

# Scientific Documentation G1015, Glycerin, Synthetic, USP, EP, BP, JP

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

Ver4.01 19.April.2016



Dear Customer,

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

Spectrum has been proudly serving our 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,

Alan Wang, MSQA, ASQ CQA Senior Manager, Global Supplier Quality Assurance gualityassurance@spectrumchemical.com

G1015, Glycerin, Synthetic, USP, EP, BP, JP

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Item Number	<u>G1015</u>		
Item	Glycerin, Synthetic, USP, EP, BP, JP		
CAS Number	56-81-5		
Molecular Formula	C <sub>3</sub> H <sub>8</sub> O <sub>3</sub>		
Molecular Weight	2.10		
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		
SPECIFIC GRAVITY @ 20°C	1.258		
APPEARANCE OF SOLUTION	TO PASS TEST		
REFRACTIVE INDEX	1.470 - 1.475		
ALDEHYDES		10 ppm	
COLOR	TO PASS TEST		
RESIDUE ON IGNITION (SULPHATED ASH)		0.01%	
CHLORIDE (CI)		0.001%	
SULFATE (SO <sub>4</sub> )		0.002%	
HEAVY METALS (as Pb)		5 μg/g	
CHLORINATED COMPOUNDS (HALOGENATED COMPOUNDS as Cl)		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		
SUGARS	TO PASS TEST		
AMMONIUM ( $NH_4$ )	TO PASS TEST		
CALCIUM (Ca)	TO PASS TEST		
ARSENIC (As)		2 ppm	
ACROLEIN, GLUCOSE OR OTHER[nREDUCING SUBSTANCES	TO PASS TEST		
READILY CARBONIZABLE SUBSTANCES	TO PASS TEST		
ESTERS	TO PASS TEST		
IDENTIFICATION	TO PASS TEST		
IDENTIFICATION: A (USP)	TO PASS TEST		
IDENTIFICATION: B (USP)	TO PASS TEST		
IDENTIFICATION: C (USP)	TO PASS TEST		
CERTIFIED KOSHER			
EXPIRATION DATE			
RESIDUAL SOLVENTS	TO PASS TEST		





## SAFETY DATA SHEET

Preparation Date: 1/22/2014	Revision Date: 1/22/2014	Revision Number: G1				
	1. IDENTIFICATION					
Product identifier						
Product code:	G1015					
Product Name:	GLYCERIN, SYNTHETIC, USP, EP, BP, JP					
Other means of identification						
Synonyms:	1,2,3-Propanetriol					
	1,2,3-Trihydroxypropane Glycerin mist					
	Glycerin, anhydrous					
	Glycerin, synthetic					
	Glycerine					
	Glyceritol					
	Glycyl alcohol					
	Grocolene					
	Osmoglyn Synthetic glycerin					
	Trihydroxypropane					
	glicerina (Spanish)					
	glycérine (French)					
CAS #:	56-81-5					
RTECS #	MA8050000					
CI#:	CI#: Not available					
Recommended use of the chem	ical and restrictions on use					
Recommended use:	Solvent. Cosmetics. Lubricant. Soaps. In foods.					
Uses advised against	No information available					
Supplier:	Spectrum Chemicals and Laboratory Products, Inc.					
<u></u>	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 considered hazardous by the 2012 OSHA Hazard Communication Standard (29 CFR 1910.1200)

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 %	Trade Secret
Glycerin	56-81-5	100	*
56-81-5			

#### **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.
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 effec	ts, both acute and delayed
Symptoms	Mild eye irritation. Mild skin irritation. Central nervous system effects. Headache. Drowsiness. Nausea. Vomiting. Dehydration. Thirst.
Indiantian of any immediate mediael	ettention and encoded tractment needed

#### 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 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 contain	ment 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 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

**U.S Occupational Exposure Limits:** 

United States

Components	OSHA	NIOSH	ACGIH	AIHA WHEEL
	15 mg/m³ TWA	None	None	None
Glycerin - 56-81-5	-			

#### Canada

Canada Occupational Exposure Limits:

Components	Alberta	British Columbia	Ontario	Quebec
	10 mg/m <sup>3</sup> TWA	10 mg/m <sup>3</sup> TWA	10 mg/m <sup>3</sup> TWA mist	10 mg/m <sup>3</sup> TWAEV mist
Glycerin - 56-81-5	-	3 mg/m <sup>3</sup> TWA respirable	-	-

#### Australia and Mexico

Occupational Exposure Limits for Australia and Mexico:

Components	Australia	Mexico
Glycerin	10 mg/m³ TWA	10 mg/m³ TWA
56-81-5		

#### 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. Safety glasses with side-shields.

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

**Respiratory protection:** Respiratory protection is not necessary for normal handling. Good room 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

#### 9. PHYSICAL AND CHEMICAL PROPERTIES

Physical state: Liquid.

Odor: Mild.

Molecular/Formula weight: 92.09

Flash Point Tested according to: Open cup Closed cup Autoignition Temperature (°C/°F): 370-392 °C/698-739 °F

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

**Density (g/cm3):** No information available

**Evaporation rate:** No information available

Odor threshold (ppm): No information available

Miscibility: No information available Appearance: Viscous. Syrupy.

**Taste** Sweet.

Flash point (°C): 160

Lower Explosion Limit (%): No information available

**pH:** No information available

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

Bulk density: 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 Upper Explosion Limit (%):

No information available

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

**Specific gravity:** 1.2613-1.2636 @ 20 °C

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 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
 Stable at normal 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.

#### 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 - 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 = > 21900 mg/kg Dermal LD50 Rat LC50/inhalation/rat = 570 mg/m<sup>3</sup> Inhalation LC50 Rat 1 h LC50/inhalation/mouse = No infomation available Other LD50 or LC50information = 27 gm/kg LD50 oral Rabbit

**Product Information** 

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

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

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

LD50/dermal/rat VALUE -Acute Tox Dermal = > 21900mg/kg

#### LC50/inhalation/rat

VALUE-Vapor = > 570mg/m<sup>3</sup> (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.

Product code: G1015

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	or heated, the Inhalation of mist or vapor can cause respiratory tract irritation. Low hazard. Ingestion may cause gastrointestinal irritation, nausea, vomiting and diarrhoea. May cause dehydration. May cause thirst. May cause hyperglycemia. affect liver . It may affect behavior/central nervous system (excitement, depression general anesthetic, headache, dizziness, convulsions, confusion, insomnia, music 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 a	s 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 liver.		
Sensitization:	No information available		
Mutagenic Effects:	May affect genetic material Experiments with human lymphocytes have shown mutagenic effects		

Carcinogenic effects: Not considered carcinogenic

Components	ACGIH - Carcinogens	IARC	NTP	OSHA HCS - Carcinogens	Australia - Prohibited Carcinogenic Substances	Australia - Notifiable Carcinogenic Substances
Glycerin	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.

<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	RCRA - F Series Wastes	RCRA - K Series Wastes	RCRA - P Series Wastes	RCRA - U Series Wastes
Glycerin	None	None	None	None

#### **14. TRANSPORT INFORMATION**

DOT

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

Not Regulated
No information available

#### ΙΑΤΑ

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

#### **15. REGULATORY INFORMATION**

#### **International Inventories**

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

#### **U.S. Regulations**

Glycerin

Massachusetts RTK: Present New Jersey RTK Hazardous Substance List: Present Pennsylvania RTK: Present RI RTK - Hazardous Substances List: Present Minnesota - Hazardous Substance List: Present FDA - Food Additives Generally Recognized as Safe (GRAS): 21 CFR 182.90 21 CFR 182.1320

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		Male Reproductive Toxicity	Female Reproductive Toxicity:
Glycerin	Not Listed	Not Listed	Not Listed	Not Listed

#### CERCLA/SARA

•	Substances and their	Hazardous	Section 302 Extremely Hazardous	Chemical Category	Section 313 - Reporting de minimis
Glycerin			Substances and RQs None		None

#### U.S. TSCA

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

#### Canada

#### WHMIS hazard class:

Non-controlled

#### Glycerin

Uncontrolled product according to WHMIS classification criteria

#### **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)
Glycerin	Present	Not Listed

Components	CEPA Schedule I - Toxic Substances	CEPA - 2010 Greenhouse Gases Subject to Manditory Reporting
Glycerin	Not listed	Not listed

#### **EU Classification**

#### R-phrase(s)

not determined

#### S -phrase(s)

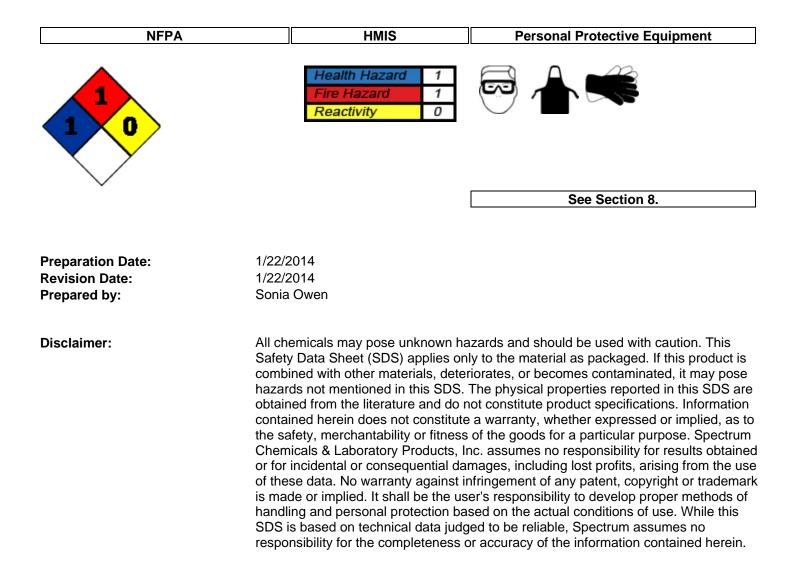
none

Components	Classification	Concentration Limits:	Safety Phrases
Glycerin		No information	

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

Indication of danger: Not dangerous

#### **16. OTHER INFORMATION**



**End of Material Safety Data Sheet** 



#### Manufacturer

Product Covered: G1015, Glycerin, Synthetic, USP, EP, BP, JP

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.

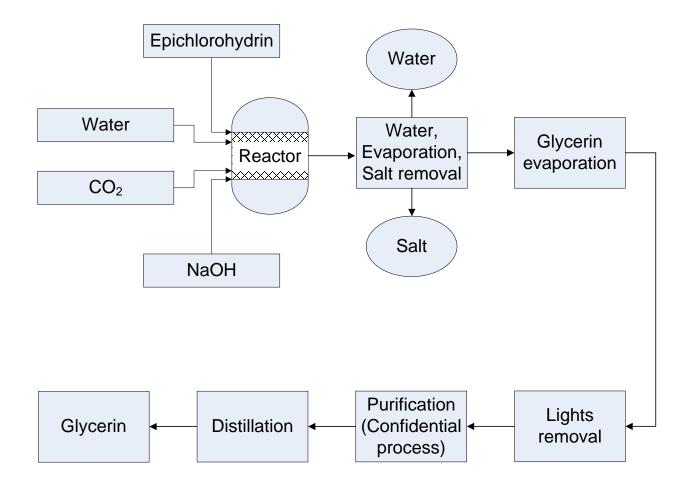
Sincerely,

Alan Wang, MSQA, ASQ CQA Senior Manager, Global Supplier Quality Assurance <u>qualityassurance@spectrumchemical.com</u>



### **Manufacturing Process Flowchart**

## Glycerin, Synthetic, USP, EP, BP, JP - G1015



#### 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, Frc

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

Additional Sites: 13915 South Main Street, Los Angeles, California, 90061, USA 755 Jersey Avenue, New Brunswick, New Jersey, 08901, USA 769 Jersey Avenue, New Brunswick, New Jersey, 08901, USA 7400 North Oracle Road, Suite 221, Tucson, Arizona, 85704, USA

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

# **ISO 9001:2008**

The quality management system is applicable to

**California and New Jersey sites:** 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.

Arizona site: Supporting Spectrum's two manufacturing facilitates by: selecting and gualifying distributors of Laboratory and Safety Equipment; processing bids and quotes to generate new sales opportunities; sourcing bulk chemicals in support of bulk bids and guotes; assisting production operations through order expediting and IT infrastructure support.

Certificate Number: 94-316m-01 Initial Certification Date: 27 December 1994 Certificate Issue Date: Certificate Expiry Date:

29 January 2016 14 September 2018

Calin Moldovean, President

Intertek Testing Services NA, Inc.

900 Chelmsford Street, Suite 301-3, Lowell, MA, USA



CERTIFICATION



Intertek Intertek

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.

# **Certificate of Registration**



This is to certify that the quality management system of

# Spectrum China Ltd.

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

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

# ISO 9001: 2008

The quality management system is applicable to:

Provision of service of purchase, testing and sales for chemical products, repacking of non-hazardous chemical products.

Organization Code: Certificate Number: Certificate Issue Date: Certificate Expiry Date: 77762704-8 111310001-01 17 November 2015 14 September 2018



014

Authorised Signature: 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 organization maintaining their system in accordance with Intertek's requirements for systems certification. Validity may be confirmed via email at <u>certificate.validation@intertek.com</u> or by scanning the code to the right with a smartphone. The annual validity of the certificate a also be checked through the website <u>http://www.cnca.gov.cn</u> of CNCA in China.



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



March 28, 2016

#### Certificate of cGMP

Dear Valued Customer:

Spectrum Chemicals and Laboratory Products certify 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 with Spectrum products. Please feel free to contact the Quality Assurance department at 310-516-8000 or via email at <u>qualityassurance@spectrumchemical.com</u> if we may be of further assistance.

Sincerely,

Michelle Wester

Michelle Weston Quality Assurance Specialist



March 31, 2016

#### Certificate of cGMP

Dear Valued Customer:

Spectrum Chemicals and Laboratory Products certify 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
G1015	Glycerin, Synthetic, USP, EP, BP, JP

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 with Spectrum products. Please feel free to contact the Quality Assurance department at 310-516-8000 or via email at <u>qualityassurance@spectrumchemical.com</u> if we may be of further assistance.

Sincerely,

Michelle Wester

Michelle Weston Quality Assurance Specialist



March 31, 2016

Re: Glycerin, Synthetic, USP, EP, BP, JP- G1015

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, Synthetic, USP, EP, BP, JP- G1015

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, Synthetic, USP, EP, BP, JP – G1015

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 (Peanuts or peanut products (butter, oil, flour), Tree nuts (almonds, pecans, walnuts, Brazil nuts, cashew, chestnuts, etc.), Plant derivates, including nuts and seeds, Eggs or egg products (whites, yolks, meringue, mayonnaise, etc.), Fish (cod, flounder, salmon, trout, tuna, etc.), Shellfish (crustaceans and mollusks), Celery (root, leaves, stalk, not seeds), Dairy or dairy derivatives, Cereals containing gluten, Wheat or wheat products, Corn or corn derivatives, Soybean or soy products (soy derived vegetable protein, tofu, etc.), Sulfites, Artificial or natural colors including FD&C Yellow #5 and #6, Preservatives and antioxidants, Umbelliferae (carrot or parsley family) and Flavors/enhancers, Nitrites/nitrates)

Glycerin, Synthetic, USP, EP, BP, JP – G1015

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



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.

<ul> <li>WARNING B</li> <li>Causes eye irritation • Causes mild skin irritation.</li> <li>• Wash face, hands and any exposed skin throughly after handling.</li> <li>FIRST AID: IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue</li> <li>Insing. If eye irritation persists: Get medical attention. If skin irritation occurs: Get medical attention.</li> <li>WARNING: This product contains a chemical known to the State of California to cause birth defects or other reproductive harm.</li> <li>KEEP FROM CHILDREN</li> </ul>	G1015 C G1015 C G1015 C G G G G G G G G G G G G G	C 3H803       90-010 or         Assay (Anhydrous Basis)       90-010 or         Specific Gravity @ 25°C       Min. 124         Specific Gravity @ 20°C       To pass te         Appearance of Solution       To pass te         Refractive index       1.470-147         Identification:       Identification         Identification B (USP)       To pass te         Identification B (USP)       To pass te         Addhydes       0.017         Color       To pass te         Addhydes       0.017         Color       To pass te         Addhydes       0.017         Chorinde (C)       0.002         Hasid (as Pb)       0.002         Hasid (as Pb)       0.002         Hasid (as Compounds (Halogenated Compounds as Cl)       30 pp         Water       2.00         Fatly Acids and Esters       To pass te         Impurity A and related substances       To pass te         Addition       To pass te         Sugars       To pass te         Addition       To pass te         Sugars       To pass te         Addition of Alkalinity       To pass te         Sugars       To pass te
SPECTRUM CHEMICAL	•	248 • New Brunswick, NJ 08901
<ul> <li>Bar Code</li> <li>Warning, Safety Data and Precautior</li> </ul>	<ul> <li>Chemical Abstracts Service (CAS) Registry Number</li> </ul>	<ul> <li>Expiration Information</li> <li>Lot Number</li> </ul>
Warning, Safety Data and Precaution Information	(CAS) Registry Number	Lot Number
<ul> <li>Warning, Safety Data and Precaution Information</li> <li>Product Catalog Number</li> </ul>	<ul> <li>(CAS) Registry Number</li> <li>Caution Information</li> <li>Toll-Free 24-Hour Chemical</li> </ul>	<ul> <li>Lot Number</li> <li>Kosher Certified by Kosher Supervision of America (KSA).</li> </ul>
Warning, Safety Data and Precaution Information	e Caution Information	<ul> <li>Lot Number</li> <li>Kosher Certified by Kosher Supervision of America (KSA).</li> </ul>
<ul> <li>Warning, Safety Data and Precaution Information</li> <li>Product Catalog Number</li> </ul>	<ul> <li>(CAS) Registry Number</li> <li>Caution Information</li> <li>Toll-Free 24-Hour Chemical Emergency Telephone Number</li> <li>Empirical Formula, Formula Weight and Technical</li> </ul>	<ul> <li>Lot Number</li> <li>Kosher Certified by Kosher Supervision of America (KSA).</li> </ul>
<ul> <li>Warning, Safety Data and Precaution Information</li> <li>Product Catalog Number</li> <li>Item Name, Form, Grade</li> </ul>	<ul> <li>(CAS) Registry Number</li> <li>Caution Information</li> <li>Toll-Free 24-Hour Chemical Emergency Telephone Number</li> <li>Empirical Formula, Formula</li> </ul>	<ul> <li>Lot Number</li> <li>Kosher Certified by Kosher Supervision of America (KSA).</li> </ul>
<ul> <li>Warning, Safety Data and Precaution Information</li> <li>Product Catalog Number</li> <li>Item Name, Form, Grade</li> <li>Size/Quantity</li> <li>Storage Color Band This color-coded band indicates the hazard r</li> </ul>	<ul> <li>(CAS) Registry Number</li> <li>Caution Information</li> <li>Toll-Free 24-Hour Chemical Emergency Telephone Number</li> <li>Empirical Formula, Formula Weight and Technical Specifications Panel</li> </ul>	<ul> <li>Lot Number</li> <li>Kosher Certified by Kosher Supervision of America (KSA).</li> </ul>
<ul> <li>Warning, Safety Data and Precaution Information</li> <li>Product Catalog Number</li> <li>Item Name, Form, Grade</li> <li>Size/Quantity</li> <li>Storage Color Band This color-coded band indicates the hazard r The criteria used to assign band colors have</li> </ul>	<ul> <li>(CAS) Registry Number</li> <li>Caution Information</li> <li>Toll-Free 24-Hour Chemical Emergency Telephone Number</li> <li>Empirical Formula, Formula Weight and Technical Specifications Panel</li> </ul>	<ul> <li>Lot Number</li> <li>Kosher Certified by Kosher Supervision of America (KSA).</li> <li>YELLOW: Oxidizer onditions. pup of the RED: Flammable</li> </ul>
<ul> <li>Warning, Safety Data and Precaution Information</li> <li>Product Catalog Number</li> <li>Item Name, Form, Grade</li> <li>Size/Quantity</li> <li>Storage Color Band This color-coded band indicates the hazard r The criteria used to assign band colors hav Society for Chemical Hazard Communication unless otherwise stated, based on the color</li> </ul>	<ul> <li>(CAS) Registry Number</li> <li>Caution Information</li> <li>Toll-Free 24-Hour Chemical Emergency Telephone Number</li> <li>Empirical Formula, Formula Weight and Technical Specifications Panel</li> </ul>	<ul> <li>Lot Number</li> <li>Kosher Certified by Kosher Supervision of America (KSA).</li> <li>YELLOW: Oxidizer</li> <li>RED: Flammable</li> <li>GREEN: General Storage</li> </ul>

#### 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

# Spectrum®

# **Certificate Of Analysis**

Item Number	G1015	Lot Number	1FA0102
Item	Glycerin, Synthetic, USP, EP, BP, JP		
CAS Number	56-81-5		
Molecular Formula	C <sub>3</sub> H <sub>8</sub> O <sub>3</sub>	Molecular Weight	92.10

Test	Spe	ecification	Result
	min	max	
ASSAY (ANHYDROUS BASIS)	99.0 - 101.0%		99.8 %
SPECIFIC GRAVITY @ 25 <sup>°</sup> C	1.249		1.262
SPECIFIC GRAVITY @ 20°C	1.258		1.2617
APPEARANCE OF SOLUTION	TO PASS TEST		PASSES TEST
REFRACTIVE INDEX	1.470 - 1.475		1.474
ALDEHYDES		10 ppm	2 ppm
COLOR	TO PASS TEST		PASSES TEST
RESIDUE ON IGNITION (SULPHATED ASH)		0.01%	0.00 %
CHLORIDE (Cl)		0.001%	<0.001 %
SULFATE (SO <sub>4</sub> )		0.002%	0.002 %
HEAVY METALS (as Pb)		5 ug/g	<5 µg/g
CHLORINATED COMPOUNDS (HALOGENATED COMPOUNDS as Cl)		30 ppm	<30 ppm
WATER		2.0%	0.008 %
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
SUGARS	TO PASS TEST		PASSES TEST
AMMONIUM ( $NH_d$ )	TO PASS TEST		PASSES TEST
CALCIUM (Ca)	TO PASS TEST		PASSES TEST
ARSENIC (As)		2 ppm	<2 ppm
ACROLEIN, GLUCOSE OR OTHER[nREDUCING SUBSTANCES	TO PASS TEST		PASSES TEST
READILY CARBONIZABLE SUBSTANCES	TO PASS TEST		PASSES TEST
ESTERS	TO PASS TEST		PASSES TEST
IDENTIFICATION	TO PASS TEST		PASSES TEST
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			KOSHER
EXPIRATION DATE			06-AUG-2018
RESIDUAL SOLVENTS	TO PASS TEST		ONLY CLASS 3 SOLVENT IS LIKELY TO BE PRESENT BELOW THE LIMIT OF 5000 ppm
APPEARANCE			CLEAR COLORLESS LIQUID
MANUFACTURE DATE			06-AUG-2015

Spectrum Chemical Mfg Corp



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

# Spectrum®

# **Certificate Of Analysis**

Item Number	G1015	Lot Number	2EL0131
Item	Glycerin, Synthetic, USP, EP, BP, JP		
CAS Number	56-81-5		
Molecular Formula	C <sub>3</sub> H <sub>8</sub> O <sub>3</sub>	Molecular Weight	92.10

Test	Spe	cification	Result
	min	max	
ASSAY (ANHYDROUS BASIS)	99.0 - 101.0%		99.8 %
SPECIFIC GRAVITY @ 25°C	1.249		1.262
SPECIFIC GRAVITY @ 20°C	1.258		1.2617
APPEARANCE OF SOLUTION	TO PASS TEST		PASSES TEST
REFRACTIVE INDEX	1.470 - 1.475		1.474
ALDEHYDES		10 ppm	2 ppm
COLOR	TO PASS TEST		PASSES TEST
RESIDUE ON IGNITION (SULPHATED ASH)		0.01%	0.00 %
CHLORIDE (Cl)		0.001%	<0.001 %
SULFATE (SO <sub>4</sub> )		0.002%	0.002 %
HEAVY METALS (as Pb)		5 ug/g	< 5 µg/g
CHLORINATED COMPOUNDS (HALOGENATED COMPOUNDS as Cl)		30 ppm	<30 ppm
WATER		2.0%	0.008 %
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
SUGARS	TO PASS TEST		PASSES TEST
AMMONIUM ( $NH_4$ )	TO PASS TEST		PASSES TEST
CALCIUM (Ca)	TO PASS TEST		PASSES TEST
ARSENIC (As)		2 ppm	<2 ppm
ACROLEIN, GLUCOSE OR OTHER[nREDUCING SUBSTANCES	TO PASS TEST		PASSES TEST
READILY CARBONIZABLE SUBSTANCES	TO PASS TEST		PASSES TEST
ESTERS	TO PASS TEST		PASSES TEST
IDENTIFICATION	TO PASS TEST		PASSES TEST
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
EXPIRATION DATE			06-AUG-2018
RESIDUAL SOLVENTS	TO PASS TEST		NO RESIDUAL SOLVENTS USED
APPEARANCE			CLEAR COLORLESS LIQUID
DATE OF MANUFACTURE			06-AUG-2015

Spectrum Chemical Mfg Corp 755 Jersey Avenue New Brunswick 08901 NJ





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



January 26, 2016

#### RE: Lot Numbering System

Dear Valued Customer:

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

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

**Example**: ZI0928 = The 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 <u>qualityassurance@spectrumchemical.com</u> if we may be of further assistance.

Sincerely,

1 lan

Michael Dang Manager, GMP Compliance



#### **Stability – Shelf Life Guidance**

#### Product Covered: G1015, Glycerin, Synthetic, USP, EP, BP, JP

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

The product, G1015, Glycerin, Synthetic, USP, EP, BP, JP, 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

Dan & Ilan (

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



בס"ד Feb 08, 2016

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	Product Name	Glycerin, Synthetic, USP, EP, BP, JP - G1015
USA	Brand	Spectrum
	UKD-ID	KSAV3-T8O3N48
	<b>D</b> / <b>P</b> / <b>M</b>	P
	Symbol Required	KSA
This certificate expires on <b>Feb 28, 2017</b>	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.