

Scientific Documentation

Polyethylene Glycol 400 Monostearate

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



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Specification for Polyethylene Glycol 400 Monostearate (P1154)

Item Number	P1154
Item	Polyethylene Glycol 400 Monostearate
CAS Number	9004-99-3
Molecular Formula	
Molecular Weight	
MDL Number	
Synonyms	PEG-8 Stearate ; Myrj 45

Test	Specification	
	Min	Max
SAPONIFICATION VALUE	83	92
HYDROXYL VALUE	80	100
pH (5% SOLUTION)	5.0	7.0
ACID VALUE		2
IODINE VALUE		1.5
MOISTURE		3.0 %
IDENTIFICATION	TO PASS TEST	
APPEARANCE		
RETEST DATE		
DATE OF MANUFACTURE		

Spectrum Chemical Mfg Corp

Corporate Headquarters:	West Coast Facility:
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	P1154	Lot Number	1NB0122
Item	Polyethylene Glycol 400 Monostearate	CAS Number	9004-99-3

TEST	SPECIFICATION		RESULT
	MIN	MAX	
SAPONIFICATION VALUE	83	92	85.76
HYDROXYL VALUE	80	100	89.42
pH (5% SOLUTION)	5.0	7.0	6.8
ACID VALUE		2	1.8
IODINE VALUE		1.5	0.29
MOISTURE		3.0 %	0.59 %
IDENTIFICATION	TO PASS TEST		PASSES TEST
APPEARANCE			WHITE SOFT WAX SOLID
RETEST DATE			01-JAN-2026
DATE OF MANUFACTURE			01-JAN-2024

Certificate of Analysis Results Entered By:

HBERMUDEZ
Hernan Bermudez
01-APR-24 11:14:35

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



Certificate of Analysis Results Approved By:

SHANSEN
Selin Hansen
01-APR-24 14:20:49

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

spectrum®

Revision date 17-May-2023



Revision Number 2

1. Identification

Product identifier

Product Name POLYETHYLENE GLYCOL 400 MONOSTEARATE

Other means of identification

Product Code(s) P1154

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

Supplier Address

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

Classification

Serious eye damage/eye irritation	Category 2B
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Hazards not otherwise classified (HNOC)

Not applicable

Label elements

Warning

Hazard statements

Causes eye irritation

Appearance Waxy

Physical state Solid

Odor No information available

Precautionary Statements - Prevention

Wash face, hands and any exposed skin thoroughly after handling

Precautionary Statements - Response

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

Other information

No information available.

3. Composition/information on ingredients

Substance

Chemical name	CAS No	Weight-%
Polyethylene Glycol 400 Monostearate	9004-99-3	100

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 effects, both acute and delayed

Symptoms	No information available.
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Indication of any immediate medical attention and special treatment needed

Note to physicians	Treat symptomatically.
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5. Fire-fighting measures

Suitable Extinguishing Media	Use extinguishing measures that are appropriate to local circumstances and the surrounding environment.
Large Fire	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 (CO ₂).
Explosion data	
Sensitivity to mechanical impact	none.

Sensitivity to static discharge none.

Special protective equipment for fire-fighters Firefighters 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 The following ingredients are the only ingredients of the product above the cut-off level (or level that contributes to the hazard classification of the mixture) which have an exposure limit applicable in the region for which this safety data sheet is intended or other recommended limit. At this time, the other relevant constituents have no known exposure limits from the sources listed here.

Appropriate engineering controls

Engineering controls Showers
Eyewash stations
Ventilation systems.

Individual protection measures, such as personal protective equipment

Eye/face protection If splashes are likely to occur, wear safety glasses with side-shields. None required for consumer use.

Skin and body protection No special protective equipment required.

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.

General hygiene considerations Avoid contact with skin, eyes or clothing.

9. Physical and chemical properties

Information on basic physical and chemical properties

Physical state	Solid
Appearance	Waxy
Color	White
Odor	No information available
Odor threshold	No information available

<u>Property</u>	<u>Values</u>	<u>Remarks • Method</u>
pH	no data available	None known
Melting point / freezing point	48 - 60 °C / 118.4 - 140 °F	None known
Boiling point / boiling range	no data available	None known
Flash point	257 °C / 494.6 °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 limits	No data available	
Lower flammability or explosive limits	No data available	
Vapor pressure	No data available	None known
Vapor density	no data available	None known
Relative density	1.1	None known
Water solubility	No data available	None known
Solubility(ies)	Soluble in Ethanol Soluble in Acetone Soluble in Toluene Soluble in Ether	None known
Partition coefficient	No data available	None known
Autoignition temperature	no data available	None known
Decomposition temperature		None known
Kinematic viscosity	no data available	None known
Dynamic viscosity	No data available	None known
<u>Other information</u>		
Explosive properties	No information available	
Oxidizing properties	No information available	
Softening point	No information available	
Molecular weight	No information available	
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.
Ingestion	Specific test data for the substance or mixture is not available.

Symptoms related to the physical, chemical and toxicological characteristics

Symptoms	May cause redness and tearing of the eyes.
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Acute toxicity

Numerical measures of toxicity

Chemical name	Oral LD50	Dermal LD50	Inhalation LC50
Polyethylene Glycol 400 Monostearate 9004-99-3	= 53 mL/kg (Rat) > 20 g/kg (Rat)	-	-

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

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

12. Ecological information

Ecotoxicity	The environmental impact of this product has not been fully investigated.
Persistence and degradability	No information available.
Bioaccumulation	Inherently biodegradable.
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

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

15. Regulatory information

International Inventories

TSCA	Complies
DSL/NDL	Complies
EINECS/ELINCS	Does not Comply
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/NDL - 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

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

This product does not contain any substances regulated under applicable state right-to-know regulations

U.S. EPA Label Information

EPA Pesticide Registration Number Not applicable

16. Other information

NFPA

Health hazards 1

Flammability 1

Instability 0

Physical and chemical properties -

HMIS

Health hazards 1

Flammability 1

Physical hazards 0

Personal protection X

Key or legend to abbreviations and acronyms used in the safety data sheet

Legend Section 8: EXPOSURE CONTROLS/PERSONAL PROTECTION

TWA TWA (time-weighted average)

STEL

STEL (Short Term Exposure Limit)

Ceiling Maximum limit value

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) (AELG(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 17-May-2023
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



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
P1154	Polyethylene Glycol 400 Monostearate

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

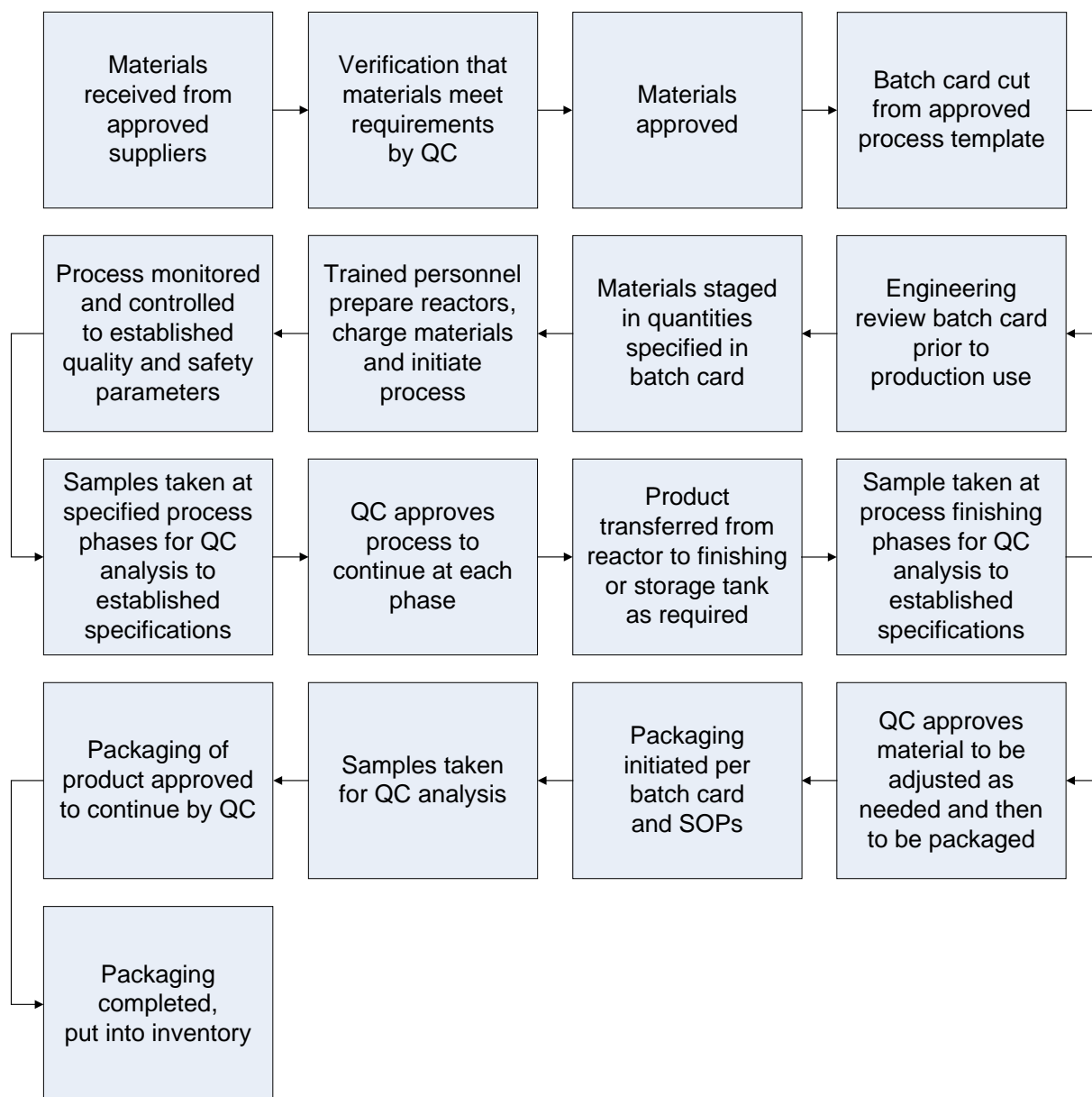
Sincerely,

A handwritten signature in black ink, appearing to read "Oralia Chavez".

Oralia Chavez
Quality Assurance Specialist

Manufacturing Process Flowchart

Polyethylene Glycol 400 Monostearate - P1154



Spectrum Chemical Mfg Corp

Corporate Headquarters:

769 Jersey Ave.
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732.214.1300

West Coast Facility:

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

P1154, Polyethylene Glycol 400 Monostearate

Source Statement

The above mentioned catalog item is manufactured using plant derived material (fatty acid from Palm Oil). No animal 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

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 or irradiation.

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 | • Parabens |
| • Antibiotics | • Pesticides |
| • Bisphenol A (BPA) | • Phthalates |
| • CMR Substances | • Preservatives |

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. Below you will find a typical label example for this catalog item.

 <p>WARNING</p> <ul style="list-style-type: none"> • Causes eye irritation. • Wash face, hands and any exposed skin thoroughly after handling. <p>FIRST AID: 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 attention.</p> <p>KEEP FROM CHILDREN</p>	<p>P1154 SIZ SY</p> <p>Polyethylene Glycol</p> <p>400 Monostearate</p> <p>CAS 9004-99-3</p> <p>CAUTION: For manufacturing, processing or repacking. Read and understand the label and Safety Data Sheet (SDS) prior to use.</p> <div style="border: 1px solid black; padding: 2px; text-align: center;"> Chemical Emergency: (800)424-9300 </div> <p>www.SpectrumChemical.com</p>	<p>Saponification Value83-92</p> <p>Hydroxyl Value80-100</p> <p>pH (5% Solution)5.0-7.0</p> <p>IdentificationTo pass test</p> <p style="text-align: center;">MAXIMUM LIMITS</p> <p>Acid Value2</p> <p>Iodine Value1.5</p> <p>Moisture3.0%</p>
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G 4/E6GHS

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Lot No. XQ####

Spectrum Chemical Mfg Corp

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