



# Scientific Documentation

PR130, Propylene Glycol, USP

Not appropriate for regulatory submission.  
Please visit [www.spectrumchemical.com](http://www.spectrumchemical.com) or  
contact Tech Services for the most up-to-date  
information contained in this information  
package.

**Spectrum Chemical Mfg Corp**

769 Jersey Avenue  
New Brunswick, NJ 08901  
Phone 732.214.1300

**PR130**, Propylene Glycol, USP

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Item Number	PR130
Item	Propylene Glycol, USP
CAS Number	57-55-6
Molecular Formula	C <sub>3</sub> H <sub>8</sub> O <sub>2</sub>
Molecular Weight	76.10
MDL Number	
Synonyms	1,2-Propanediol ; (+/-)-Propane-1,2-diol

Test	Specification	
	Min	Max
ASSAY	99.5 %	
SPECIFIC GRAVITY @ 25°C	1.035	1.037
ACIDITY		0.20 ml
WATER DETERMINATION		0.2 %
RESIDUE ON IGNITION		3.5 mg/50 g
CHLORIDE (Cl)		70 ppm
SULFATES (SO <sub>4</sub> )		60 ppm
ELEMENTAL IMPURITIES	AS REPORTED	
IDENTIFICATION A (FTIR)	SPECTRUM MATCHES REFERENCE	
IDENTIFICATION (B)		0.10 %
IDENTIFICATION (C)	RETENTION TIME CORRESPONDS TO STANDARD	
CERTIFIED KOSHER		
CERTIFIED HALAL		
EXPIRATION DATE		
MANUFACTURE DATE		
APPEARANCE		
RESIDUAL SOLVENTS		AS REPORTED

**Spectrum Chemical Mfg Corp**

**Corporate Headquarters:**  
 769 Jersey Ave.  
 New Brunswick, NJ 08901  
 732.214.1300

**West Coast Facility:**  
 14422 S. San Pedro St.  
 Gardena, CA 90248  
 310.516.8000

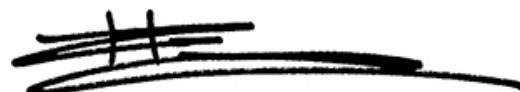
Item Number	PR130	Lot Number	2JL0471
Item	Propylene Glycol, USP		
CAS Number	57-55-6		
Molecular Formula	C <sub>3</sub> H <sub>8</sub> O <sub>2</sub>	Molecular Weight	76.10

Test	Specification		Result
	min	max	
ASSAY	99.5 %		99.96 %
SPECIFIC GRAVITY @ 25°C	1.035	1.037	1.036
ACIDITY		0.20 ml	0.02 mL
WATER DETERMINATION		0.2 %	0.011 %
RESIDUE ON IGNITION		3.5 mg/50 g	0.0 mg/50g
CHLORIDE (Cl)		70 ppm	< 70 ppm
SULFATES (SO <sub>4</sub> )		60 ppm	< 60 ppm
ELEMENTAL IMPURITIES	AS REPORTED		NO ELEMENTAL IMPURITIES PRESENT
IDENTIFICATION A (FTIR)	SPECTRUM MATCHES REFERENCE		SPECTRUM MATCHES REFERENCE
IDENTIFICATION (B)		0.10 %	< 0.10 %
IDENTIFICATION (C)	RETENTION TIME CORRESPONDS TO STANDARD		RETENTION TIME CORRESPONDS TO STANDARD
CERTIFIED KOSHER			CERTIFIED KOSHER
CERTIFIED HALAL			CERTIFIED HALAL
EXPIRATION DATE			16-NOV-2022
MANUFACTURE DATE			16-NOV-2020
APPEARANCE			CLEAR COLORLES LIQUID
RESIDUAL SOLVENTS		AS REPORTED	NO RESIDUAL SOLVENTS USED
MONOGRAPH EDITION			(USP) 43

Spectrum Chemical Mfg Corp  
755 Jersey Avenue  
New Brunswick 08901 NJ



Certificate of Analysis Results Certified by:



Himanshu Patel  
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.

## SAFETY DATA SHEET

Preparation Date: 9/18/2014

Revision Date: 10/25/2018

Revision Number: G3

### 1. IDENTIFICATION

**Product identifier**

**Product code:** PR130  
**Product Name:** PROPYLENE GLYCOL, USP

**Other means of identification**

**Synonyms:** 1,2,-propanediol;  
 1,2-dihydroxypropane;  
 1,2-Propylene glycol;  
 alpha-Propyleneglycol;  
 Methyethylene glycol;  
 Monopropylene glycol;  
 Propane-1,2-Diol;  
 (+-)-Propane-1,2-diol

**CAS #:** 57-55-6  
**RTECS #** TY2000000  
**CI#:** Not available

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

**Recommended use:** Solvent. Lubricant. Preservative. Skin-conditioning agent- humectant.  
**Uses advised against** No information available

**Supplier:** Spectrum Chemical Mfg. Corp  
 14422 South San Pedro St.  
 Gardena, CA 90248  
 (310) 516-8000

**Order Online At:** <https://www.spectrumchemical.com>  
**Emergency telephone number** Chemtrec 1-800-424-9300  
**Contact Person:** Martin LaBenz (West Coast)  
**Contact Person:** Ibad Tirmiz (East Coast)

### 2. HAZARDS IDENTIFICATION

**Classification**

This chemical is not considered hazardous according to the 2012 OSHA Hazard Communication Standard (29 CFR 1910.1200)  
 Not a dangerous substance or mixture according to the Globally Harmonized System (GHS)

**Label elements**

Not classified

**Hazards not otherwise classified (HNOC)**

Not Applicable

**Other hazards**

Not available

**3. COMPOSITION/INFORMATION ON INGREDIENTS**

Components	CAS-No.	Weight %
Propylene Glycol	57-55-6	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 effects, both acute and delayed**

- Symptoms**
- May cause eye/skin irritation
  - May cause digestive (gastrointestinal) tract irritation
  - May cause nausea and vomiting
  - Central nervous system effects

**Indication of any immediate medical attention and special treatment needed**

- Notes to Physician:** Treat symptomatically.

**Protection of first-aiders**

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

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

**Suitable Extinguishing Media:** Carbon dioxide (CO<sub>2</sub>). Dry chemical. Water spray mist or foam.

**Unsuitable Extinguishing Media:** No information available.

**Specific hazards arising from the chemical**

**Hazardous Combustion Products:** Carbon Monoxide, Carbon Dioxide.

**Product code:** PR130

**Product name:** PROPYLENE  
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**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. Prevent product from entering drains. Prevent entry into waterways, sewers, basements or confined areas.

**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 hygiene and safety practice.

**Conditions for safe storage, including any incompatibilities**

**Technical Measures/Storage Conditions:**

Hygroscopic. Protect from moisture. 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
- Bases
- Reducing agents

**8. EXPOSURE CONTROLS/PERSONAL PROTECTION**

**Control parameters**

**National occupational exposure limits**



## United States

Components	CAS-No.	OSHA	NIOSH	ACGIH	AIHA WEEL
Propylene Glycol	57-55-6	None	None	None	10 mg/m <sup>3</sup> TWA

## Canada

Components	CAS-No.	Canada - Alberta	Canada - British Columbia	Canada - Ontario	Canada - Quebec
Propylene Glycol	57-55-6	None	None	None	None

## Australia and Mexico

Components	CAS-No.	Australia	Mexico
Propylene Glycol	57-55-6	150 ppm TWA 474 mg/m <sup>3</sup> TWA 10 mg/m <sup>3</sup> TWA	None

## 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 or 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

#### Physical state:

Liquid

#### Appearance:

No information available.

#### Color:

Clear. Colorless.

#### Odor:

Practically odorless.

#### Taste

Practically tasteless.

#### Formula:

C<sub>3</sub>H<sub>8</sub>O<sub>2</sub>

#### Molecular/Formula weight (g/mole):

76.10

#### Flammability:

No information available

#### Flashpoint (°C/°F):

99 °C/210 °F  
107 °C/224.6 °F

#### Flash Point Tested according to:

#### Autoignition Temperature (°C/°F):

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Closed cup Open cup	371 °C/700 °F	<b>Lower Explosion Limit (%):</b> 2.6%
<b>Upper Explosion Limit (%):</b> 12.5%	<b>Melting point/range(°C/°F):</b> -59 °C/-74.2 °F	<b>Decomposition temperature(°C/°F):</b> No information available
<b>Boiling point/range(°C/°F):</b> 188 °C/370.4 °F	<b>Bulk density:</b> No information available	<b>Density (g/cm3):</b> 1.036 @ 20 °C
<b>Specific gravity:</b> No information available	<b>pH:</b> No information available	<b>Vapor pressure @ 20°C (kPa):</b> 0.017
<b>Evaporation rate:</b> No information available	<b>Vapor density:</b> 2.62	<b>VOC content (g/L):</b> No information available
<b>Odor threshold (ppm):</b> No information available	<b>Partition coefficient (n-octanol/water):</b> -0.92	<b>Viscosity:</b> No information available
<b>Miscibility:</b> No information available	<b>Solubility:</b> No information available	

## 10. STABILITY AND REACTIVITY

### Reactivity

Incompatible with chloroformates, strong acids (nitric acid, hydrofluoric acid), caustics, aliphatic amines, isocyanates, strong oxidizers, acid anhydrides, silver nitrate, reducing agents.

### 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 moisture. Exposure to moist air. Incompatible materials.

**Incompatible Materials:** Oxidizing agents  
Acids  
Bases  
Reducing agents

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

### Other Information

**Corrosivity:** No information available

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

## 11. TOXICOLOGICAL INFORMATION

### Information on likely routes of exposure

**Principal Routes of Exposure:** Skin. Ingestion. Eyes.

### Acute Toxicity

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## Component Information

Propylene Glycol	
CAS-No.	57-55-6

**LD50/oral/rat** = 20 g/kg Oral LD50 Rat  
**LD50/oral/mouse** = 20300-22000 mg/kg Oral LD50 Mouse  
**LD50/dermal/rabbit** = 20800 mg/kg Dermal LD50Rabbit  
**LD50/dermal/rat** = No information available  
**LC50/inhalation/rat** = No information available  
**LC50/inhalation/mouse** = No information available  
**Other LD50 or LC50information** = 22000 mg/kg Oral LD50 Dog  
18350-19600 mg/kg Oral LD50 Guinea Pig  
18500 mg/kg Oral LD50 Rabbit

## Product Information

**LD50/oral/rat** =  
**VALUE- Acute Tox Oral** = 20000 mg/kg

**LD50/oral/mouse** =  
**Value - Acute Tox Oral** = 20300-22000 mg/kg

**LD50/dermal/rabbit**  
**VALUE-Acute Tox Dermal** = 20800 mg/kg

**LD50/dermal/rat**  
**VALUE -Acute Tox Dermal** = No information available

**LC50/inhalation/rat**  
**VALUE-Vapor** = No information available  
**VALUE-Gas** = No information available  
**VALUE-Dust/Mist** = 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 and cause systemic effects similar to those of ingestion.

**Eye Contact:** May cause eye irritation. May cause mild eye irritation with some immediate, transitory stinging, lacrimation, blepharospasm, and mild transient conjunctival hyperemia. There is no residual discomfort or injury once it is washed away. No corneal injury has been reported.

**Inhalation** May cause irritation of respiratory tract.

**Ingestion** Low acute toxicity. It may cause gastrointestinal tract irritation with nausea and vomiting. It may affect behavior/central nervous system(CNS depression, drowsiness, dizziness, fatigue, stupor, confusion, dysarthria, general anesthetic, convulsions, seizures, ataxia, tetany, somnolence, stupor, muscle contraction or spasticity, coma), brain (changes in surface EEG). It may cause metabolic acidosis.

Effects on the cardiovascular system(hypotension, bradycardia, arrhythmias, cardiac arrest) have been noted in cases with rapid intravenous injection.

**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 skin contact may dryness and redness of the skin, mild irritation, and rarely allergic contact dermatitis. Ingestion: Prolonged or repeated ingestion may cause hyperglycemia or hypoglycemia and may affect behavior/CNS (stupor, seizures, and other symptoms similar to that of acute ingestion). Chronic ingestion of larger amounts may also cause lactic acidosis or metabolic acidosis. Chronic exposure may also affect the kidneys and blood (changes in serum composition, reduction in red blood cell count, elevation in white blood cell count). Medical Conditions Aggravated by Exposure: Kidney disease, impaired renal function. Lactic acidosis has been reported in individuals with renal impairment or failure.

**Sensitization:** No information available.

**Mutagenic Effects:** May affect genetic material

**Carcinogenic effects:** Not considered carcinogenic.

Components	CAS-No.	IARC	ACGIH - Carcinogens	NTP	OSHA HCS - Carcinogens	Australia - Notifiable Carcinogenic Substances	Australia - Prohibited Carcinogenic Substances
Propylene Glycol	57-55-6	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.

*Propylene Glycol - 57-55-6*

**Freshwater Algae Data:** 19000 mg/L EC50 *Pseudokirchneriella subcapitata* 96 h

**Freshwater Fish Species Data:** 51600 mg/L LC50 *Oncorhynchus mykiss* 96 h static 1 41 - 47 mL/L LC50

**Water Flea Data:** Oncorhynchus mykiss 96 h static 1 51400 mg/L LC50 Pimephales promelas 96 h static 1 710 mg/L LC50 Pimephales promelas 96 h 1000 mg/L EC50 Daphnia magna 48 h 10000 mg/L EC50 Daphnia magna 24 h

**Persistence and degradability:** No information available

**Bioaccumulative potential:** Potential for bioconcentration in aquatic organisms is low.

**Mobility:** It is expected to have very high mobility based on estimated Koc.

### 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
Propylene Glycol	57-55-6	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 Number:** No information available  
**Marine Pollutant:** No data available  
**DOT RQ (lbs):** No information available  
**Special Provisions:** No Information available  
**Symbol(s):** No information available  
**Description:** No information available

#### TDG (Canada)

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

#### ADR

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

#### IMO / IMDG

**Product code:** PR130

**Product name:** PROPYLENE GLYCOL, USP

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

**RID**

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

**ICAO**

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

**IATA**

**UN-No:** Not regulated  
**Proper Shipping Name:** No information available  
**Hazard Class:** No information available  
**Subsidiary Risk:** No information available  
**Packing Group:** No information available  
**ERG Code:** No information available  
**Special Provisions** No information available

**15. REGULATORY INFORMATION**

**International Inventories**

Components	CAS-No.	U.S. TSCA	KOREA KECL	Philippines (PICCS)	Japan ENCS	CHINA	Australia (AICS)	EINECS-No.
<i>Propylene Glycol</i>	57-55-6	PresentACTIVE	Present KE-29267	Present	Present (2)-234	Present	Present	Present 200-338-0

**U.S. Regulations**

*Propylene Glycol*

**New Jersey RTK Hazardous Substance List:** 3595

**Pennsylvania RTK:** Present

**Minnesota - Hazardous Substance List:** Present

**FDA - Food Additives Generally Recognized as Safe (GRAS):** 21 CFR 184.1666

**FDA - 21 CFR - Total Food Additives** 169.175, 175.300, 175.320, 176.180, 176.210, 177.1390, 177.1680, 177.2420, 177.2600,

**- List Sourced from EAFUS** 177.2800, 178.3300, 184.1666, 73.30

**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 Reproductive Toxicity	Female Reproductive Toxicity:

Propylene Glycol	57-55-6	Not Listed	Not Listed	Not Listed	Not Listed
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### 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
Propylene Glycol	57-55-6	None	None	None	None	None

### U.S. TSCA

Components	CAS-No.	TSCA Section 5(a)2 - Chemicals With Significant New Use Rules (SNURS)	TSCA 8(d) -Health and Safety Reporting
Propylene Glycol	57-55-6	Not Applicable	Not Applicable

### Canada

#### WHMIS 2015 - GHS Classifications

WHMIS 2015 Hazard Classification Information:

Component  
Propylene Glycol  
57-55-6 ( 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

Components	WHMIS Ingredient Disclosure List -
Propylene Glycol	1 %

#### Inventory

Components	CAS-No.	Canada (DSL)	Canada (NDSL)
Propylene Glycol	57-55-6	Present	Not Listed

Components	CAS-No.	CEPA Schedule I - Toxic Substances
Propylene Glycol	57-55-6	Not listed
Components	CAS-No.	CEPA - 2010 Greenhouse Gases Subject to Mandatory Reporting
Propylene Glycol	57-55-6	Not listed

### EU Classification

#### EU GHS - SV - CLP 1272/2008

Components	CAS-No.	EU GHS - SV - CLP (1272/2008)
Propylene Glycol	57-55-6	

#### EU - CLP (1272/2008)

#### R-phrase(s)

not determined (not applicable)

#### S -phrase(s)

none

Product code: PR130

Product name: PROPYLENE  
GLYCOL, USP

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Components	CAS-No.	Classification	Concentration Limits:	Safety Phrases
Propylene Glycol	57-55-6		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:** 9/18/2014  
**Revision Date:** 10/25/2018  
**Prepared by:** Sonia Owen

**Disclaimer:**

All chemicals may pose unknown hazards and should be used with caution. This Safety Data Sheet (SDS) applies only to the material as packaged. If this product is combined with other materials, deteriorates, or becomes contaminated, it may pose hazards not mentioned in this SDS. The physical properties reported in this SDS are obtained from the literature and do not constitute product specifications. Information contained herein does not constitute a warranty, whether expressed or implied, as to the safety, merchantability or fitness of the goods for a particular purpose. Spectrum Chemicals & Laboratory Products, Inc. assumes no responsibility for results obtained or for incidental or consequential damages, including lost profits, arising from the use of these data. No warranty against infringement of any patent, copyright or trademark is made or implied. It shall be the user's responsibility to develop proper methods of handling and personal protection based on the actual conditions of use. While this SDS is based on technical data judged to be reliable, Spectrum assumes no responsibility for the completeness or accuracy of the information contained herein.

**End of Safety Data Sheet**



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.



**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
PR130	Propylene Glycol, USP

Spectrum is an FDA registered and inspected Drug Establishment. Our United States Food and Drug Administration (USFDA) Registration numbers are as follows:

Spectrum-Gardena, CA: 2020632

Spectrum-New Brunswick, NJ: 2246824

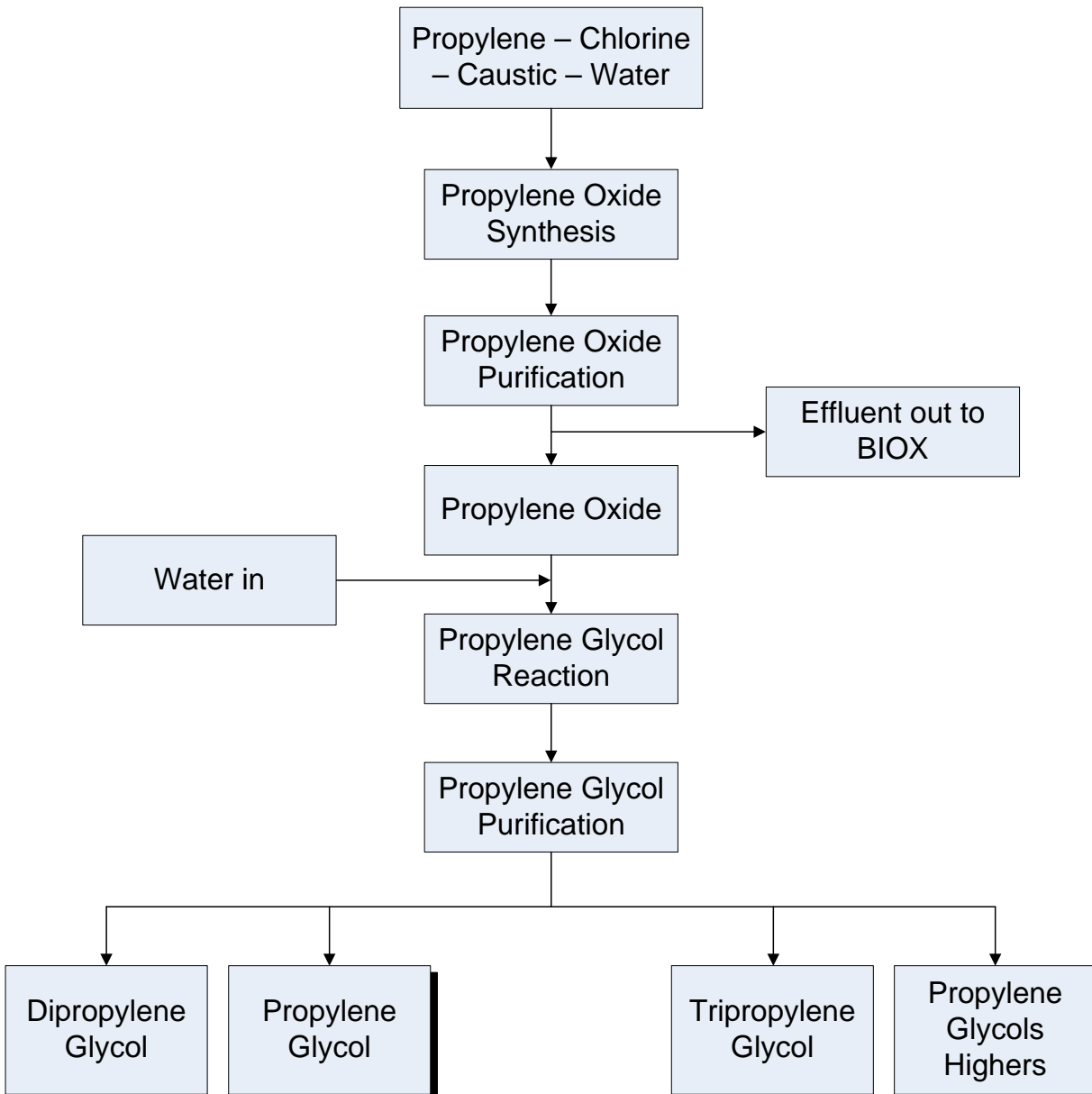
Thank you for your interest in Spectrum products. If we may be of further assistance, please feel free to contact the Quality Assurance department at 310-516-8000 or via email at [qualityassurance@spectrumchemical.com](mailto:qualityassurance@spectrumchemical.com)

Sincerely,

Oralia Chavez  
Quality Assurance Specialist

## Manufacturing Process Flowchart

### Propylene Glycol, USP - PR130



#### ***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

## PR130, Propylene Glycol, USP

### Source Statement

The above mentioned catalog item is manufactured by chemical synthesis. No animal or plant derived products are used in the manufacturing process.

### BSE/TSE Statement

The above mentioned catalog item does not contain nor is manufactured using any animal derived products and is therefore, BSE/TSE free.

### Allergen Statement

The above mentioned catalog item does not contain any of the following:

- Milk
- Egg
- Fish
- Shellfish
- Tree Nuts
- Wheat
- Peanuts
- Soy
- Cereals containing Gluten
- Celery
- Mustard
- Sesame Seed
- Corn
- Latex
- Sulfites > 10 ppm

### EU Fragrance Allergen Statement

The above mentioned catalog item does not contain any of the 26 EU fragrance allergens listed in Annex III lines 67-92. These substances are not intentionally added to the following chemical and therefore are not expected to be present.

### GMO Statement

The above mentioned catalog item is manufactured without the use of genetically modified organisms and is therefore GMO free.

### Melamine Statement

The above mentioned catalog does not use or add melamine to the manufacturing process and is considered melamine-free.

## Nitrosamine Statement

Based on knowledge of the manufacturing process, nitrosamine impurities are not known or suspected to be present in this material.

## Animal Testing Statement

The above mentioned catalog item has not been tested on animals.

## 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 24 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



**RE: Elemental Impurities - Propylene Glycol, USP (Cat# PR130)**

To Whom It May Concern:

Thank you for your interest in Spectrum high quality chemicals.

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

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

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

Sincerely,

Technical Services  
Spectrum Chemical Mfg. Corp.

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

CORPORATE HEADQUARTERS

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

WEST COAST FACILITY

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



**RE: Residual Solvents - Propylene Glycol, USP (Cat# PR130)**

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 the USP <467> Residual Solvents and the ICH Q3C Residual Solvents Guideline. No Class 1, Class 2, Class 3 or other solvents are used or produced in the manufacture 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 [TechServices@spectrumchemical.com](mailto:TechServices@spectrumchemical.com).

Sincerely,

Technical Services  
Spectrum Chemical Mfg. Corp.

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CORPORATE HEADQUARTERS

769 Jersey Avenue  
New Brunswick, NJ 08901  
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FAX 732.246.7132

WEST COAST FACILITY

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

## 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.

**spectrum®**  
CHEMICAL MFG CORP

**PR130** **4 L**

**Propylene Glycol**  
(1,2-Propanediol)

**CAS 57-55-6**

**U.S.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**  
www.SpectrumChemical.com

**C<sub>3</sub>H<sub>8</sub>O<sub>2</sub>** **F.W. 76.10**

Assay ..... Min. 99.5%  
Specific Gravity @ 25°C ..... 1.035-1.037  
**MAXIMUM LIMITS**

Acidity ..... To pass test  
Water Determination ..... 0.2%  
Residue on Ignition ..... 3.5 mg/50 g  
Chloride (Cl) ..... 70 ppm  
Sulfate (SO<sub>4</sub>) ..... 60 ppm  
Elemental Impurities ..... As reported  
Residual Solvents ..... To pass test

**HYGROSCOPIC:** Keep tightly closed.

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

**Lot No. 062233**

**SPECTRUM CHEMICAL MFG. CORP.** **Gardena, CA 90248 • New Brunswick, NJ 08901**

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

This color-coded band indicates the hazard most likely to be posed by that material under storage conditions. The criteria used to assign band colors have been established by the Storage Code working group of the Society for Chemical Hazard Communication (SCHC). It is recommended that like colors be stored together, unless otherwise stated, based on the color codes indicated to the right. However, it is the responsibility of the customer to check with their local fire department for possible conflicts with our recommendations when storing hazardous chemicals.

- **YELLOW:** Oxidizer
- **RED:** Flammable
- **GREEN:** General Storage
- **BLUE:** Health Hazard
- WHITE:** Corrosive

### Spectrum Chemical Mfg Corp

#### Corporate Headquarters:

769 Jersey Ave.  
New Brunswick, NJ 08901  
732.214.1300

#### West Coast Facility:

14422 S. San Pedro St.  
Gardena, CA 90248  
310.516.8000





**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
- 4 = Pharmacy, NJ Facility

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

**Example:** 2AA0706 = The 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 [quality\\_assurance@spectrumchemical.com](mailto:quality_assurance@spectrumchemical.com) if we may be of further assistance.

Sincerely,

Oralia Chavez,  
Quality Assurance Specialist

CORPORATE HEADQUARTERS

769 Jersey Avenue  
New Brunswick, NJ 08901  
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WEST COAST FACILITY

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Gardena, California 90248  
PHONE 310.516.8000  
FAX 310.516.9843



KOSHER SUPERVISION OF AMERICA

בס"ד  
Jan 28, 2021

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** PR130, Propylene Glycol, USP

**Brand** Spectrum

**UKD-ID** KSAV3-H8Y2M1

**D/P/M** P

**Symbol Required** KSA

**Special Conditions**

This certificate expires on  
**Feb 01, 2022**

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.



المجلس الإسلامي الأمريكي للغذاء و التغذية  
THE ISLAMIC FOOD AND NUTRITION COUNCIL OF AMERICA

IFANCA HALAL PRODUCT CERTIFICATE شهادة حلال

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

Date: July 16, 2020

Document #: 11205.11209.II201354

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

Plant Name & Address: **Spectrum Laboratory Products, Inc.** 14422 South San Pedro Street Gardena, California 90248 USA

ProductName	Product Code	Halal-ID	Product Certificate #
1. Propylene Glycol, USP	PR130	B94094	HC-20SPQN96

*Muhammad Munir Chaudry*  
Muhammad Munir Chaudry, Ph.D.  
President



This Certificate is valid until **August 31, 2021** and subject to renewal at that time.



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