDIENTS

Components	CAS-No.	Weight %
Glycerin	56-81-5	100

4. FIRST AID MEASURES

First aid measures	
General Advice:	National Capital Poison Center in the United States can provide assistance if you have a poison emergency and need to talk to a poison specialist. Call 1-800-222-1222.
Skin Contact:	Wash off immediately with soap and plenty of water removing all contaminated clothing and shoes. Get medical attention if irritation develops.
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 effe	cts, both acute and delayed
Symptoms	Mild eye irritation Mild skin irritation Central nervous system effects Headache Drowsiness Nausea Vomiting Dehydration Thirst

Product name: GLYCERIN, NATURAL, USP, EP, BP, JP

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. May be ignited by heat, sparks or flames. Container explosion may occur under fire conditions or when heated.				
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 R	6. ACCIDENTAL RELEASE MEASURES				

Personal precautions, protective equipment and emergency procedures

 Personal Precautions:
 Ensure adequate ventilation. Use personal protective equipment. Avoid contact with skin, eyes and clothing. Remove all sources of ignition.

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

Methods and material for containment and cleaning up

Methods for containment	Stop leak if you can do it without risk. Absorb spill with inert material (e.g. vermiculite, dry sand or earth).
Methods for cleaning up	Use appropriate tools to put the spilled material in a suitable chemical waste disposal container. 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. Do not ingest. Do not breathe vapors or spray mist. Keep away from heat and sources of ignition. Handle in accordance with good industrial

Product code: G1016

hygiene and safety practice.

Conditions for safe storage, including any incompatibilities

Technical Measures/Storage Conditions:

Hygroscopic. 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

Acids Acid anhydrides Aniline Nitrobenzene

8. EXPOSURE CONTROLS/PERSONAL PROTECTION

Control parameters

National occupational exposure limits

United States

[Components	CAS-No.	OSHA	NIOSH	ACGIH	AIHA WEEL
	Glycerin	56-81-5	15 mg/m³ TWA 5 mg/m³ TWA	None	None	None

Canada

Components	CAS-No.	Canada - Alberta	Canada - British Columbia	Canada - Ontario	Canada - Quebec
Glycerin	56-81-5	10 mg/m³ TWA	10 mg/m³ TWA 3 mg/m³ TWA respirable	None	None

Australia and Mexico

Components	CAS-No.	Australia	Mexico
Glycerin	56-81-5	10 mg/m³ TWA	10 mg/m³ TWA

Appropriate engineering controls

Engineering measures to reduce exposure:

Ensure adequate ventilation. Provide exhaust ventilation or other engineering controls to keep the airborne concentrations of vapors and mist below their respective threshold limit value.

Individual protection measures, such as personal protective equipment

Personal Protective Equipment

Eye protection:	Goggles
Skin and body protection:	Long sleeved clothing Chemical resistant apron Gloves
Respiratory protection:	Respiratory protection is not necessary for normal handling. Good room
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ventilation or use of local exhaust (fume hood) is sufficient. Use a vapor respirator under conditions where exposure to the substance is apparent (e.g. generation of high concentrations of mist or vapor, 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: Liquid

Odor: Mild (Slight).

Molecular/Formula weight: 92.09

Flash Point Tested according to: Open cup Closed cup Upper Explosion Limit (%): No information available

Boiling point/range(°C/°F): 290 °C/554 °F

Specific gravity: 1.2613-1.2636 @ 20 °C

Evaporation rate: No information available

Odor threshold (ppm): No information available

Miscibility: No information available Appearance: Viscous. Syrupy.

Taste Sweet.

Flammability: No information available

Autoignition Temperature (°C/°F): 370-392 °C/698-739 °F

Melting point/range(°C/°F): 19-20 °C/66.2-68 °F

Bulk density: No information available

pH: No information available

Vapor density: 3.17

Partition coefficient (n-octanol/water): -1.76

Solubility:

Freely soluble in water Insoluble in Benzene Insoluble in Chloroform Insoluble in Carbon disulfide Insoluble in Carbon tetrachloride Insoluble in Petroleum ether Color: Clear. Colorless.

Formula: C3-H8-O3

Flashpoint (°C/°F): 177°C/350.6 °F 160 °C/320 °F Lower Explosion Limit (%): No information available

Decomposition temperature(°C/°F): No information available

Density (g/cm3): No information available

Vapor pressure @ 20°C (kPa): 0

VOC content (g/L): No information available

Viscosity: No information available

10. STABILITY AND REACTIVITY

Reactivity

Reactive with oxidizing agents

Reactive with acids

It can react vigorously, violently or explosively with oxidizers

Glycerin is incompatible with strong oxidizers such as chromium trioxide, potassium chlorate, or potassium permanganate and may explode on contact

Explosive glyceryl nitrate is formed from a mixture of glycerin and nitric and sulfuric acids

When Perchloric acid and Lead oxide are mixed with glycerin, perchloric esters are formed, which may be explosive

Glycerin and chlorine may explode if heated and confined

Glycerin may react violently with acetic anhydride, aniline, nitrobenzene, chromic oxide, lead oxide, fluorine, phosphorous triiodide, ethylene oxide, silver perchlorate, sodium peroxide, and sodium hydride

Chemical stability			
Stability:	Stable under recommended storage conditions.		
Possibility of Hazardous Reactions:	Hazardous polymerization does not occur		
Conditions to avoid:	Heat. Ignition sources. Exposure to moist air. Exposure to moisture.		
Incompatible Materials:	Oxidizing agents Acids Acid anhydrides Aniline Nitrobenzene		
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: Skin. Ingestion. Eyes.

Acute Toxicity

Component Information

Glycerin CAS-No.

56-81-5

LD50/oral/rat = 12600 mg/kg Oral LD50 Rat LD50/oral/mouse = 4090 mg/kg LD50/dermal/rabbit = >10 g/kg Dermal LD50Rabbit LD50/dermal/rat = No information available LC50/inhalation/rat = >570 mg/m³ Inhalation LC50 Rat 1 h LC50/inhalation/mouse = No information available Other LD50 or LC50information = 27 gm/kg LD50 oral Rabbit

Product Information

LD50/oral/rat = VALUE- Acute Tox Oral = 12600 mg/kg

LD50/oral/mouse = Value - Acute Tox Oral = 4090 mg/kg

LD50/dermal/rabbit VALUE-Acute Tox Dermal = > 10000 mg/kg

LD50/dermal/rat

Product code: G1016

Product name: GLYCERIN, NATURAL, USP, EP, BP, JP

VALUE -Acute Tox Dermal = > 21900 mg/kg

LC50/inhalation/rat		
VALUE-Vapor = > 570 mg/m ³ (1-hr)		
VALUE-Gas = No information available		
VALUE-Dust/Mist = No information available		

LC50/Inhalation/mouse VALUE-Vapor = No information available VALUE - Gas = No information available VALUE - Dust/Mist = No information available

Symptoms _____

Skin Contact:	May cause skin irritation. Mild skin irritation. It may be absorbed through the skin. Prolonged skin contact is unlikely to result in absorption of harmful amounts.
Eye Contact:	Contact with eyes may cause irritation. Mild eye irritation. Symptoms may include stinging, tearing, redness.
Inhalation	May cause irritation of respiratory tract. This material has a very low vapor pressure. Not expected to be an inhalation hazard for normal handling. If the product is misted or heated, the inhalation of mist or vapor can cause respiratory tract irritation.
Ingestion	Low hazard. Ingestion may cause gastrointestinal irritation, nausea, vomiting and diarrhea. May cause dehydration. May cause thirst. May cause hyperglycemia. May affect liver. It may affect behavior/central nervous system (excitement, depression, general anesthetic, headache, dizziness, convulsions/seizures, confusion, insomnia, muscle weakness). It may affect behavior/central nervous system (drowsiness). May affect blood (changes in serum composition).
Aspiration hazard	No information available.
Delayed and immediate effects	as well as chronic effects from short and long-term exposure
Chronic Toxicity	Prolonged or repeated ingestion may affect the blood (changes in white blood cell count). Prolonged or repeated ingestion may affect the blood (changes in serum composition). Chronic ingestion of Glycerin may increase blood serum glyceride concentration. Prolonged or repeated ingestion may affect the kidneys. Prolonged or repeated ingestion may affect the kidneys.
Sensitization:	No information available.
Mutagenic Effects:	May affect genetic material

Experiments with human lymphocytes have shown mutagenic effects

Carcinogenic effects:

Not considered carcinogenic.

Components	CAS-No.	IARC	ACGIH - Carcinogens	NTP	OSHA HCS - Carcinogens	Australia - Notifiable Carcinogenic Substances	Australia - Prohibited Carcinogenic Substances
Glycerin	56-81-5	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:	Aquatic environment.	
<i>Glycerin - 56-81-5</i> Freshwater Fish Species Data: Water Flea Data:	51 - 57 mL/L LC50 Oncorhynchus mykiss 96 h static 1 500 mg/L EC50 Daphnia magna 24 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
Glycerin	56-81-5	None	None	None	None

14. TRANSPORT INFORMATION

DOT

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

Product name: GLYCERIN, NATURAL, USP, EP, BP, JP

Special Provisions Symbol(s): **Description:**

TDG (Canada)

UN-No: **Proper Shipping Name:** Hazard Class: Subsidiary Risk: Packing Group: **Marine Pollutant Description:**

ADR

UN-No: Proper Shipping Name: Hazard Class: Packing Group: **Subsidiary Risk:**

IMO / IMDG

UN-No: **Proper Shipping Name:** Hazard Class: Subsidiary Risk: Packing Group: Marine Pollutant

RID

UN-No:	
Proper Shipping Name:	
Hazard Class:	
Subsidiary Risk:	
Packing Group:	

ICAO

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

ΙΑΤΑ

UN-No: **Proper Shipping Name:** Hazard Class: Subsidiary Risk: Packing Group: ERG Code: **Special Provisions**

No Information available No information available No information available

Not Regulated

No information available No information available

Not Regulated No information available No information available No information available No information available

Not Regulated No information available No information available No information available No information available No information available

Not Regulated No information available No information available No information available No information available

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15. REGULATORY INFORMATION

International Inventories

Components	CAS-No.	U.S. TSCA	KOREA KECL	Philippines (PICCS)	Japan ENCS	CHINA	Australia (AICS)	EINECS-No.
Glycerin	56-81-5	PresentACTIV E	Present KE-29297	Present	Present (2)-242	Present	Present	Present 200-289-5

U.S. Regulations

Glycerin Massachusetts RTK: Present New Jersey RTK Hazardous Substance List: 3319 Pennsylvania RTK: Present Minnesota - Hazardous Substance List: Present FDA - Food Additives Generally Recognized as Safe (GRAS): 21 CFR 182.90,21 CFR 182.1320 FDA - Direct Food Additives FDA - 21 CFR - Total Food Additives 169.175, 172.811, 175.300, 175.320, 176.210, 177.1390, 177.2420, 177.2800, 178.3500, 182.1320, 182.90; 172.866, 178.3500 (synthetic)

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	Female
		-		Reproductive	Reproductive
				Toxicity	Toxicity:
Glycerin	56-81-5	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
Glycerin	56-81-5	None	None	None	None	None

U.S. TSCA

Components		TSCA Section 5(a)2 - Chemicals With Significant New Use Rules (SNURS)	
Glycerin	56-81-5	Not Applicable	Not Applicable

Canada

WHIMIS 2015 - GHS Classifications

WHMIS 2015 Hazard Classification Information:

Not a dangerous product according to HPR classification criteria.

Component Glycerin 56-81-5 (100) WHMIS 2015 Hazard Classification Not a dangerous product according to HPR classification criteria

Canada Hazardous Products Regulation This product has been classified according to the hazard criteria of the HPR (Hazardous Products Regulation) and the SDS contains all of the information required by the HPR

WHMIS 1988 Hazard Class Non-controlled

Components Glycerin WHMIS 1988 Uncontrolled product according to WHMIS classification criteria

Product name: GLYCERIN, NATURAL, USP, EP, BP, JP

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)
Glycerin	56-81-5	Present	Not Listed
Components		CAS-No.	CEPA Schedule I - Toxic Substances
Glycerin	56-81-5 Not listed		Not listed
Components CAS-No.		CEPA - 2010 Greenhouse Gases Subject to Mandatory Reporting	
Glycerin		56-81-5	Not listed

EU Classification

EU GHS - SV - CLP 1272/2008

Components	CAS-No.	EU GHS - SV - CLP (1272/2008)
Glycerin	56-81-5	

EU - CLP (1272/2008)

R-phrase(s)

not determined (not applicable)

S -phrase(s)

none

Components	CAS-No.	Classification	Concentration Limits:	Safety Phrases
Glycerin	56-81-5		No information	

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

Indication of danger:

Not dangerous

16. OTHER INFORMATION

Preparation Date:	1/22/2014
Revision Date:	7/5/2018
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

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	NATURAL, USP, EP, BP, JP	

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: G1016, Glycerin, Natural, USP, EP, BP

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,

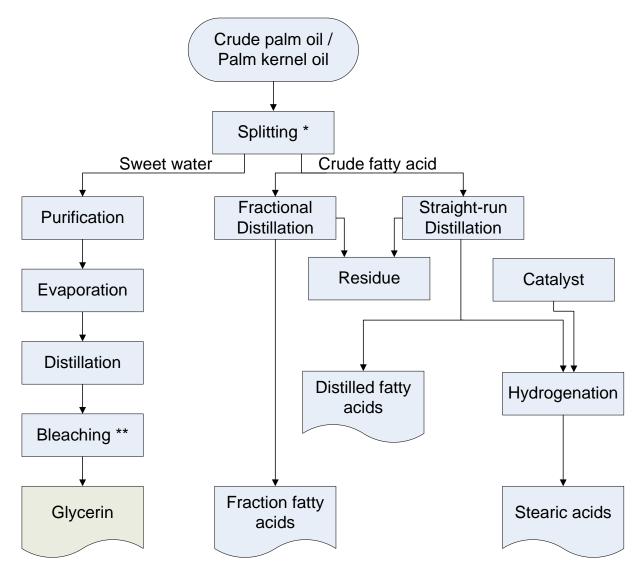
1 Jan

Michael Dang Director, Quality Systems & GMP Compliance <u>mdang@spectrumchemical.com</u>



Manufacturing Process Flowchart

Glycerin, Natural, USP, EP, BP - G1016



* Using high temperature steam fractionation

** Non chemical refining by filtration media

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



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



Authorized Signature Calin Moldovean President Business Assurance

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





In the issuance of this certificate, Intertek assumes no liability to any party other than to the Client, and then only in accordance with the agreed upon Certification Agreement. This certificate's validity is subject to the organization maintaining their system in accordance with Intertek's requirements for systems certification. Validity may be confirmed via email at certificate.validation@intertek.com or by scanning the code to the right with a smartphone. The certificate remains the property of Intertek, to whom it must be returned upon request



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.





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The certificate remains the property of Intertek, to whom it must be returned upon request.



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



Calin Moldovean President, Business Assurance

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

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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



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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.



In the issuance of this certificate, Intertek assumes no liability to any party other than to the Client, and then only in accordance with the agreed upon Certification Agreement. This certificate's validity is subject to the organisation maintaining their system in accordance with Intertek's requirements for systems certification. Validity may be confirmed via email at certificate.validation@intertek.com or by scanning the code to the right with a smartphone. The certificate remains the property of Intertek, to whom it must be returned upon request.

The annual validity of the certificate can also be checked through the website http://www.cnca.gov.cn of CNCA in China.



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: Spectrum-New Brunswick, NJ: Spectrum-Shanghai, China: 2020632 2246824 3006174778

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 <u>gualityassurance@spectrumchemical.com</u>

Sincerely,

Oula Clany

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.

Catalog Number	Product Name
G1016	Glycerin, Natural, USP, EP, BP

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: Spectrum-New Brunswick, NJ: Spectrum-Shanghai, China: 2020632 2246824 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 <u>qualityassurance@spectrumchemical.com</u>

Sincerely,

Oulu Clony

Oralia Chavez Quality Assurance Specialist



March 31, 2016

Re: Glycerin, Natural, USP, EP, BP-G1016

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

Glycerin, Natural, USP, EP, BP-G1016

is BSE/TSE free.

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

Sincerely,

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

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



March 31, 2016

Re: Glycerin, Natural, USP, EP, BP-G1016

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 and its products, Egg and its products, Fish and its products, Shellfish/Crustaceans and its products, any type of Tree Nut and its products, Peanuts and its products, Soy and its products, Cereals containing Gluten, Celery and its products, Mustard and its products, Pork (or any other animal), Sulfur dioxide or sulfating agents are present at levels exceeding 10mg/kg, and Sesame Seed and its products).

Glycerin, Natural, USP, EP, BP-G1016

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

Sincerely,

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

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



April 1, 2016

Re: Glycerin, Natural, USP, EP, BP- G1016

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.

Glycerin, Natural, USP, EP, BP- G1016

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

Sincerely,

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

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

Spectrum®

Certificate Of Analysis

Item Number	G1016	Lot Number	1HI0025
Item	Glycerin, Natural, USP, EP, BP		
CAS Number	56-81-5		
Molecular Formula	C ₃ H ₈ O ₃	Molecular Weight	92.10

Test	Speci	fication	Result
	min	max	
ASSAY (ANHYDROUS BASIS)	99.0	101.0%	99.93 %
SPECIFIC GRAVITY @ 25°C	1.249		1.261
APPEARANCE OF SOLUTION	TO PASS TEST		PASSES TEST
REFRACTIVE INDEX	1.470	1.475	1.473
COLOR	TO PASS TEST		PASSES TEST
RESIDUE ON IGNITION (SULPHATED ASH)		0.01%	<0.01 %
CHLORIDE (CI)		10 ppm	<10 ppm
SULFATE (SO ₄)		20 ppm	<20 ppm
ELEMENTAL IMPURITIES	AS REPORTED		NO ELEMENTAL IMPURITIES PRESENT
CHLORINATED COMPOUNDS (HALOGENATED COMPOUNDS as CI)		30 ppm	<30 ppm
WATER		2.0%	0.09 %
FATTY ACIDS AND ESTERS	TO PASS TEST		PASSES TEST
RELATED COMPOUNDS (USP)	TO PASS TEST		PASSES TEST
IMPURITY A AND RELATED SUBSTANCES	TO PASS TEST		PASSES TEST
ACIDITY OR ALKALINITY	TO PASS TEST		PASSES TEST
ALDEHYDES		10 ppm	<10 ppm
SUGARS	TO PASS TEST		PASSES TEST
ESTERS	TO PASS TEST		PASSES TEST
IDENTIFICATION:			
IDENTIFICATION: A (USP)	TO PASS TEST		PASSES TEST
IDENTIFICATION: B (USP)	TO PASS TEST		PASSES TEST
IDENTIFICATION: C (USP)	TO PASS TEST		PASSES TEST
CERTIFIED KOSHER			CERTIFIED KOSHER
CERTIFIED HALAL			CERTIFIED HALAL
EXPIRATION DATE			18-JUL-2021
DATE OF MANUFACTURE			18-JUL-2018
APPEARANCE			CLEAR COLORLESS LIQUID
RESIDUAL SOLVENTS	TO PASS TEST		NO RESIDUAL SOLVENTS USED

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.



RED: Flammable

GREEN: General Storage

BLUE: Health Hazard WHITE: Corrosive

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.

 skin irritation. Wash face, hands and any exposed skin thoroughly after handling. FIRST AID: IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue or insing. If eye irritation persists: Get medical attention. If skin irritation occurs: Get medical attention. WARNING: This product contains a chemical known to the State of California to cause cancer. WARNING: This product contains a chemical known to the State of California to cause birth defects or other reproductive harm. 	G1016 P F-4 L Glycerol; 1,2,3-Propanetriol) Natural U.S.P., E.P., B.P. CAUTION: For manufacturing, processing or repacking. Read and understand the label and Safety Data Sheet (SDS) prior to use. Chemical Emergency: (800)424-9300	C ₃ H ₈ O ₃ K F.W. 922. Assay (Ahydrous Basis) 99.0-10' Specific Gravity @ 25°C Min 1 Appearance of Solution To pass Refractive Index 1.470-1 Identification: 1.470-1 Identification A (USP) To pass Identification B (USP) To pass Identification B (USP) To pass Identification B (USP) To pass Color To pass Residue on Ignition (Sulphated Ash) 0.0 Chloride (Cl) .0.0 Sultate (So.) .0.0 Heatory Metals (as Pb) .5 Chlorinated Compounds (Halogenated Compounds as Cl) .30 Water .7 To pass Related Compounds (USP) .7 .7 To pass .7 pass Macids and Esters .7 .7 Related Compounds (USP) .7 .7 Sugars .7 .7 Residue Solvents .70 pass Related Substances .7 .7 Morety Corety Corety Corety Corety Corety Corety Corety Co
KEEP FROM CHILDREN	, ,	
E * KEEP FRUM CHILDREN J	www.SpectrumChemical.com	g 20/D1GHS A Lot No. 06223 248 • New Brunswick, NJ 08901
	www.SpectrumChemical.com	G 20/D1GHS A COLOT NO. 06223 248 • New Brunswick, NJ 08901 & Empirical Formula, Formula
 SPECTRUM CHEMICAL M Bar Code GHS Hazard Pictograms 	www.SpectrumChemical.com AFG. CORP. Gardena, CA 902 Size/Quantity Chemical Abstracts Service	g 20/D1GHS A OLOT NO. 06223
SPECTRUM CHEMICAL M Bar Code	www.SpectrumChemical.com AFG. CORP. Gardena, CA 902 B Size/Quantity Chemical Abstracts Service (CAS) Registry Number	G 20/D1GHS A Lot No. 06223 248 • New Brunswick, NJ 08901 C Empirical Formula, Formula Weight and Technical
 SPECTRUM CHEMICAL M Bar Code GHS Hazard Pictograms Warning, Safety Data and Precautiona 	www.SpectrumChemical.com AFG. CORP. Gardena, CA 902 Size/Quantity Chemical Abstracts Service	G 20/D1GHS A Lot No. 0622. 248 • New Brunswick, NJ 08901 C Empirical Formula, Formula Weight and Technical Specifications Panel

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.

Spectrum Chemical Mfg Corp

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

732.214.1300

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: 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 <u>qualityassurance@spectrumchemical.com</u> if we may be of further assistance.

Sincerely,

1 Jan

Michael Dang Director, Quality Systems & GMP Compliance mdang@spectrumchemical.com



Stability – Shelf Life Guidance

Product Covered: G1016, Glycerin, Natural, USP, EP, BP

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

The product, G1016, Glycerin, Natural, USP, EP, BP, 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

Bun & lle same

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



בס"ד Feb 23, 2018

The following product(s) prepared by the named company are certified kosher with the stated requirements:

Spectrum Laboratory Products, Inc.

S-0032

14422 S. San Pedro Street Gardena CA 90248 USA	Product Name	G1016, Glycerin, Natural, USP, EP, BP
	Brand	Spectrum
	UKD-ID	KSAV3-U4W2B39
	D / P / M	Р
	Symbol Required	KSA
This certificate expires on Feb 01, 2019	Special Conditions	

Rabbi Binyomin Lisbon Kashrus Administrator

Placing the KSA logo on products not listed above constitutes an un-authorized use of the KSA symbol, which is a federally registered trademark.



شهادة حلال IFANCA HALAL PRODUCT CERTIFICATE

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: August 16, 2018

Document #: 11205.11206.II181281

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

Plant Name & Address:

Plant Name & Address:			
ProductName	Product Code	Halal-ID	Product Certificate #
1. Glycerin, Natural, USP, EP, BP	G1016	B94100	HC-18SPFD53

