



Scientific Documentation

PO131, Polyethylene Glycol 8000, NF

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

Spectrum Chemical Mfg Corp

769 Jersey Avenue
New Brunswick, NJ 08901
Phone 732.214.1300

Ver4.01 27.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,

A handwritten signature in black ink, appearing to read "Alan Wang", with a large, sweeping flourish at the end.

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

27.Apr.2016

PO131, Polyethylene Glycol 8000, NF

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spectrum[®]
CHEMICAL MFG CORP



Specification for Polyethylene Glycol 8000, NF (PO131)

Item Number	PO131
Item	Polyethylene Glycol 8000, NF
CAS Number	25322-68-3
Molecular Formula	$H(OCH_2CH_2)_nOH$
Molecular Weight	
MDL Number	
Synonyms	Base E ; PEG-150

Test	Specification	
	Min	Max
AVERAGE MOLECULAR WEIGHT	7000-9000	
COMPLETENESS AND COLOR OF SOLUTION		TO PASS TEST
VISCOSITY @98.9 C (210 F) +/-0.3 C	470- 900 cSt	
pH OF A 5% SOLUTION @ 25°C	4.5- 7.5	
RESIDUE ON IGNITION		0.1 %
HEAVY METALS		5 ppm
FREE ETHYLENE OXIDE		10 ug/g
FREE 1,4-DIOXANE		10 ug/g
IDENTIFICATION		TO PASS TEST
RETEST DATE		
RESIDUAL SOLVENTS		TO PASS TEST

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

SAFETY DATA SHEET

Preparation Date: 03/17/2015

Revision Date: 03/17/2015

Revision Number: G1

Product identifier

Product code:

PO131

Product Name:

POLYETHYLENE GLYCOL 8000, NF

Other means of identification

Synonyms:

1,2-Ethenediol homopolymer
Alcox E 30
Alcox E 100
Alcox E 130
Alcox E 160
Alcox E 240
Alcox E 45
Alcox E 60
Alcox E 75
Alcox R 1000
Alcox R 15
Alcox R 150
Alcox R 400
Alcox SR
Antarox E 4000
Aquacide III
Aquaffin
Atpreg 300
BDH 301
Badimol
Bradsyn PEG
Breox 2000
Breox 20M
Breox 4000
Breox 550
Breox PEG 300
CAFO 154
Carbowax
Carbowax 100
Carbowax 1000
Carbowax 1350
Carbowax 14000
Carbowax 1500
Carbowax 20
Carbowax 200
Carbowax 20000
Carbowax 25000
Carbowax 300
Carbowax 3350
Carbowax 400
Carbowax 4000
Carbowax 4500
Carbowax 4600
Carbowax 600
Carbowax Sentry
DD 3002
Deactivator H
Emkapol 4200
Ethoxylated 1,2-ethenediol
Ethylene glycol homopolymer
Ethylene glycol polymer
Gafanol E 200
Glycols, polyethylene
HM 500
Lutrol
Macrogol
Merpol OJ
Miralax
Modopeg

Nosilen
Nycoline
Oxide Wax AN
Oxyethylene polymer
PEG
PEG 3350
PEG 400
PEG 4000
PEG 6000DS
Pluracol E
Pluracol E 400, E 600, E 1450
Pluriol E 200
Poly(oxy-1,2-ethanediyl, alpha-hydro-omega-hydroxy-
Poly-G
Poly-G600
Polyoxyethylene ether
alpha-Hydro-omega-hydroxypoly(oxy-1,2-ethanediyl)
alpha-Hydro-omega-hydroxypoly(oxyethylene)
CAS #: 25322-68-3
RTECS # TQ4105000
Cl#: Not available

Recommended use of the chemical and restrictions on use

Recommended use: No information available.
Uses advised against No information available

Supplier: Spectrum Chemicals and Laboratory Products, Inc.
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 by 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 %	Trade Secret
Polyethylene Glycol 8000 25322-68-3	25322-68-3	100	*

4. FIRST AID MEASURES

First aid measures

General Advice:

Poison information centers 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 skin irritation persists, call a physician.

Eye Contact:

Flush eye with water for 15 minutes. Get medical attention.

Inhalation:

Move to fresh air. If breathing is difficult, give oxygen. If not breathing, give artificial respiration. 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

Mild eye irritation. Mild skin irritation. Irritating to respiratory system.

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. Alcohol-resistant foam. Water spray.

Unsuitable Extinguishing Media:

Do not use a solid (straight) water stream as it may scatter and spread fire.

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
Fire may produce irritating, corrosive and/or toxic gases

Special Protective Actions for Firefighters

Specific Methods:

Water mist may be used to cool closed containers. For larger fires, use water spray or fog. Cool containers with flooding quantities of water until well after fire is out.

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. Keep people away from and upwind of spill/leak. Avoid contact with skin, eyes and clothing. Use personal protective equipment. Remove all sources of ignition. Pay attention to flashback. Take precautionary measures against static discharges. All equipment used when handling the product must be grounded. Use spark-proof tools and explosion-proof equipment. In case of large spill, water spray or vapor suppressing foam may be used to reduce vapors, but may not prevent ignition in closed spaces.

Environmental precautions

Prevent further leakage or spillage if safe to do so. Prevent entry into waterways, sewers, basements or confined areas. In case of large spill, dike if needed. Dike far ahead of liquid spill for later disposal.

Methods and material for containment and cleaning up

Methods for containment

Absorb spill with inert material (e.g. vermiculite, dry sand or earth), then place in a suitable chemical waste container.

Methods for cleaning up

Use appropriate tools to put the spilled material in a suitable chemical waste disposal container. Use only non-sparking tools. 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. Remove all sources of ignition. To avoid ignition of vapors by static electricity discharge, all metal parts of the equipment must be grounded. Keep away from incompatible materials.

Safe Handling Advice:

Wear personal protective equipment. Use only in well-ventilated areas. Avoid contact with skin, eyes and clothing. Keep away from heat and sources of ignition. Do not breathe vapors or spray mist. Do not ingest. When using do not smoke. Handle in accordance with good industrial hygiene and safety practice.

Conditions for safe storage, including any incompatibilities**Technical Measures/Storage Conditions:**

Keep container tightly closed in a dry and well-ventilated place. Store at room temperature in the original container. Keep away from heat and sources of ignition. Store in a segregated and approved area. Store away from incompatible materials.

Incompatible Materials:

Oxidizing agents. Acids.

8. EXPOSURE CONTROLS/PERSONAL PROTECTION

Control parameters**National occupational exposure limits****United States**

Components	OSHA	NIOSH	ACGIH	AIHA WHEEL

Polyethylene Glycol 8000 - 25322-68-3	None	None	None	10 mg/m ³ TWA
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Canada

Components	Alberta	British Columbia	Ontario	Quebec
Polyethylene Glycol 8000 - 25322-68-3	None	None	None	None

Australia and Mexico

Components	Australia	Mexico
Polyethylene Glycol 8000 25322-68-3	None	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. Safety glasses with side-shields.
- Skin and body protection:** Chemical resistant apron. Long sleeved clothing. Gloves.
- Respiratory protection:** Effective dust mask. Be sure to use an approved/certified respirator or equivalent..
- Hygiene measures:** Avoid contact with skin, eyes and clothing. When using, do not eat, drink or smoke. Wash hands before breaks and immediately after handling the product.

9. PHYSICAL AND CHEMICAL PROPERTIES

9. PHYSICAL AND CHEMICAL PROPERTIES

Physical state: Solid.	Appearance: No information available	Color: White.
Odor: No information available	Taste No information available	Molecular/Formula weight: 8000 g/mol
Formula: H(OCH ₂ CH ₂) _n OH	Flash point (°C): 260°C	Flashpoint (°C/°F): >260 °C/ 500 °F
Flash Point Tested according to: Closed cup	Lower Explosion Limit (%): No information available	Upper Explosion Limit (%): No information available
Autoignition Temperature (°C/°F): 395°C/ 743°F	pH: No information available	Melting point/range(°C/°F): 60°C/ 1401°F
Boiling point/range(°C/°F): No information available	Decomposition temperature(°C/°F): No information available	Bulk density: No information available
Specific gravity: 1.21	Density (g/cm³): No information available	Vapor pressure @ 20°C (kPa): No information available
Evaporation rate: No information available	Vapor density: No information available	VOC content (g/L): No information available
Odor threshold (ppm): No information available	Partition coefficient (n-octanol/water): No information available	Viscosity: No information available
Miscibility: No information available	Solubility: Soluble in Water	

10. STABILITY AND REACTIVITY

Reactivity

Reactive with oxidizing agents

Reactive with acids

Hygroscopic. It absorbs moisture from the air

Chemical stability

Stability: Stable under recommended storage conditions

Possibility of Hazardous Reactions: Hazardous polymerization does not occur

Conditions to avoid: Heat. Ignition sources. Incompatible materials.

Incompatible Materials: Oxidizing agents. Acids.

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:
None.

Acute Toxicity

Component Information

Polyethylene Glycol 8000 - 25322-68-3

LD50/oral/rat = 22 g/kg Oral LD50 Rat
LD50/oral/mouse = No information available
LD50/dermal/rat = No information available
LD50/dermal/rabbit = 20 mL/kg Dermal LD50Rabbit
LC50/inhalation/rat = No information available
LC50/inhalation/mouse = No information available
Other LD50 or LC50 information = No information available

Product Information

LD50/oral/rat =
VALUE- Acute Tox Oral = 50000mg/kg

LD50/oral/mouse =
Value - Acute Tox Oral = No information available

LD50/dermal/rabbit
VALUE-Acute Tox Dermal = 20mL/kg

LD50/dermal/rat
VALUE -Acute Tox Dermal = 20000mg/kg

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. May be absorbed through the skin in harmful amounts.

Eye Contact: May cause slight or mild eye irritation.

**Inhalation
Ingestion** May cause respiratory irritation.
Harmful if swallowed. Low hazard. May cause allergic reaction in sensitized individuals.

Aspiration hazard No information available

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

Chronic Toxicity No information available

Sensitization: No information available

Mutagenic Effects: No information available

Carcinogenic effects: Not considered carcinogenic

Components	ACGIH - Carcinogens	IARC	NTP	OSHA HCS - Carcinogens	Australia - Prohibited Carcinogenic Substances	Australia - Notifiable Carcinogenic Substances
Polyethylene Glycol 8000	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: Ecotoxicity in water (LC50): >5000 mg/l 24 hours [Goldfish].

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
Polyethylene Glycol 8000	None	None	None	None

14. TRANSPORT INFORMATION

14. TRANSPORT INFORMATION

DOT

UN-No:	Not Regulated
Proper Shipping Name:	No information available
Hazard Class:	No information available
Subsidiary Risk:	No information available
Packing Group:	None
ERG No:	No information available
Marine Pollutant	No data 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:	Not Regulated
Proper Shipping Name:	No information available
Hazard Class:	No information available
Packing Group:	No information available
Subsidiary Risk:	No information available
Classification Code:	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

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

14. TRANSPORT INFORMATION

Description: 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
Description: No information available

15. REGULATORY INFORMATION**International Inventories**

Components	U.S. TSCA	KOREA KECL	Philippines (PICCS)	Japan ENCS	CHINA	Australia (AICS)	EINECS-No.
<i>Polyethylene Glycol 8000</i>	Present XU	Present KE-20228	Present	Present (8)-429 (7)-129 (2)-441	Not present	Present	Not present

U.S. Regulations

Polyethylene Glycol 8000

Minnesota - Hazardous Substance List: Present

FDA - Direct Food Additives 21 CFR 172.210 21 CFR 172.820 21 CFR 173.310 21 CFR 173.340

FDA - 21 CFR - Total Food Additives 172.210 172.820 173.310 173.340 175.105 175.300 176.180 178.3750 73.1

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	Developmental Toxicity	Male Reproductive Toxicity	Female Reproductive Toxicity:
<i>Polyethylene Glycol 8000</i>	Not Listed	Not Listed	Not Listed	Not Listed

CERCLA/SARA

Components	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 <i>de minimis</i>
<i>Polyethylene Glycol 8000</i>	None	None	None	None	None

U.S. TSCA

Components	TSCA Section 5(a)2 - Chemicals With Significant New Use Rules (SNURS)	TSCA 8(d) -Health and Safety Reporting
<i>Polyethylene Glycol 8000</i>	Not Applicable	Not Applicable

Canada**WHMIS hazard class:**

Non-controlled

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)
Polyethylene Glycol 8000	Present	Not Listed

Components	CEPA Schedule I - Toxic Substances	CEPA - 2010 Greenhouse Gases Subject to Mandatory Reporting
Polyethylene Glycol 8000	Not listed	Not listed

EU Classification**R-phrase(s)**

R-phrase(s)

S -phrase(s)

none

Components	Classification	Concentration Limits:	Safety Phrases
Polyethylene Glycol 8000		No information	

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

Indication of danger:

None.

16. OTHER INFORMATION

16. OTHER INFORMATION

Preparation Date: 03/17/2015
Revision Date: 03/17/2015
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

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

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 certificate.validation@intertek.com or by scanning the code to the right with a smartphone.
The annual validity of the certificate can also be checked through the website <http://www.cnca.gov.cn> 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:	<u>2020632</u>
Spectrum-New Brunswick, NJ:	<u>2246824</u>
Spectrum -Shanghai, China:	<u>3006174778</u>

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 qualityassurance@spectrumchemical.com if we may be of further assistance.

Sincerely,

A handwritten signature in cursive script that reads "Michelle Weston".

Michelle Weston
Quality Assurance Specialist



April 13, 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
PO131	Polyethylene Glycol 8000, NF

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

Spectrum-Gardena, CA: 2020632
Spectrum-New Brunswick, NJ: 2246824
Spectrum-Shanghai, China: 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 qualityassurance@spectrumchemical.com if we may be of further assistance.

Sincerely,

Michelle Weston
Quality Assurance Specialist



April 27, 2016

Re: Polyethylene Glycol 8000, NF-PO131

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

Polyethylene Glycol 8000, NF-PO131

is BSE/TSE free.

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

Sincerely,

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

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



April 27, 2016

Re: Polyethylene Glycol 8000, NF-PO131

To Whom It May Concern:

Thank you for your interest in Spectrum high quality chemicals.

We at Spectrum Chemical Mfr. Corp. understand the concern regarding the presence of allergens in raw materials. Please be assured that the following chemical does not contain (Milk; Egg; Fish; Shellfish; Sulfur dioxide and sulfites at concentrations of more than 10 mg/kg or 10 mg/liter expressed as SO₂; Lupin; Tree nuts; Mollusks; Wheat; Peanuts; Soy; Cereals containing Gluten; Celery; Mustard; Sesame Seed).

Polyethylene Glycol 8000, NF-PO131

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

Sincerely,

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

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



April 26, 2016

Re: Polyethylene Glycol 8000, NF-PO131

To Whom It May Concern:

Thank you for your interest in Spectrum high quality chemicals.

We at Spectrum Chemical Mfg. Corp. understand the concern regarding Aflatoxins in raw materials. To the best of our knowledge, the product listed below is not contaminated with Aflatoxins. Aflatoxins are not used in production. The following product does not come in contact with Aflatoxins at any stage of production.

Polyethylene Glycol 8000, NF-PO131

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

Sincerely,

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

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

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.

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

KEEP FROM CHILDREN

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

WARNING: This product contains a chemical known to the State of California to cause cancer.

WARNING: This product contains a chemical known to the State of California to cause birth defects or other reproductive harm.

FLUSHED WITH NITROGEN

Technical Specifications:

Average Molecular Weight	12
Completeness and Color of Solution	To pass test
Actual Viscosity @ 98.9 ± 0.3°C (210°F)	12 cSt
pH of a 5% Solution @ 25°C	4.5-7.5
MAXIMUM LIMITS	
Residue on Ignition	0.1%
Heavy Metals	5 ppm
Free Ethylene Oxide	10 µg/g
Free 1,4-Dioxane	10 µg/g
Residual Solvents	To pass test

Chemical Formula: H(OCH₂CH₂)_nOH

Product Information: P0131, 12 KG, Polyethylene Glycol 8000 (PEG-150), N.F., CAS 25322-68-3, Lot No. 062233

Company Information: SPECTRUM CHEMICAL MFG. CORP., Gardena, CA 90248 • New Brunswick, NJ 08901

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

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

Item Number	PO131	Lot Number	1EG0303
Item	Polyethylene Glycol 8000, NF		
CAS Number	25322-68-3		
Molecular Formula	$H(OCH_2CH_2)_nOH$	Molecular Weight	

Test	Specification		Result
	min	max	
AVERAGE MOLECULAR WEIGHT	7000-9000		8349
COMPLETENESS AND COLOR OF SOLUTION		TO PASS TEST	PASSES TEST
VISCOSITY @98.9 C (210 F) +/-0.3 C	470- 900 cSt		760 cSt
pH OF A 5% SOLUTION @ 25°C	4.5- 7.5		6.9
RESIDUE ON IGNITION		0.1 %	<0.1 %
HEAVY METALS		5 ppm	<5 ppm
FREE ETHYLENE OXIDE		10 ug/g	0 ug/g
FREE 1,4-DIOXANE		10 ug/g	0 ug/g
IDENTIFICATION		TO PASS TEST	PASSES TEST
RETEST DATE			04-MAR-2018
RESIDUAL SOLVENTS		TO PASS TEST	.
CLASS 2 (solvent) / ETHYLENE GLYCOL			<620 ppm
CLASS 3 (solvent) / ACETIC ACID			<5000 ppm
APPEARANCE			WHITE POWDER
MANUFACTURE DATE			04-MAR-2015

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

Certificate of Analysis Results Certified By:



Adan Hernandez
Quality Control Manager
Spectrum Chemicals & Laboratory Products



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

Item Number	PO131	Lot Number	2EH0254
Item	Polyethylene Glycol 8000, NF		
CAS Number	25322-68-3		
Molecular Formula	$H(OCH_2CH_2)_nOH$	Molecular Weight	

Test	Specification		Result
	min	max	
AVERAGE MOLECULAR WEIGHT	7000-9000		8349
COMPLETENESS AND COLOR OF SOLUTION		TO PASS TEST	PASSES TEST
VISCOSITY @98.9 C (210 F) +/-0.3 C	470- 900 cSt		760 cSt
pH OF A 5% SOLUTION @ 25°C	4.5- 7.5		6.9
RESIDUE ON IGNITION		0.1 %	<0.1 %
HEAVY METALS		5 ppm	<5 ppm
FREE ETHYLENE OXIDE		10 ug/g	0 ug/g
FREE 1,4-DIOXANE		10 ug/g	0 ug/g
IDENTIFICATION		TO PASS TEST	PASSES TEST
RETEST DATE			04-MAR-2018
RESIDUAL SOLVENTS		TO PASS TEST	.
CLASS 2 (solvent) / 1,4-DIOXANE			<380 ppm
CLASS 2 (solvent) / ETHYLENE GLYCOL			<620 ppm
CLASS 3 (solvent) / ACETIC ACID			<5000 ppm
APPEARANCE			WHITE SOLID
DATE OF MANUFACTURE			04-MAR-2015

Spectrum Chemical Mfg Corp
755 Jersey Avenue
New Brunswick 08901 NJ

Certificate of Analysis Results Certified By:




Mulbah F. Dwanah
Laboratory Supervisor
Spectrum Chemicals & Laboratory Products

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 928th material produced in California in September 2010

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

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

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

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

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

Sincerely,



Michael Dang
Manager, GMP Compliance



Stability – Shelf Life Guidance

Product Covered: PO131, Polyethylene Glycol 8000, NF

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

The product, PO131, Polyethylene Glycol 8000, NF, 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

A handwritten signature in black ink, appearing to read "Adan R. Hernandez".

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