



Scientific Documentation

PO138, Polysorbate 80, 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

Ver4.04 19.September.2018



Dear Customer,

Thank you for your interest in Spectrum's quality products and services.

Spectrum has been proudly serving the 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 blue ink, appearing to read "Michael Dang", with a long horizontal flourish extending to the right.

Michael Dang
Director, Quality Systems & GMP Compliance
mdang@spectrumchemical.com

PO138, Polysorbate 80, NF

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spectrum[®]
CHEMICAL MFG CORP



Specification for Polysorbate 80, NF (PO138)

Item Number	PO138
Item	Polysorbate 80, NF
CAS Number	9005-65-6
Molecular Formula	
Molecular Weight	
MDL Number	
Synonyms	Polyoxyethylene (20) Sorbitan Monooleate ; Tween 80

Test	Specification	
	Min	Max
COMPOSITION OF FATTY ACIDS	TO PASS TEST	
HYDROXYL VALUE	65	80
SAPONIFICATION VALUE	45	55
SPECIFIC GRAVITY @ 25°C	1.06	1.09
VISCOSITY @ 25°C	300	500 cSt
ACID VALUE		2.0
DIOXANE		10 ppm
ETHYLENE OXIDE		1 ppm
PEROXIDE VALUE		10
RESIDUE ON IGNITION		0.25 %
WATER DETERMINATION		3.0 %
ELEMENTAL IMPURITIES:		
CADMIUM (Cd)	AS REPORTED	
LEAD (Pb)	AS REPORTED	
ARSENIC (As)	AS REPORTED	
IDENTIFICATION A	TO PASS TEST	
IDENTIFICATION B	TO PASS TEST	
CERTIFIED KOSHER		
CERTIFIED HALAL		
EXPIRATION DATE		
DATE OF MANUFACTURE		
APPEARANCE		
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: 2/27/2014

Revision Date: 4/5/2018

Revision Number: G2

1. IDENTIFICATION

Product identifier

Product code: PO138
Product Name: POLYSORBATE 80, NF

Other means of identification

Synonyms: TWEEN 80
Polyoxyethylene 20 sorbitan monooleate
Polyethylene oxide sorbitan mono-oleate
Polyoxyethylene sorbitan monooleate
Polyoxyethylene sorbitan oleate
Sorbitan mono-9-octadecenoate poly(oxy-1,2-ethanediyl) derivatives
Sorethytan (20) monooleate

CAS #: 9005-65-6
RTECS # WG2932500
CI#: Not available

Recommended use of the chemical and restrictions on use

Recommended use: Emulsifying agent.
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 %
Polysorbate 80	9005-65-6	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

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. Water spray mist or foam.

Unsuitable Extinguishing Media: No information available.

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.

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.

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:

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:

Strong oxidizing agents

8. EXPOSURE CONTROLS/PERSONAL PROTECTION

Control parameters

National occupational exposure limits

United States

Components	CAS-No.	OSHA	NIOSH	ACGIH	AIHA WEEL
Polysorbate 80	9005-65-6	None	None	None	None

Canada

Product code: PO138

Product name: POLYSORBATE 80,
NF

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Components	CAS-No.	Canada - Alberta	Canada - British Columbia	Canada - Ontario	Canada - Quebec
Polysorbate 80	9005-65-6	None	None	None	None

Australia and Mexico

Components	CAS-No.	Australia	Mexico
Polysorbate 80	9005-65-6	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 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:
Oily.

Color:
Light yellow. Yellow. Amber.

Odor:
No information available.

Taste
No information available.

Formula:
No information available

Molecular/Formula weight:
No information available

Flammability:
No information available

Flash point (°C):
>149

Flashpoint (°C/°F):
>149 °C/>300 °F

Flash Point Tested according to:
Not available

Autoignition Temperature (°C/°F):
No information available

Lower Explosion Limit (%):
No information available

Upper Explosion Limit (%):
No information available

Melting point/range(°C/°F):
-20.56 °C/-5 °F

Decomposition temperature(°C/°F):
No information available

Boiling point/range(°C/°F):
>100 °C/>212 °F

Bulk density:
No information available

Density (g/cm3):

Product code: PO138

Product name: POLYSORBATE 80,
NF

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No information available

Specific gravity:
1.06-1.10

pH:
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:
Freely soluble in water
Soluble in Methanol
Soluble in hot alcohol
Soluble in Toluene
Soluble in ethyl acetate
Insoluble in mineral oil
Soluble in cotton seed oil and corn oil

10. STABILITY AND REACTIVITY

Reactivity

May react with strong oxidizers

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: Strong oxidizing agents

Hazardous decomposition products: Carbon oxides. When heated to decomposition it emits acrid smoke and irritating fumes.

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

Component Information

Polysorbate 80

CAS-No. 9005-65-6

LD50/oral/rat = 34500 µL/kg Oral LD50 Rat; >38000 mg/kg

LD50/oral/mouse = 25000 mg/kg

Product code: PO138

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LD50/dermal/rabbit = No information available
LD50/dermal/rat = No information available
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 = > 38000 mg/kg

LD50/oral/mouse =
Value - Acute Tox Oral = 25000 mg/kg

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

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.

Eye Contact: May cause eye irritation.

Inhalation May cause irritation of respiratory tract. However, no irritation is expected to be associated with the inhalation of this material. No toxic effects are known to be associated with the inhalation of this material.

Ingestion Health injuries are not known or expected under normal use. Not expected to be a health hazard. This material is not likely to cause irritation upon ingestion. It is classified as "relatively harmless" by ingestion and considered to be a low ingestion hazard. Ingestion of very large doses may cause abdominal spasms and diarrhea. Animal studies have shown it to cause cardiac changes, changes in behavior (altered sleep time) upon IV administration. However, no similar human data has been reported.

Aspiration hazard No information available.

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

Chronic Toxicity La ingestión prolongada o repetida puede causar hipermotilidad y diarrea. Prolonged or repeated ingestion may cause weight loss.

Sensitization: No information available.

Mutagenic Effects: May affect genetic material

Product code: PO138

Product name: POLYSORBATE 80,
NF

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Carcinogenic effects: Not considered carcinogenic. Equivocal tumorigenic agent by Registry of Toxic Effects of Chemical Substances (RTECS) criteria.

Components	CAS-No.	IARC	ACGIH - Carcinogens	NTP	OSHA HCS - Carcinogens	Australia - Notifiable Carcinogenic Substances	Australia - Prohibited Carcinogenic Substances
Polysorbate 80	9005-65-6	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: No data available.

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	CAS-No.	RCRA - F Series Wastes	RCRA - K Series Wastes	RCRA - P Series Wastes	RCRA - U Series Wastes
Polysorbate 80	9005-65-6	None	None	None	None

14. TRANSPORT INFORMATION

DOT

UN-No: No regulado
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

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: No information available
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.
Polysorbate 80	9005-65-6	PresentACTIVE	Present KE-25511	Present	Present (8)-55	Present	Present	Not present

U.S. Regulations

Polysorbate 80

FDA - Direct Food Additives 21 CFR 172.515, 21 CFR 172.840, 21 CFR 173.340

FDA - 21 CFR - Total Food Additives 172.515, 172.836, 172.838, 172.840, 172.842, 173.340, 175.105, 176.180, 178.3400, 573.860, 73.1, 73.1001

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:
Polysorbate 80	9005-65-6	Not Listed	Not Listed	Not Listed	Not Listed

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
Polysorbate 80	9005-65-6	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
Polysorbate 80	9005-65-6	Not Applicable	Not Applicable

Canada

WHMIS 2015 - GHS Classifications

WHMIS 2015 Hazard Classification Information: 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

WHMIS 1988 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	CAS-No.	Canada (DSL)	Canada (NDSL)
Polysorbate 80	9005-65-6	Present	Not Listed

Components	CAS-No.	CEPA Schedule I - Toxic Substances
Polysorbate 80	9005-65-6	Not listed
Components	CAS-No.	CEPA - 2010 Greenhouse Gases Subject to Mandatory Reporting
Polysorbate 80	9005-65-6	Not listed

EU Classification**EU GHS - SV - CLP 1272/2008**

Components	CAS-No.	EU GHS - SV - CLP (1272/2008)
Polysorbate 80	9005-65-6	

EU - CLP (1272/2008)**R-phrase(s)**

not determined (not applicable)

S -phrase(s)

none

Components	CAS-No.	Classification	Concentration Limits:	Safety Phrases
Polysorbate 80	9005-65-6		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: 2/27/2014
Revision Date: 4/5/2018
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



Manufacturer

Product Covered: PO138, Polysorbate 80, NF

Spectrum takes ownership as the manufacturer for the Spectrum product listed above and provides full quality assurance, customer service, and technical product support.

While information concerning the raw material manufacturer of our starting materials is considered proprietary, such information can be made available upon request contingent on demonstration of business volume justification and successful execution of confidential disclosure agreement (CDA).

Requests for disclosure of proprietary raw material manufacturer information may be submitted to the assigned account representative for consideration.

Sincerely,

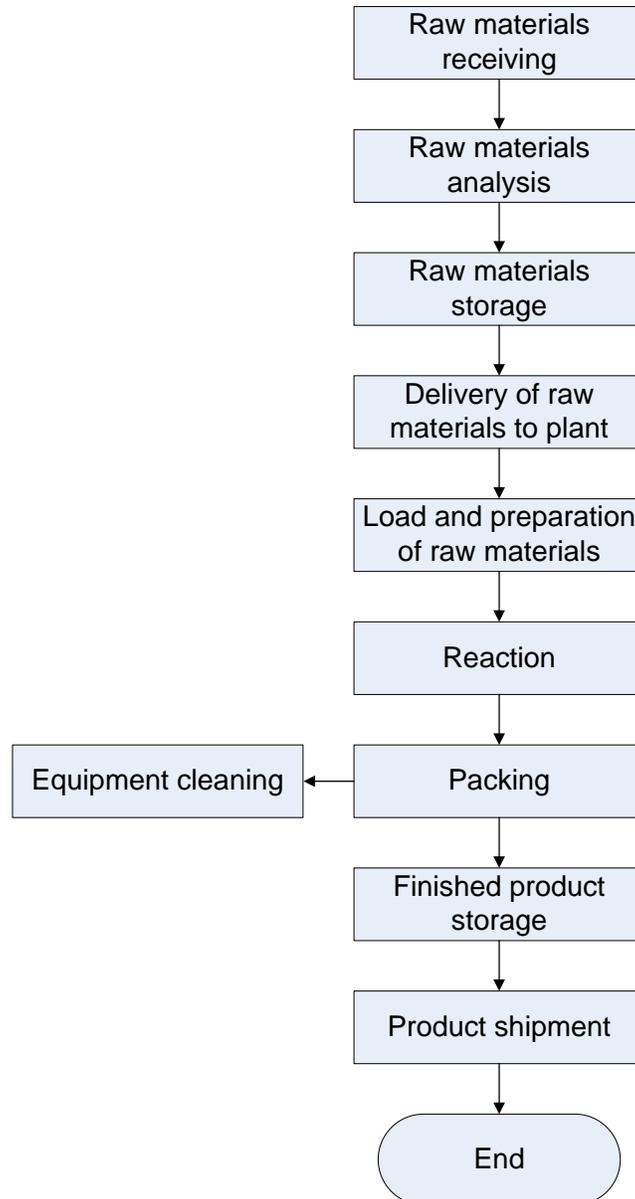
A handwritten signature in blue ink, appearing to read "Michael Dang", with a long horizontal flourish extending to the right.

Michael Dang
Director, Quality Systems & GMP
Compliance
mdang@spectrumchemical.com

19.September.2018

Manufacturing Process Flowchart

Polysorbate 80, NF - PO138



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

CERTIFICATE OF REGISTRATION

This is to certify that the quality management system of:

Spectrum Chemicals and Laboratory Products, Inc.

Main Site: 14422 South San Pedro Street, Gardena, California, 90248,
USA,

Additional sites: 13915 South Main Street, Los Angeles, California,
90061, USA

769 Jersey Avenue, New Brunswick, New Jersey, 08901, USA

755 Jersey Avenue, New Brunswick, New Jersey, 08901, USA

777 Jersey Avenue, New Brunswick, New Jersey, 08901, USA

400 N. Oracle, Suite 221, Tucson, Arizona, 85704, USA, USA

has been assessed and registered by Intertek as conforming to the
requirements of:

ISO 9001:2015

The quality management system is applicable to:

Main Site: The manufacture and distribution of specialty fine
chemicals, solutions, equipment, supplies and products for the
laboratory, pharmaceutical, food, healthcare, cosmetic, fragrance,
biotechnology, environmental and process industries.

Certificate Number:

94-316m-03

Initial Certification Date:

27 December 1994

Certificate Issue Date:

31 July 2017

Certificate Expiry Date:

28 January 2019



A handwritten signature in black ink, appearing to read 'Calin Moldovean', written over a horizontal line.

Authorized Signature

Calin Moldovean

President Business Assurance

Intertek Testing Services NA, Inc. dba Intertek
900 Chelmsford Street, Lowell, MA, USA



APPENDIX TO CERTIFICATE OF REGISTRATION

This appendix identifies the locations by the management system of

Spectrum Chemicals and Laboratory Products, Inc.

755 and 769 Jersey Avenue: The manufacture and distribution of specialty fine chemicals, solutions, equipment, supplies and products for the laboratory, pharmaceutical, food, healthcare, cosmetic, fragrance, biotechnology, environmental and process industries.

777 Jersey Avenue: The manufacture and distribution of specialty fine chemicals, solutions, equipment, supplies and products for Compounding Pharmacies.

7400 N. Oracle: The manufacture and distribution of specialty fine chemicals, solutions, equipment, supplies and products for the laboratory, pharmaceutical, food, healthcare, cosmetic, fragrance, biotechnology, environmental and process industries.



管理体系认证 注册证书

兹证明，以下组织：

斯百全化学（上海） 有限公司

上海市松江区申港路3802弄A20

的管理体系，符合以下标准要求并予以注册：

ISO 9001:2015

此管理体系适用于：

药用辅料销售，化学品销售

统一社会信用代码：

91310000777627048K

证书编号：

111310001

首次认证日期：

2015年11月17日

认证决定日期：

2017年12月26日

签发日期：

2017年12月26日

有效期至：

2018年11月10日



014

Calin Moldovean

President, Business Assurance

Intertek Certification Limited, 10A Victory
Park, Victory Road, Derby DE24 8ZF, United
Kingdom

Intertek Certification Limited
是 UKAS 认可的认证机构，
注册号为 014



CERTIFICATE OF REGISTRATION

This is to certify that the management system of:

Spectrum China Ltd.

Building A20, No. 3802, Shengang Road, Songjiang District, Shanghai, China

has been registered by Intertek as conforming to the requirements of:

ISO 9001:2015

The management system is applicable to:

Sales for Pharmaceutical Excipients, Sales for Chemicals

Unified Social Credit Identifier:

91310000777627048K

Certificate Number:

111310001

Initial Certification Date:

17 November 2015

Date of Certification Decision:

26 December 2017

Issuing Date:

26 December 2017

Valid Until:

10 November 2018



014

A handwritten signature in black ink, appearing to read 'Calin Moldovean'.

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.



July 13, 2017

Certification of Compliance with current Good Manufacturing Practices

Dear Valued Customer:

Spectrum Chemical Mfg Corp certifies 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 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,



Oralia Chavez
Quality Assurance Specialist

September 19, 2018

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
PO138	Polysorbate 80, 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: 03006174778

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,



Oralia Chavez
Quality Assurance Specialist



April 8, 2016

RE: Polysorbate 80, NF – PO138

To Whom It May Concern:

Thank you for your interest in Spectrum high quality chemicals.

Spectrum Chemical Mfg. Corp. shares your concern regarding Bovine Spongiform Encephalopathy (BSE). This will certify that the following chemical is BSE/TSE free.

Polysorbate 80, NF – PO138

If you have any further questions, please contact us by telephone at 1-800-772-8786 or 1-310-516-8000 extension 5741, or by email at techservices@spectrumchemical.com.

Sincerely,

Rose Briceño
Technical Services
Spectrum Chemical Mfg Corp.

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



April 8, 2016

RE: Polysorbate 80, NF – PO138

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 the presence of allergens in raw materials. Please be assured that the following chemical does not contain (Milk, Egg, Fish, Shellfish, Tree nuts, Wheat, Peanuts, Soy, Cereals containing Gluten, Celery, Mustard, Sesame Seed).

Polysorbate 80, NF – PO138

If you have any further questions, please contact us by telephone at 1-800-772-8786 or 1-310-516-8000 extension 5471, or by email at techservices@spectrumchemical.com.

Sincerely,

Rose Briceño
Technical Services
Spectrum Chemical Mfg Corp.

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



April 14, 2016

RE: Polysorbate 80, NF – PO138

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 the presence of aflatoxins in raw materials. Please be assured that the product does not contain nor is it manufactured using aflatoxins.

Polysorbate 80, NF – PO138

If you have any further questions, please contact us by telephone at 1-800-772-8786 or 1-310-516-8000 extension 5471, or by email at techservices@spectrumchemical.com.

Sincerely,

Rose Briceño
Technical Services
Spectrum Chemical Mfg Corp.

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

Item Number	PO138	Lot Number	1HH0992
Item	Polysorbate 80, NF		
CAS Number	9005-65-6		
Molecular Formula		Molecular Weight	

Test	Specification		Result
	min	max	
COMPOSITION OF FATTY ACIDS	TO PASS TEST		PASSES TEST
HYDROXYL VALUE	65	80	71.4
SAPONIFICATION VALUE	45	55	47.2
SPECIFIC GRAVITY @ 25°C	1.06	1.09	1.075
VISCOSITY @ 25°C	300	500 cSt	411.1 cSt
ACID VALUE		2.0	1.0
DIOXANE		10 ppm	0 ppm
ETHYLENE OXIDE		1 ppm	0 ppm
PEROXIDE VALUE		10	3.5
RESIDUE ON IGNITION		0.25 %	0.059 %
WATER DETERMINATION		3.0 %	2.7 %
ELEMENTAL IMPURITIES:			
CADMIUM (Cd)	AS REPORTED		<0.05 µg/g
LEAD (Pb)	AS REPORTED		<1 µg/g
ARSENIC (As)	AS REPORTED		<1 µg/g
IDENTIFICATION A	TO PASS TEST		PASSES TEST
IDENTIFICATION B	TO PASS TEST		PASSES TEST
CERTIFIED KOSHER			CERTIFIED KOSHER
CERTIFIED HALAL			CERTIFIED HALAL
EXPIRATION DATE			29-MAY-2020
DATE OF MANUFACTURE			30-MAY-2018
APPEARANCE			CLEAR YELLOW LIQUID
RESIDUAL SOLVENTS	TO PASS TEST		PASSES TEST

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.

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.

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[®]

P0138 **4 L**

Polysorbate 80
[Polyoxyethylene (20) Sorbitan Monooleate; Tween™ 80]

N.F.

CAS 9005-65-6

CAUTION: For manufacturing, processing or repacking.
Read and understand the label and the Safety Data Sheet (SDS) prior to use.

KEEP FROM CHILDREN

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.

Keep tightly closed, protect from light.

Lot No. 062233

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.

Retest Date: 03-31-2025

Composition of Fatty Acids To Pass Test
Hydroxyl Value 65-80
Saponification Value 45-55
Specific Gravity @ 25°C 1.06-1.09
Viscosity @ 25°C 300-500 cSt

MAXIMUM LIMITS
Acid Value 2.0
Dioxane 10 ppm
Ethylene Oxide 1 ppm
Heavy Metals 10 ppm
Peroxide Value 10
Residue on Ignition 0.25%
Water 3.0%
Residual Solvents To pass test

G 18/F1GHs A L

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

- A** Bar Code
- B** Warning, Safety Data and Precautionary Information
- C** Product Catalog Number
- D** Item Name, Form, Grade
- E** Size/Quantity
- F** Chemical Abstracts Service (CAS) Registry Number
- G** Caution Information
- H** Toll-Free 24-Hour Chemical Emergency Telephone Number
- I** Expiration Information
- J** Lot Number
- K** Kosher Certified by Kosher Supervision of America (KSA).
- L** 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

June 15, 2018

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: Z10928 = 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
Director, Quality Systems & GMP Compliance
mdang@spectrumchemical.com



Stability – Shelf Life Guidance

Product Covered: PO138, Polysorbate 80, NF

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

The product, PO138, Polysorbate 80, NF, is assigned a 24 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", is positioned above the printed name and title.

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



KOSHER SUPERVISION OF AMERICA

בס"ד
Feb 23, 2018

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 PO138, Polysorbate 80, NF

Brand Spectrum

UKD-ID KSAV3-G4X2Q7

D/P/M P

Symbol Required KSA

Special Conditions

This certificate expires on
Feb 01, 2019

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: August 16, 2018

Document #: 11205.11206.II181428

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

Plant Name & Address:

ProductName	Product Code	Halal-ID	Product Certificate #
1. Polysorbate 80, NF	PO138	C13713	HC-18SPEY74

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



This Certificate is valid until **August 31, 2019** and subject to renewal at that time.



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