

Scientific Documentation

Polyoxyl 40 Stearate, Type II, 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



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Specification for Polyoxyl 40 Stearate, Type II, NF (P1159)

Item Number	P1159
Item	Polyoxyl 40 Stearate, Type II, NF
CAS Number	9004-99-3
Molecular Formula	
Molecular Weight	
MDL Number	
Synonyms	Myrj 52 ; Polyethylene Glycol (40) Monostearate ; PEG-40 Stearate

Test	Specification	
	Min	Max
STEARIC ACID AND PALMITIC ACID	96.0 %	
STEARIC ACID	90.0	99.0 %
FREE POLYETHYLENE GLYCOLS	17	27 %
ALKALINITY	DOES NOT TURN RED	
HYDROXYL VALUE	25	40
SAPONIFICATION VALUE	25	35
CONGEALING TEMPERATURE	37°	47°C
ELEMENTAL IMPURITIES	AS REPORTED	
ETHYLENE OXIDE		1 ppm
DIOXANE		380 ppm
ACID VALUE		6.0
IODINE VALUE		3.0
PEROXIDE VALUE		10.0
ARTICLES OF BOTANICAL ORIGIN (TOTAL ASH)		0.3 %
WATER DETERMINATION		3.0 %
IDENTIFICATION A (FTIR)	SPECTRUM MATCHES REFERENCE	
IDENTIFICATION B (stearic acid)	90.0	99.0 %
IDENTIFICATION B (stearic acid and palmitic acid)	96.0 %	
RETEST DATE		

Test	Specification	
	Min	Max
MANUFACTURE DATE		
APPEARANCE		
RESIDUAL SOLVENTS	AS REPORTED	

Spectrum Chemical Mfg Corp

<i>Corporate Headquarters:</i>	<i>West Coast Facility:</i>
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	P1159	Lot Number	IND0016
Item	Polyoxyl 40 Stearate, Type II, NF	CAS Number	9004-99-3

TEST	SPECIFICATION		RESULT
	MIN	MAX	
STEARIC ACID AND PALMITIC ACID	96.0 %		99.4 %
STEARIC ACID	90.0	99.0 %	95.6 %
FREE POLYETHYLENE GLYCOLS	17	27 %	20 %
ALKALINITY	DOES NOT TURN RED		DOES NOT TURN RED
HYDROXYL VALUE	25	40	31
SAPONIFICATION VALUE	25	35	30
CONGEALING TEMPERATURE	37°	47°C	42°C
ELEMENTAL IMPURITIES	AS REPORTED		NO ELEMENTAL IMPURITIES PRESENT
ETHYLENE OXIDE		1 ppm	0 ppm
DIOXANE		380 ppm	0 ppm
ACID VALUE		6.0	0.6
IODINE VALUE		3.0	0.5
PEROXIDE VALUE		10.0	0.3
ARTICLES OF BOTANICAL ORIGIN (TOTAL ASH)		0.3 %	0.1 %
WATER DETERMINATION		3.0 %	0.3 %
IDENTIFICATION A (FTIR)	SPECTRUM MATCHES REFERENCE		SPECTRUM MATCHES REFERENCE
IDENTIFICATION B (stearic acid)	90.0	99.0 %	95.6 %
IDENTIFICATION B (stearic acid and palmitic acid)	96.0 %		99.4 %
RETEST DATE			27-JUN-2026
MANUFACTURE DATE			28-JUN-2023
APPEARANCE			LIGHT TAN PASTILLES

TEST	SPECIFICATION		RESULT
	MIN	MAX	
RESIDUAL SOLVENTS	AS REPORTED		MEETS REQUIREMENTS IN USP <467>
MONOGRAPH EDITION			(USP-NF) 2023

Certificate of Analysis Results Entered By:

HBERMUDEZ
Hernan Bermudez
08-APR-24 10:13:53

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



Certificate of Analysis Results Approved By:

SHANSEN
Selin Hansen
10-APR-24 09:58:47

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

Read and understand label and SDS before handling any chemicals. All Spectrum's chemicals are for manufacturing, processing, repacking or research purposes by experienced personnel only. It is the customer's responsibility to provide adequate hazardous material training and ensure that appropriate Personal Protective Equipment (PPE) is used before handling any chemical.

The Elemental Impurities standards implemented by USP and other Pharmaceutical Compendia reflect a growing understanding of the toxicology of trace levels of elemental impurities that can remain in drug substances originating from either raw materials or manufacturing processes. Identifying and quantifying impurities can be critical to predicting the best possible patient outcomes. Elemental Impurities has been a requirement of all products meeting USP/NF, EP and BP monographs since January 1, 2018. More information can be found in USP sections <232> Elemental Impurities – Limits and <233> Elemental Impurities – Procedures. Data for drug substances furnished by Spectrum Chemical Mfg. Corp can be used to ensure that patient daily exposures by oral administration to the selected elements are not exceeded in the formulation of pharmaceutical products.

SAFETY DATA SHEET

spectrum®

Revision date 07-June-2023



Revision Number 4

1. Identification

Product identifier

Product Name POLYOXYL 40 STEARATE, NF

Other means of identification

Product Code(s) P1159

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

This chemical is not considered hazardous by the 2012 OSHA Hazard Communication Standard (29 CFR 1910.1200).

Hazards not otherwise classified (HNOC)

Not applicable

Label elements

Hazard statements

This chemical is not considered hazardous by the 2012 OSHA Hazard Communication Standard (29 CFR 1910.1200).

The product contains no substances which at their given concentration, are considered to be hazardous to health.

Physical state Solid

Odor No information available

Other information

No information available.

3. Composition/information on ingredients**Substance**

Chemical name	CAS No	Weight-%
Polyoxyl 40 Stearate	9004-99-3	100

4. First-aid measures**Description of first aid measures**

Inhalation	Remove to fresh air.
Eye contact	Rinse thoroughly with plenty of water for at least 15 minutes, lifting lower and upper eyelids. Consult a physician.
Skin contact	Wash skin with soap and water.
Ingestion	Clean mouth with water and drink afterwards plenty of water.

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 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 Ensure adequate ventilation.

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 container tightly closed in a dry 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 No special protective equipment required.

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 Handle in accordance with good industrial hygiene and safety practice.

9. Physical and chemical properties

Information on basic physical and chemical properties

Physical state Solid
Appearance No information available
Color beige 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	37 - 47 °C / 98.6 - 116.6 °F	None known
Boiling point / boiling range	no data available	None known
Flash point	149 °C / 300.2 °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)	no data available	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

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.
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 No information available.

Acute toxicity

Numerical measures of toxicity

Chemical name	Oral LD50	Dermal LD50	Inhalation LC50
Polyoxyl 40 Stearate 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 No information available.

Serious eye damage/eye irritation No information available.

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/NDSL 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/NDSL - Canadian Domestic Substances List/Non-Domestic Substances List
EINECS/ELINCS - European Inventory of Existing Chemical Substances/European List of Notified Chemical Substances
ENCS - Japan Existing and New Chemical Substances
IECSC - China Inventory of Existing Chemical Substances
KECL - Korean Existing and Evaluated Chemical Substances
PICCS - Philippines Inventory of Chemicals and Chemical Substances

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 0

Flammability 1

Instability 0

Physical and chemical properties -

HMIS

Health hazards 0

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) (AEGL(s))
U.S. Environmental Protection Agency Federal Insecticide, Fungicide, and Rodenticide Act
U.S. Environmental Protection Agency High Production Volume Chemicals
Food Research Journal
Hazardous Substance Database
International Uniform Chemical Information Database (IUCLID)
Japan GHS Classification
Australia National Industrial Chemicals Notification and Assessment Scheme (NICNAS)
NIOSH (National Institute for Occupational Safety and Health)
National Library of Medicine's ChemID Plus (NLM CIP)
National Library of Medicine's PubMed database (NLM PUBMED)
National Toxicology Program (NTP)
New Zealand's Chemical Classification and Information Database (CCID)
Organization for Economic Co-operation and Development Environment, Health, and Safety Publications
Organization for Economic Co-operation and Development High Production Volume Chemicals Program
Organization for Economic Co-operation and Development Screening Information Data Set
World Health Organization

Revision date 07-June-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
P1159	Polyoxyl 40 Stearate, Type II, 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

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

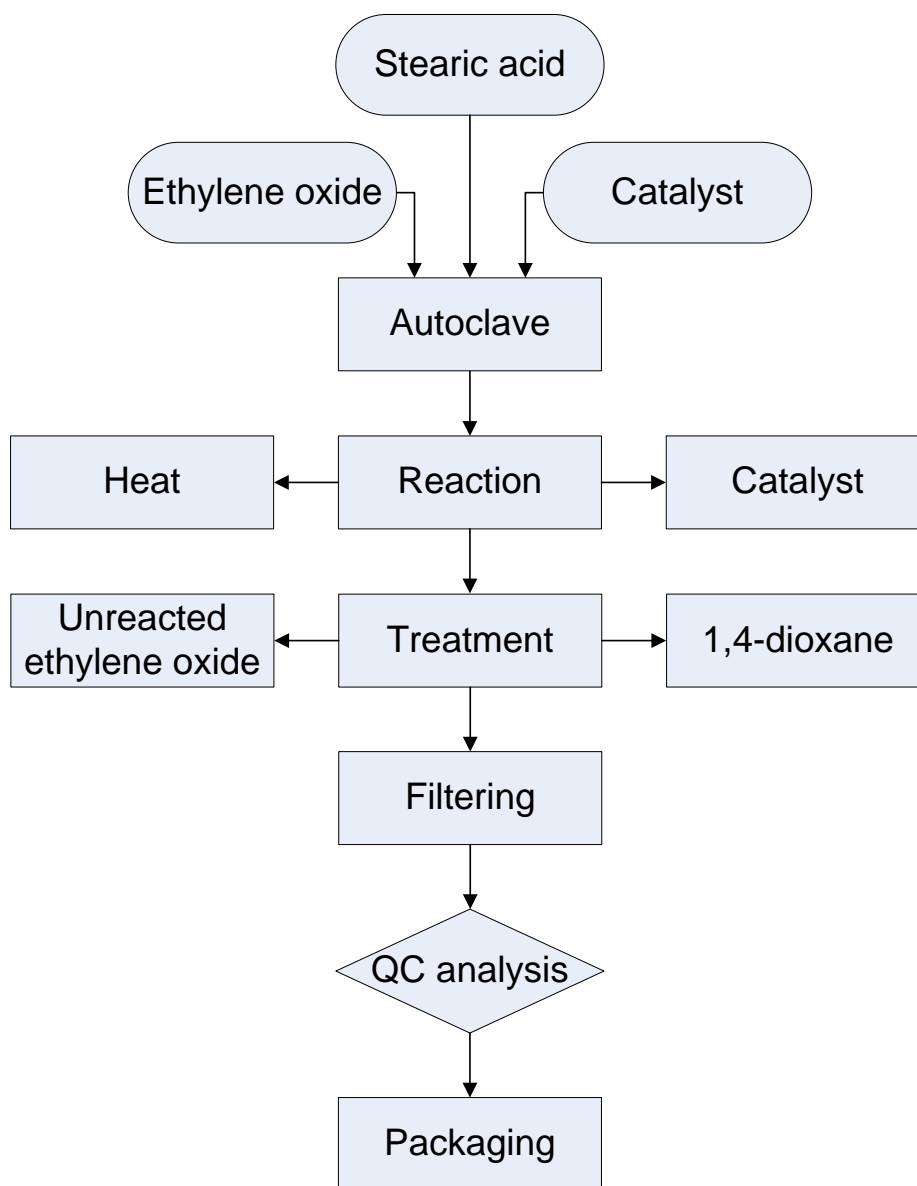
Sincerely,

A handwritten signature in black ink, appearing to read "Oralia Chavez", written in a cursive style.

Oralia Chavez
Quality Assurance Specialist

Manufacturing Process Flowchart

Polyoxyl 40 Stearate, Type II, NF - P1159



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

P1159, Polyoxyl 40 Stearate, Type II, NF

Source Statement

The above mentioned catalog item is manufactured from animal origin (bovine and/or porcine tallow) and synthetic origin (petrochemical). No plant derived products are used in the manufacturing process.

BSE/TSE Statement

The above mentioned catalog item is produced from tallow derived from cattle and swine in accordance with the FDA's Rule concerning *Use of Materials Derived from Cattle in Human Food and Cosmetics*, 21 CFR Parts 189 and 700. The above mentioned catalog item is processed under extremely high temperatures and with sterilizing agent, ethylene oxide, which should kill most life that may have survived intermediate processing. Therefore, P1159 is considered 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
- Cereals containing Gluten
- Celery
- Mustard
- Sesame Seed
- Soy
- 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 last animal testing performed on the above mentioned catalog item was in March 1969.

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
- Bisphenol A (BPA)
- CMR Substances
- Pesticides
- Phthalates
- Preservatives



RE: Elemental Impurities – Polyoxyl 40 Stearate, Type II, NF (Cat# P1159)

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.

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 - Polyoxyl 40 Stearate, Type II, NF (Cat# P1159)

To Whom It May Concern:

Thank you for your interest in Spectrum high quality chemicals.

The above mentioned catalog item complies with the requirements of USP <467> Residual Solvents and ICH Q3C Residual Solvents Guideline. The following solvents are likely to be present:

Residual Solvent	Class	Expected Concentration
1,4-Dioxane	2	< 380 ppm *

* 1,4-Dioxane is present below the limit of 10 ppm under the specification, *Limit of Ethylene Oxide and Dioxane*, as required by the USP monograph.

No Class 1, Class 3 or other solvents are used or produced in the manufacturing process of this material.

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.

Sincerely,

Technical Services
Spectrum Chemical Mfg. Corp.

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

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

P1159 **SIZ SY**
Polyoxyl 40 Stearate
 [Myrj® 52; Polyethylene Glycol (40) Monostearate]
 Type II
 NF
 CAS 9004-99-3

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

Animal origin.

A mixture of monoesters and diesters of mainly stearic (octadecanoic) acid and palmitic (hexadecanoic) acid and polyethylene glycols. Myrj® is a registered trademark of Croda, Inc.

Stearic Acid and Palmitic Acid	Min. 96.0%
Stearic Acid	90.0-99.0%
Free Polyethylene Glycols	17-27%
Alkalinity	To pass test
Hydroxyl Value	25-40
Saponification Value	25-35
Congealing Temperature	37°-47°C

MAXIMUM LIMITS

Elemental Impurities	As reported
Ethylene Oxide	1 ppm
Dioxane	380 ppm
Acid Value	6.0
Iodine Value	3.0
Peroxide Value	10.0
Articles of Botanical Origin (Total Ash)	0.3%
Water Determination	3.0%
Residual Solvents	To pass test

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

G 12/F8GHS

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Lot No. XQ####

Spectrum Chemical Mfg Corp

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 732.214.1300

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