

Scientific Documentation

Palmitic Acid, FCC

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 Palmitic Acid, FCC (P1513)

Item Number	P1513
Item	Palmitic Acid, FCC
CAS Number	57-10-3
Molecular Formula	C ₁₆ H ₃₂ O ₂
Molecular Weight	256.42
MDL Number	
Synonyms	Hexadecanoic Acid

Test	Specification	
	Min	Max
ACID VALUE	204	220
SAPONIFICATION VALUE	205	221
TITER (SOLIDIFICATION POINT)	53.3° - 62°C	
IODINE VALUE		2.0
LEAD (Pb)		0.1 mg/kg
RESIDUE ON IGNITION		0.1 %
UNSAAPONIFIABLE MATTER		1.5 %
WATER		0.2 %
IDENTIFICATION	TO PASS TEST	
APPEARANCE		
EXPIRATION 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	P1513	Lot Number	2NB0190
Item	Palmitic Acid, FCC	CAS Number	57-10-3
Molecular Formula	C ₁₆ H ₃₂ O ₂	Molecular Weight	256.42

TEST	SPECIFICATION		RESULT
	MIN	MAX	
ACID VALUE	204	220	207.0 ml
SAPONIFICATION VALUE	205	221	212.0
TITER (SOLIDIFICATION POINT)	53.3° - 62°C		61.0 °C
IODINE VALUE		2.0	< 0.1
LEAD (Pb)		0.1 mg/kg	< 0.1 mg/kg
RESIDUE ON IGNITION		0.1 %	0.1 %
UNSAPONIFIABLE MATTER		1.5 %	0.1 %
WATER		0.2 %	< 0.1 %
IDENTIFICATION	TO PASS TEST		PASSES TEST
APPEARANCE			WHITE CRYSTALLINE FLAKES
EXPIRATION DATE			01-JUN-2027
DATE OF MANUFACTURE			08-SEP-2022
MONOGRAPH EDITION			FCC 13

Certificate of Analysis Results Entered By:

CMARIN
Catherine Marin
07-MAR-24 07:04:54

Spectrum Chemical Mfg Corp
755 Jersey Avenue
New Brunswick 08901 NJ



Certificate of Analysis Results Approved By:

GHERRERA
Genaro Herrera
19-MAR-24 08:05:22

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

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

SAFETY DATA SHEET

Preparation Date: 03/19/2015

Revision Date: 06/15/2018

Revision Number: G2

1. IDENTIFICATION

Product identifier

Product code: P1513
Product Name: PALMITIC ACID, FCC

Other means of identification

Synonyms: Hexadecanoic acid; Cetylic acid; 1-Pentadecanecarboxylic acid; Emersol; Hexadecylic acid; Hydrofol; Hystrene; n-Hexadecoic acid
CAS #: 57-10-3
RTECS # RT4550000
CI#: Not available

Recommended use of the chemical and restrictions on use

Recommended use: No information available.
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 %
Palmitic Acid	57-10-3	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. Consult a physician if necessary.
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	Health injuries are not known or expected under normal use
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Indication of any immediate medical attention and special treatment needed

Notes to Physician:	Treat symptomatically.
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Protection of first-aiders

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

5. FIRE-FIGHTING MEASURES

Extinguishing Media

Suitable Extinguishing Media:	Carbon dioxide (CO ₂). Dry chemical. Water spray mist or foam.
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Unsuitable Extinguishing Media:	No information available.
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Specific hazards arising from the chemical

Hazardous Combustion Products:	Carbon Monoxide, Carbon Dioxide.
Specific hazards:	May be combustible at high temperatures.

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. Cover with plastic sheet to prevent spreading.

Methods for cleaning up Sweep up and shovel into suitable containers for disposal. 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. Keep away from heat and sources of ignition. Do not ingest. Do not breathe dust. 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:

Oxidizing agents
Reducing agents
Bases

8. EXPOSURE CONTROLS/PERSONAL PROTECTION

Control parameters

National occupational exposure limits

United States

Components	CAS-No.	OSHA	NIOSH	ACGIH	AIHA WEEL
Palmitic Acid	57-10-3	None	None	None	None

Canada

Components	CAS-No.	Canada - Alberta	Canada - British Columbia	Canada - Ontario	Canada - Quebec
Palmitic Acid	57-10-3	None	None	None	None

Australia and Mexico

Components	CAS-No.	Australia	Mexico
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Palmitic Acid	57-10-3	None	None
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Appropriate engineering controls

Engineering measures to reduce exposure:

Ensure adequate ventilation. Use process enclosures, local exhaust ventilation, or other engineering controls to keep airborne levels below recommended exposure limits. If user operations generate dust, fume or mist, use ventilation to keep exposure to airborne contaminants below the exposure limit.

Individual protection measures, such as personal protective equipment

Personal Protective Equipment

Eye protection:	Safety glasses with side-shields
Skin and body protection:	Chemical resistant apron Gloves Long sleeved clothing
Respiratory protection:	Effective dust mask. Use a dust respirator under conditions where exposure to the substance is apparent (e.g. generation of high concentration of dust (dust clouds) , 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: Solid	Appearance: Crystalline. Crystals.	Color: White.
Odor: No information available.	Taste No information available.	Formula: C16H32O2
Molecular/Formula weight: 256.42	Flammability: No information available	Flashpoint (°C/°F): No information available.
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): 61°-64°C/141.8°-147.2°F	Decomposition temperature(°C/°F): No information available
Boiling point/range(°C/°F): 350°C/662°F	Bulk density: No information available	Density (g/cm3): No information available
Specific gravity: 0.853	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):	

Viscosity:

No information available

Miscibility:

No information available

Solubility:

Freely soluble in Chloroform
 Freely soluble in hot alcohol
 Freely soluble in propyl alcohol
 Practically insoluble in cold water
 Soluble in Acetone
 Soluble in aromatic and oxygenated solvents
 Soluble in diethyl ether
 Soluble in Ethanol

10. STABILITY AND REACTIVITY

Reactivity

Reactive with alkalis
 Reactive with oxidizing agents
 Reacts with reducing agents

Chemical stability**Stability:**

Stable under recommended storage conditions.

Possibility of Hazardous Reactions: Hazardous polymerization does not occur**Conditions to avoid:**

Heat. Avoid dust formation. Incompatible materials.

Incompatible Materials:

Oxidizing agents
 Reducing agents
 Bases

Hazardous decomposition products:

Carbon oxides.

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:**

Ingestion. Inhalation.

Acute Toxicity**Component Information**

Palmitic Acid

CAS-No. 57-10-3

LD50/oral/rat = > 10 g/kg Oral LD50 Rat**LD50/oral/mouse** = No information available**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 LC50information = No information available

Product Information

LD50/oral/rat =
VALUE- Acute Tox Oral = > 10000 mg/kg

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

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.
Ingestion Health injuries are not known or expected under normal use.
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	CAS-No.	IARC	ACGIH - Carcinogens	NTP	OSHA HCS - Carcinogens	Australia - Notifiable Carcinogenic Substances	Australia - Prohibited Carcinogenic Substances
Palmitic Acid	57-10-3	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)

Reproductive toxicity No data is available

Reproductive Effects: No information available

Developmental Effects: No information available

Teratogenic Effects: No information available

Specific Target Organ Toxicity

STOT - single exposure No information available.

STOT - repeated exposure No information available.

Target Organs: No information available.

12. ECOLOGICAL INFORMATION

Ecotoxicity

Ecotoxicity effects: Aquatic environment.

Palmitic Acid - 57-10-3

Freshwater Fish Species Data: 150 mg/L LC50 Oryzias latipes 96 h 1

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
Palmitic Acid	57-10-3	None	None	None	None

14. TRANSPORT INFORMATION

DOT

UN-No: Not Regulated

Proper Shipping Name: No information available

Hazard Class: No information available

Subsidiary Class No information available

Packing group: No information available

Emergency Response Guide No information available

Number

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.
Palmitic Acid	57-10-3	PresentACTIVE	PresentKE-18438	Present	Present(2)-608	Present	Present	Present200-312-9

U.S. Regulations

Product code: P1513

Product name: PALMITIC ACID, FCC

Palmitic Acid

FDA - Direct Food Additives 21 CFR 172.860
FDA - 21 CFR - Total Food Additives 172.210, 172.860, 173.340

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:
Palmitic Acid	57-10-3	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
Palmitic Acid	57-10-3	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
Palmitic Acid	57-10-3	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)
Palmitic Acid	57-10-3	Present	Not Listed

Components	CAS-No.	CEPA Schedule I - Toxic Substances
Palmitic Acid	57-10-3	Not listed
Components	CAS-No.	CEPA - 2010 Greenhouse Gases Subject to Mandatory Reporting
Palmitic Acid	57-10-3	Not listed

EU Classification

EU GHS - SV - CLP 1272/2008

Components	CAS-No.	EU GHS - SV - CLP (1272/2008)
Palmitic Acid	57-10-3	

EU - CLP (1272/2008)

R-phrases(s)

not determined (not applicable)

S -phrase(s)

none

Components	CAS-No.	Classification	Concentration Limits:	Safety Phrases
Palmitic Acid	57-10-3		No information	

The product is classified in accordance with Annex VI to Directive 67/548/EEC**Indication of danger:**

None.

16. OTHER INFORMATION

Preparation Date: 03/19/2015
Revision Date: 06/15/2018
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



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
P1513	Palmitic Acid, FCC

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

P1513, Palmitic Acid, FCC

Source Statement

The above mentioned catalog item is manufactured by plant derived material (Palm). 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

EU Fragrance Allergen Statement

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

GMO Statement

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

Melamine Statement

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

Nitrosamine Statement

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

Animal Testing Statement

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

Organic Compliance Statement

The above mentioned catalog item has not been produced using GMOs, irradiation, ethylene oxide (EtO) or sewage sludge.

Shelf Life Statement

The above mentioned catalog item is typically assigned a shelf life of 60 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.

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

P1513 SIZ SY Palmitic Acid

F.C.C.

CAS 57-10-3

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

$C_{16}H_{32}O_2$

F.W. 256.42

Acid Value204-220
Saponification Value205-221
Titer (Solidification Point) 53.3°-62°C

MAXIMUM LIMITS

Iodine Value2.0
Lead0.1 mg/kg
Residue on Ignition0.1%
Unsaponifiable Matter1.5%
Water0.2%

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

G 3/G7GHS

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Lot No. XQ####

Spectrum Chemical Mfg Corp

Corporate Headquarters:

769 Jersey Ave.
New Brunswick, NJ 08901
732.214.1300

West Coast Facility:

14422 S. San Pedro St.
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