

Scientific Documentation

Glycerin, Synthetic, USP, EP, BP, JP

Not appropriate for regulatory submission. Please visit www.spectrumchemical.com or contact Tech Services for the most up-to-date information contained in this information package.

Spectrum Chemical Mfg Corp 769 Jersey Avenue New Brunswick, NJ 08901 Phone 732.214.1300





Table of Contents

Product Specification Certificate of Analysis Safety Data Sheet (SDS) Certification of Current Good Manufacturing Practices (cGMP) Manufacturing Process Flowchart Technical Statements Elemental Impurities Statement Residual Solvents Statement Kosher Certification



Specification for Glycerin, Synthetic, USP, EP, BP, JP (G1015)

Item Number	G1015
Item	Glycerin, Synthetic, USP, EP, BP, JP
CAS Number	56-81-5
Molecular Formula	C ₃ H ₈ O ₃
Molecular Weight	92.10
MDL Number	
Synonyms	

Test	Specification	
	Min	Max
APPEARANCE		
ASSAY (ANHYDROUS BASIS)	99.0	101.0 %
SPECIFIC GRAVITY @ 25°C	1.249	
SPECIFIC GRAVITY @ 20°C	1.258	
APPEARANCE OF SOLUTION	CLEAR AND COLORLESS	
REFRACTIVE INDEX	1.470	1.475
ALDEHYDES		10 ppm
COLOR	LESS THAN STANDARD	
RESIDUE ON IGNITION (SULPHATED ASH)		0.01 %
CHLORIDE (Cl)		0.001 %
ACIDITY OR ALKALINITY (EP)	COLORLESS <0.2mL	
SULFATE (SO ₄)		0.002 %
CHLORIDE (Cl) E.P		10 ppm
ELEMENTAL IMPURITIES	AS REPORTED	
HEAVY METALS (JP)		5 ppm
CHLORINATED COMPOUNDS (HALOGENATED COMPOUNDS as Cl)		30 ppm
WATER		2.0%
FATTY ACIDS AND ESTERS		1 ml
RELATED COMPOUNDS:		

Test	Specification		
	Min	Max	
INDIVIDUAL IMPURITIES		0.1 %	
TOTAL IMPURITIES		1.0 %	
IMPURITY A		0.1 %	
RELATED SUBSTANCES:			
OTHER IMPURITIES		0.1 % EACH	
TOTAL IMPURITIES WITH RETENTION TIMES GREATER THAN GLYCERIN		0.5 %	
ACIDITY OR ALKALINITY	COLORLESS <0.2 mL		
SUGARS	REMAINS BLUE /NO PRECIPITATE		
AMMONIUM (NH ₄)	NO BLUE COLOR		
CALCIUM (Ca)	NO CHANGE TO SOLUTION		
ARSENIC (As)		2 ppm	
ACROLEIN, GLUCOSE OR OTHER[nREDUCING SUBSTANCES	NO TURBIDITY		
READILY CARBONIZABLE SUBSTANCES	LESS COLOR THAN STANDARD		
ESTERS	8.0 ML		
CERTIFIED KOSHER			
IDENTIFICATION			
IDENTIFICATION: A (USP)	SPECTRUM MATCHES REFERENCE		
IDENTIFICATION: B (USP)		0.10 % EACH	
IDENTIFICATION: C (USP)	RETENTION TIME CORRESPONDS TO STANDARD		
IDENTIFICATION : A (EP/BP)	1.470	1.475	
IDENTIFICATION : B (EP/BP)	SPECTRUM MATCHES REFERENCE		
IDENTIFICATION : C (EP/BP)	1.258	1.268	
MONOGRAPH EDITION.			
MONOGRAPH EDITION			
MONOGRAPH EDITION			
EXPIRATION DATE			
DATE OF MANUFACTURE			
RESIDUAL SOLVENTS		AS REPORTED	
MANUFACTURER NAME:			

Spectrum Chemical Mfg Corp

 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	G1015	Lot Number	1NC0100
Item	Glycerin, Synthetic, USP, EP, BP, JP	CAS Number	56-81-5
Molecular Formula	C ₃ H ₈ O ₃	Molecular Weight	92.10

TECT	SPECIFICATION			
TEST	MIN	MAX	RESULT	
APPEARANCE			CLEAR COLORLESS LIQUID	
ASSAY (ANHYDROUS BASIS)	99.0	101.0 %	99.9 %	
SPECIFIC GRAVITY @ 25 ⁰ C	1.249		1.262	
SPECIFIC GRAVITY @ 20 ⁰ C	1.258		1.261	
APPEARANCE OF SOLUTION	CLEAR AND COLORLESS		CLEAR AND COLORLESS	
REFRACTIVE INDEX	1.470	1.475	1.474	
ALDEHYDES		10 ppm	<10 ppm	
COLOR	LESS THAN STANDARD		LESS THAN STANDARD	
RESIDUE ON IGNITION (SULPHATED ASH)		0.01 %	0.00 %	
CHLORIDE (CI)		0.001 %	<0.001 %	
ACIDITY OR ALKALINITY (EP)	COLORLESS <0.2mL		<0.2 ml	
SULFATE (SO ₄)		0.002 %	<0.002 %	
CHLORIDE (CI) E.P		10 ppm	<10 ppm	
ELEMENTAL IMPURITIES	AS REPORTED		NO ELEMENTAL IMPURITIES PRESENT	
HEAVY METALS (JP)		5 ppm	<1.2 ppm	
CHLORINATED COMPOUNDS (HALOGENATED COMPOUNDS as CI)		30 ppm	<30 ppm	
WATER		2.0%	0.022 %	
FATTY ACIDS AND ESTERS		1 ml	<1 ml	
RELATED COMPOUNDS:				
INDIVIDUAL IMPURITIES		0.1 %	<0.1 %	

	SPECIF	ICATION	
TEST	MIN	МАХ	RESULT
TOTAL IMPURITIES		1.0 %	0.1 %
IMPURITY A		0.1 %	0.0 %
RELATED SUBSTANCES:			
OTHER IMPURITIES		0.1 % EACH	0.1 %
TOTAL IMPURITIES WITH RETENTION TIMES GREATER THAN GLYCERIN		0.5 %	<0.1 %
ACIDITY OR ALKALINITY	COLORLESS <0.2 mL		<0.2 ml
SUGARS	REMAINS BLUE /NO PRECIPITATE		REMAINS BLUE / NO PRECIPITATE
AMMONIUM (NH ₄)	NO BLUE COLOR		NO BLUE COLOR
CALCIUM (Ca)	NO CHANGE TO SOLUTION		NO CHANGE TO SOLUTION
ARSENIC (As)		2 ppm	<0.01 ppm
ACROLEIN, GLUCOSE OR OTHER[nREDUCING SUBSTANCES	NO TURBIDITY		NO TURBIDITY
READILY CARBONIZABLE SUBSTANCES	LESS COLOR THAN STANDARD		LESS COLOR THAN STANDARD
ESTERS	8.0 ML		9.7 ML
CERTIFIED KOSHER			CERTIFIED KOSHER
IDENTIFICATION			
IDENTIFICATION: A (USP)	SPECTRUM MATCHES REFERENCE		SPECTRUM MATCHES REFERENCE
IDENTIFICATION: B (USP)		0.10 % EACH	<0.10 %
IDENTIFICATION: C (USP)	RETENTION TIME CORRESPONDS TO STANDARD		RETENTION TIME CORRESPONDS TO STANDARD
IDENTIFICATION : A (EP/BP)	1.470	1.475	1.474
IDENTIFICATION : B (EP/BP)	SPECTRUM MATCHES REFERENCE		SPECTRUM MATCHES REFERENCE
IDENTIFICATION : C (EP/BP)	1.258	1.268	1.261
MONOGRAPH EDITION.			(USP-NF) 2023
MONOGRAPH EDITION			(EP) 11, (BP) 2023
MONOGRAPH EDITION			(JP) 18
EXPIRATION DATE			03-MAY-2026
DATE OF MANUFACTURE			04-MAY-2023
RESIDUAL SOLVENTS		AS REPORTED	ONLY CLASS 3 SOLVENT ARE LIKELY TO BE PRESENT BELOW THE

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

Revision date 12-May-2022

1. Identification	
Product identifier	
Product Name	GLYCERIN, SYNTHETIC, USP, EP, BP, JP
Other means of identification	
Product Code(s)	G1015
Synonyms	None
Recommended use of the chemical	and restrictions on use
Recommended use	No information available
Restrictions on use	No information available
Details of the supplier of the safety	data sheet
<u>Supplier Address</u> Spectrum Chemical Mfg. Corp. 14422 South San Pedro St. Gardena, CA 90248 (310) 516-8000	
Emergency telephone number	
Emergency Telephone	Chemtrec 1-800-424-9300
2. Hazard(s) identification	
<u>Classification</u>	
Serious eye damage/eye irritation	Category 2B

Hazards not otherwise classified (HNOC) Not applicable

Label elements		
Warning		
Hazard statements Causes eye irritation		
Appearance viscous	Physical state Liquid	Odor Sligh



Revision Number 3

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

Other information

Causes mild skin irritation.

3. Composition/information on ingredients

Substance

Chemical name	CAS No	Weight-%	Trade secret
Glycerin	56-81-5	100	*

*The exact percentage (concentration) of composition has been withheld as a trade secret.

4. First-aid measures		
Description of first aid measures		
General advice	Show this safety data sheet to the doctor in attendance.	
Inhalation	Remove to fresh air.	
Eye contact	Rinse immediately with plenty of water, also under the eyelids, for at least 15 minutes. Keep eye wide open while rinsing. Get medical attention if irritation develops and persists. Remove contact lenses, if present and easy to do. Continue rinsing.	
Skin contact	Wash skin with soap and water.	
Ingestion	Clean mouth with water and drink afterwards plenty of water. Never give anything by mouth to an unconscious person. Do NOT induce vomiting. Call a physician.	
Most important symptoms and effe	cts, both acute and delayed	
Symptoms	Prolonged contact may cause redness and irritation.	
Indication of any immediate medical attention and special treatment needed		
Note to physicians	Treat symptomatically.	
5. Fire-fighting measures		
Suitable Extinguishing Media Large Fire	Use extinguishing measures that are appropriate to local circumstances and the surrounding environment. CAUTION: Use of water spray when fighting fire may be inefficient.	
Unsuitable extinguishing media	Do not scatter spilled material with high pressure water streams.	
Specific hazards arising from the chemical	No information available.	
Hazardous combustion products	Carbon Monoxide, Carbon Dioxide.	
Explosion data		

Sensitivity to mechanical impact none.

Sensitivity to static discharge none.

Special protective equipment for
fire-fightersFirefighters should wear self-contained breathing apparatus and full firefighting turnout
gear. Use personal protection equipment.

6. Accidental release measures

Personal precautions, protective equipment and emergency procedures

Personal precautions	Avoid contact with skin, eyes or clothing. Use personal protective equipment as required.
Other information	Refer to protective measures listed in Sections 7 and 8.

Methods and material for containment and cleaning up

Methods for containment	Prevent further leakage or spillage if safe to do so.
Methods for cleaning up	Pick up and transfer to properly labeled containers.

7. Handling and storage

Precautions for safe handling		
Advice on safe handling	Handle in accordance with good industrial hygiene and safety practice.	
Conditions for safe storage, including any incompatibilities		
Storage Conditions	Keep containers tightly closed in a dry, cool and well-ventilated place.	

8. Exposure controls/personal protection

Control parameters

Exposure Limits

Chemical name	ACGIH TLV	OSHA PEL	NIOSH IDLH
Glycerin	No data available	15 mg/m³ TWA	-
56-81-5		5 mg/m³ TWA	

Appropriate engineering controls

Engineering controls Showers Eyewash stations Ventilation systems.

Individual protection measures, such as personal protective equipment

Eye/face protection	None required for consumer use. Wear safety glasses with side shields (or goggles).
Hand protection	Wear suitable gloves.
Skin and body protection	Wear suitable protective clothing.
Respiratory protection	No protective equipment is needed under normal use conditions. If exposure limits are exceeded or irritation is experienced, ventilation and evacuation may be required.

9. Physical and chemical properties

Information on basic physical and chemical properties

Physical state	Liquid	
Appearance	viscous	
Color	clear; Colorless	
Odor	Slight	
Odor threshold	No information available	
Property	<u>Values</u>	Remarks • Method
рН	no data available	None known
Melting point / freezing point	19 - 20 °C / 66.2 - 68 °F	None known
Boiling point / boiling range	290 °C / 554 °F	None known
Flash point	160 °C / 320 °F	None known
Evaporation rate	no data available	None known
Flammability (solid, gas)	no data available	None known
Flammability Limit in Air		None known
Upper flammability or explosive	No data available	
limits		
Lower flammability or explosive	No data available	
limits		
Vapor pressure	0	None known
Vapor density	3.17	None known
Relative density	1.2613 - 1.2636	None known
Water solubility	Soluble in water	None known
Solubility(ies)	Insoluble in Benzene	None known
	Insoluble in Chloroform	
	Insoluble in Carbon disulfide	
	Insoluble in Carbon tetrachloride	
	Insoluble in Petroleum ether	
Partition coefficient	-1.76	None known
Autoignition temperature	370 - 392 °C / 698 - 737.6 °F	None known
Decomposition temperature		None known
Kinematic viscosity	no data available	None known
Dynamic viscosity	No data available	None known
Other information		
Explosive properties	No information available	
Oxidizing properties	No information available	
Softening point	No information available	
Molecular weight	92.09	
VOC Content (%)	No information available	
Liquid Density	No information available	
Bulk density	No information available	

10. Stability and reactivity

Reactivity	No information available.
Chemical stability	Stable under normal conditions.
Possibility of hazardous reactions	None under normal processing.
Conditions to avoid	None known based on information supplied.
Incompatible materials	None known based on information supplied.

Hazardous decomposition products None known based on information supplied.

11. Toxicological information

Information on likely routes of exposure

Product Information	
Inhalation	Specific test data for the substance or mixture is not available.
Eye contact	Specific test data for the substance or mixture is not available. Causes eye irritation. May cause redness, itching, and pain.
Skin contact	Specific test data for the substance or mixture is not available. Causes mild skin irritation.
Ingestion	Specific test data for the substance or mixture is not available.
Symptoms related to the physical,	chemical and toxicological characteristics

SymptomsMay cause redness and tearing of the eyes. Prolonged contact may cause redness and
irritation.

Acute toxicity

Numerical measures of toxicity

Component Information

Chemical name	Oral LD50	Dermal LD50	Inhalation LC50
Glycerin	= 12600 mg/kg (Rat)	= 21900 mg/kg (Rat)	> 570 mg/m³ (Rat)1 h
56-81-5		> 10 g/kg (Rabbit)	-

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

Skin corrosion/irritation Serious eye damage/eye irritation Respiratory or skin sensitization Germ cell mutagenicity	May cause skin irritation. Classification based on data available for ingredients. Classification based on data available for ingredients. Irritating to eyes. No information available. No information available.
Reproductive toxicity	No information available.
STOT - single exposure STOT - repeated exposure Target organ effects	No information available. No information available. kidney, respiratory system, Eyes, Skin.
Aspiration hazard	No information available.
Other adverse effects	No information available.
Interactive effects	No information available.

12. Ecological information

Ecotoxicity

Chemical name	Algae/aquatic plants	Fish	Toxicity to	Crustacea
			microorganisms	
Glycerin	-	LC50: 51 - 57mL/L (96h,	-	EC50: >500mg/L (24h,
56-81-5		Oncorhynchus mykiss)		Daphnia magna)

Persistence and degradability Bioaccumulation

No information available. Inherently biodegradable.

Component Information

Chemical name	Partition coefficient
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Glycerin	-1.76
56-81-5	

Other adverse effects

No information available.

13. Disposal considerations		
Waste treatment methods		
Waste from residues/unused products	Dispose of in accordance with local regulations. Dispose of waste in accordance with environmental legislation.	
Contaminated packaging	Do not reuse empty containers.	

14. Transport information

DOT	not regulated
<u>TDG</u>	not regulated
<u>MEX</u>	not regulated
ICAO (air)	not regulated
IATA	not regulated
IMDG_	not regulated
RID	not regulated
ADR	not regulated
ADN	not regulated

15. Regulatory information

International Inventories

TSCA

Complies

DSL/NDSL	Complies
EINECS/ELINCS	Complies
ENCS	This product complies with ENCS:
IECSC	This product complies with China:
KECL	Complies
PICCS	Complies
AICS	All the constituents of this material are listed on the Australian Inventory of Chemical
	Substances (AICS).

Legend:

TSCA - United States Toxic Substances Control Act Section 8(b) Inventory

DSL/NDSL - Canadian Domestic Substances List/Non-Domestic Substances List

EINECS/ELINCS - European Inventory of Existing Chemical Substances/European List of Notified Chemical Substances

ENCS - Japan Existing and New Chemical Substances

IECSC - China Inventory of Existing Chemical Substances

KECL - Korean Existing and Evaluated Chemical Substances

PICCS - Philippines Inventory of Chemicals and Chemical Substances

Complies

US Federal Regulations

SARA 313

Section 313 of Title III of the Superfund Amendments and Reauthorization Act of 1986 (SARA). This product does not contain any chemicals which are subject to the reporting requirements of the Act and Title 40 of the Code of Federal Regulations, Part 372.

SARA 311/312 Hazard Categories

Should this product meet EPCRA 311/312 Tier reporting criteria at 40 CFR 370, refer to Section 2 of this SDS for appropriate classifications.

CWA (Clean Water Act)

This product does not contain any substances regulated as pollutants pursuant to the Clean Water Act (40 CFR 122.21 and 40 CFR 122.42).

CERCLA

This material, as supplied, does not contain any substances regulated as hazardous substances under the Comprehensive Environmental Response Compensation and Liability Act (CERCLA) (40 CFR 302) or the Superfund Amendments and Reauthorization Act (SARA) (40 CFR 355). There may be specific reporting requirements at the local, regional, or state level pertaining to releases of this material.

US State Regulations

California Proposition 65

This product does not contain any Proposition 65 chemicals.

U.S. State Right-to-Know Regulations

	Chemical name	New Jersey	Massachusetts	Pennsylvania
Γ	Glycerin	3319	Present	Present
	56-81-5			

U.S. EPA Label Information

EPA Pesticide Registration Number Not applicable

16. Other information

NFPA_ Health hazards 2 Flammability 1 Instability 0 Physical and chemical properties -<u>HMIS_</u> Health hazards 2 Flammability 1 Physical hazards 0 Personal protection X

Key or legend to abbreviations and acronyms used in the safety data sheetLegendSection 8: EXPOSURE CONTROLS/PERSONAL PROTECTIONTWATWA (time-weighted average)STELCeilingMaximum limit value

STEL (Short Term Exposure Limit)

Key literature references and sources for data used to compile the SDS

Agency for Toxic Substances and Disease Registry (ATSDR) U.S. Environmental Protection Agency ChemView Database European Food Safety Authority (EFSA)

EPA (Environmental Protection Agency) Acute Exposure Guideline Level(s) (AEGL(s)) U.S. Environmental Protection Agency Federal Insecticide, Fungicide, and Rodenticide Act U.S. Environmental Protection Agency High Production Volume Chemicals Food Research Journal Hazardous Substance Database International Uniform Chemical Information Database (IUCLID) Japan GHS Classification Australia National Industrial Chemicals Notification and Assessment Scheme (NICNAS) NIOSH (National Institute for Occupational Safety and Health) National Library of Medicine's ChemID Plus (NLM CIP) National Library of Medicine's PubMed database (NLM PUBMED) National Toxicology Program (NTP) New Zealand's Chemical Classification and Information Database (CCID) Organization for Economic Co-operation and Development Environment, Health, and Safety Publications Organization for Economic Co-operation and Development High Production Volume Chemicals Program Organization for Economic Co-operation and Development Screening Information Data Set World Health Organization **Revision date** 12-May-2022 **Revision Note** No information available.

Disclaimer

The information provided in this Safety Data Sheet is correct to the best of our knowledge, information and belief at the date of its publication. The information given is designed only as a guidance for safe handling, use, processing, storage, transportation, disposal and release and is not to be considered a warranty or quality specification. The information relates only to the specific material designated and may not be valid for such material used in combination with any other materials or in any process, unless specified in the text.

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
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: 2020632 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 <u>qualityassurance@spectrumchemical.com</u>

Sincerely,

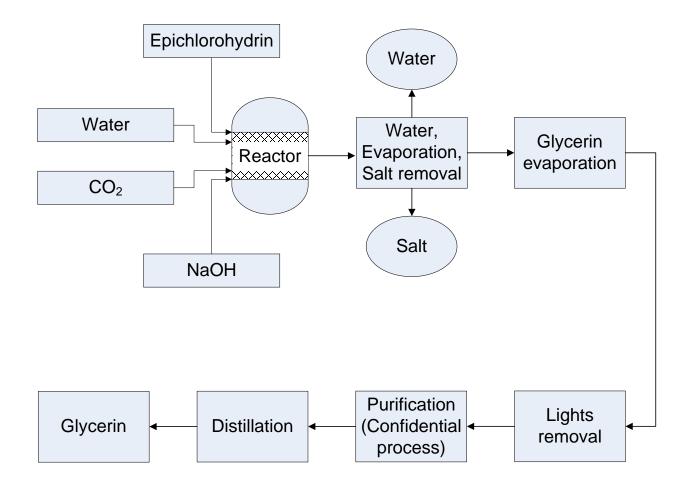
Oulu Clamy

Oralia Chavez Quality Assurance Specialist



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

Spectrum[®] **G1015**, Glycerin, Synthetic, USP, EP, BP, JP

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
- 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.

Animal Testing Statement

The above mentioned catalog item has been tested on animals. Last date of testing was 1964, but not for cosmetic purposes.

Organic Compliance Statement

The above mentioned catalog item has not been produced using GMOs, irradiation, ethylene oxide (EtO) or sewage sludge.

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
- Antibiotics
- Bisphenol A (BPA)
- CMR Substances

- Parabens
- Pesticides
- Phthalates
- Preservatives

spectrum

RE: Elemental Impurities - Glycerin, Synthetic, USP, EP, BP, JP (Cat# G1015)

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

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

AN ISO 9001:2015 REGISTERED COMPANY

spectrum

RE: Residual Solvents - Glycerin, Synthetic, USP, EP, BP, JP (Cat# G1015)

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. Class 3 solvent is present below the limit of 5000ppm in the above material. The nature of this solvent is not disclosed as the manufacturing process is proprietary. None of the listed Class 1, Class 2, or other solvents are used or produced in the manufacturing of this product.

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

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

AN ISO 9001:2015 REGISTERED COMPANY

www.spectrumchemical.com



בס"ד Jan 18, 2024

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

Spectrum Laboratory Products, Inc.

S-0032

14422 South San Pedro Street, Gardena, CA 90248 755-769 Jersey Ave. New Brunswick NJ 08901 USA	Product Name	G1015, Glycerin, Synthetic, USP, EP, BP, JP
	Brand	Spectrum
	UKD-ID	KSAV3-T8O3N48
	D/P/M	P
	Symbol Required	KSA
This certificate expires on Feb 01, 2025	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.