

Scientific Documentation

Vitamin A Palmitate, 1.70 MIU/g, USP

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 Vitamin A Palmitate, 1.70 MIU/g, USP (V1159)

| Item Number | V1159 |
|-------------------|---------------------------------------|
| Item | Vitamin A Palmitate, 1.70 MIU/g, USP |
| CAS Number | 79-81-2 |
| Molecular Formula | $C_{36}H_{60}O_2$ |
| Molecular Weight | 524.87 |
| MDL Number | |
| Synonyms | Retinol Palmitate ; Retinyl Palmitate |

| Test | Specification | | |
|-----------------------|------------------------------|------|--|
| | Min | Max | |
| ASSAY | 1.62 MIU/g | | |
| ABSORBANCE RATIO: | | | |
| A300/A326 | | 0.60 | |
| A350/A326 | | 0.54 | |
| A370/A326 | | 0.14 | |
| ELEMENTAL IMPURITIES: | AS REPORTED | | |
| IDENTIFICATION (A) | BLUE COLOR APPEARS | | |
| IDENTIFICATION (B) | Rf VALUE MATCHES STANDARD | | |
| APPEARANCE | | | |
| EXPIRATION DATE | | | |
| DATE OF MANUFACTURE | | | |
| RESIDUAL SOLVENTS | AS REPORTED | | |

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 | V1159 | Lot Number | 2LJ0005 |
|-------------------|--------------------------------------|------------------|---------|
| Item | Vitamin A Palmitate, 1.70 MIU/g, USP | CAS Number | 79-81-2 |
| Molecular Formula | $C_{36}H_{60}O_2$ | Molecular Weight | 524.87 |

| TECT | SPECIF | ICATION | DECLUT |
|---|---------------------------------|---------|---------------------------|
| TEST | MIN | MAX | RESULT |
| ASSAY | 1.62 MIU/g | | 1.82 MIU/g |
| ABSORBANCE RATIO: | | | |
| A300/A326 | | 0.60 | 0.58 |
| A350/A326 | | 0.54 | 0.53 |
| A370/A326 | | 0.14 | 0.13 |
| ELEMENTAL IMPURITIES: | AS REPORTED | | COMPLIES WITH STANDARD |
| IDENTIFICATION (A) | BLUE COLOR APPEARS | | BLUE COLOR APPEARS |
| IDENTIFICATION (B) | Rf VALUE MATCHES STANDARD | | Rf VALUE MATCHES STANDARD |
| APPEARANCE | | | LIQUID LIGHT YELLOW |
| EXPIRATION DATE | | | 28-JAN-2025 |
| DATE OF MANUFACTURE | | | 29-JAN-2022 |
| RESIDUAL SOLVENTS | AS REPORTED | | |
| CLASS 2 (solvent) / HEXANE | | | <290 ppm |
| CLASS 2 (SOLVENT) / METHANOL | | | <3000 ppm |
| CLASS 2 (solvent) / METHYLENE CHLORIDE | | | <600 ppm |
| CLASS 2 (solvent) / PYRIDINE | | | <200 ppm |

Certificate of Analysis Results Entered By:

SVANGOOR Swetha Vangoor 10-OCT-22 05:55:14

Spectrum Chemical Mfg Corp 755 Jersey Avenue New Brunswick 08901 NJ



Certificate of Analysis Results Approved By:

AWILLIAMS Allison Williams 10-OCT-22 14:22:07

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 21-November-2022 Revision Number 2

1. Identification

Product identifier

Product Name VITAMIN A PALMITATE, USP

Other means of identification

Product Code(s) V1159

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

Reproductive toxicity Category 1A

Hazards not otherwise classified (HNOC)

Not applicable

Label elements

Danger

Hazard statements

May damage fertility or the unborn child



Appearance viscous clear or Hazy Liquid

Physical state Semi-solid

Odor No information available

or Low melting point solid

Precautionary Statements - Prevention

Obtain special instructions before use

Do not handle until all safety precautions have been read and understood Wear protective gloves/protective clothing/eye protection/face protection

Precautionary Statements - Response

IF exposed or concerned: Get medical advice/attention

Precautionary Statements - Storage

Store locked up.

Precautionary Statements - Disposal

Dispose of contents/container to an approved waste disposal plant

Other information

No information available.

3. Composition/information on ingredients

Substance

| Chemical name | CAS No | Weight-% |
|---------------------|---------|----------|
| Vitamin A Palmitate | 79-81-2 | 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 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.

Indication of any immediate medical attention and special treatment needed

5. Fire-fighting measures

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.

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. Avoid contact with

skin, eyes or clothing. Do not eat, drink or smoke when using this product. Remove

contaminated clothing and shoes.

Conditions for safe storage, including any incompatibilities

Storage Conditions Store locked up.

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.

Hand protection Wear suitable gloves.

Skin and body protectionWear suitable protective clothing.

exceeded or irritation is experienced, ventilation and evacuation may be required.

None known

General hygiene considerations Do not eat, drink or smoke when using this product. Wash hands before breaks and

immediately after handling the product.

9. Physical and chemical properties

Information on basic physical and chemical properties

Physical state Semi-solid

Appearance viscous clear or Hazy Liquid or Low melting point solid

Color Yellow to Orange
Odor No information available
Odor threshold No information available

<u>Property</u> <u>Values</u> <u>Remarks • Method</u>

no data available рΗ None known **Melting point / freezing point** 26 °C / 78.8 °F None known Boiling point / boiling range no data available None known Flash point no data available 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 No data available

limits

Lower flammability or explosive No data available

limits

Vapor pressureNo data availableNone knownVapor densityno data availableNone knownRelative density0.92None knownWater solubilityInsoluble in waterNone known

Solubility(ies) Soluble in Ether
Slightly soluble in alcohol

Partition coefficientNo data availableNone knownAutoignition temperatureno data availableNone knownDecomposition temperature100 - °C 212 °FNone knownKinematic viscosityno data availableNone knownDynamic viscosityNo data availableNone known

Other information

Explosive properties

Oxidizing properties

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 materialsNone 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.

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 |
|---------------------|--------------------|-------------|-----------------|
| Vitamin A Palmitate | = 7910 mg/kg (Rat) | - | - |
| 79-81-2 | | | |

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

Skin corrosion/irritation
Serious eye damage/eye irritation
Respiratory or skin sensitization
Germ cell mutagenicity

No information available.
No information available.
No information available.

Reproductive toxicity Contains a known or suspected reproductive toxin. Classification based on data available

for ingredients. May damage fertility or the unborn child.

STOT - single exposure
STOT - repeated exposure
Aspiration hazard

No information available.
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

Bioaccumulation

No information available. 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

DOT not regulated

TDG not regulated

MEX not regulated

ICAO (air) not regulated

<u>IATA</u> not regulated

IMDG not regulated

RID not regulated

ADR not regulated

ADN not regulated

15. Regulatory information

International Inventories

TSCA Complies

DSL/NDSL Complies EINECS/ELINCS Complies

ENCS IECSCThis product complies with ENCS:
This product complies with China:

KECL Does not Comply

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

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

Retinyl ester, in excess of 10,000 IU or 3,000 retinol equivalents.

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 0

Instability 0

Physical and chemical properties -

HMIS

Health hazards * 1 Flammability 0 Physical hazards 0

Personal protection X Chronic Hazard Star Legend

* = Chronic Health Hazard

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

Legend Section 8: EXPOSURE CONTROLS/PERSONAL PROTECTIONTWA TWA (time-weighted average) STEL

TWA TWA (time-weighted Ceiling Maximum limit value

STEL (Short Term Exposure Limit)

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 21-November-2022 Revision Note 21-November-2022 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 |
|----------------|--------------------------------------|
| V1159 | Vitamin A Palmitate, 1.70 MIU/g, USP |

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,

Oralia Chavez

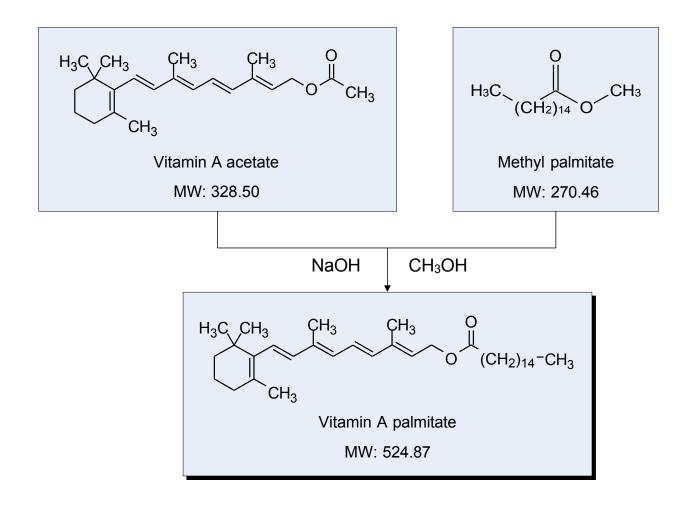
Quality Assurance Specialist

Order Clony



Manufacturing Process Flowchart

Vitamin A Palmitate, 1.70 MIU/g, USP - V1159



Spectrum Chemical Mfg Corp



V1159, Vitamin A Palmitate, 1.70 MIU/g, USP

Source Statement

The above mentioned catalog item is manufactured by chemical synthesis. No animal or plant 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.

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 36 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
- Pesticides

- Phthalates
- Preservatives



RE: Elemental Impurities - Vitamin A Palmitate, 1.70 MIU/g, USP (Cat# V1159)

To Whom It May Concern:

Thank you for your interest in Spectrum high quality chemicals.

The above material complies with the USP<232>, <233> Elemental Impurities and the ICH Q3D Elemental Impurities Guideline. The following elemental impurities are likely to be present:

| Elemental Impurity | | Class | Expected Concentration |
|--------------------|----|-------|------------------------|
| Thallium | TI | 2B | Not tested |
| Gold | Au | 2B | Not tested |
| Osmium | Os | 2B | Not tested |
| Silver | Ag | 2B | Not tested |
| Lithium | Li | 3 | Not tested |
| Barium | Ва | 3 | Not tested |
| Tin | Sn | 3 | Not tested |

Elements indicated as "Not tested" are not intentionally added to the manufacturing process.

Other elemental impurities considered by USP <232>, <233> and ICH Q3D which are not addressed in the above mentioned table are not 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.

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



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 - Vitamin A Palmitate, 1.70 MIU/g, USP (Cat# V1159)

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 |
|--------------------|-------|------------------------|
| Hexane | 2 | < 290 ppm |
| Methanol | 2 | < 3000 ppm |
| Methylene Chloride | 2 | < 600 ppm |
| Pyridine2 | 2 | < 200 ppm |

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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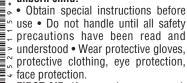
Label Information

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.



DANGER

May damage fertility or the unborn child.



FIRST AID: If exposed or concerned: Get medical attention.

KEEP FROM CHILDREN

V1159 SIZ SY Vitamin A Palmitate

1.70 MIU/g USP

CAS 79-81-2

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

REFRIGERATE

 $C_{36}H_{60}O_{2}$

F.W. 524.87

Note: 1 MIU/g = 550 mg/g of Vitamin A Palmitate. Prior to use, heat unopened container in warm water bath (45°-50°C) until completely dissolved, shaking vigorously from time to time.

| Assay | Min. 1.62 MIU/g |
|----------------------|-----------------|
| MAXIMUM | LIMITS |
| Absorbance Ratio: | |
| A300/A326 | 0.60 |
| A350/A326 | |
| A370/A326 | |
| Elemental Impurities | As reported |
| Residual Solvents | To pass test |

 $\label{light-sensitive} LIGHT\,SENSITIVE, AIR\,SENSITIVE: Keep tightly closed in light-resistant containers under inert gas.$

FLUSHED WITH NITROGEN

WARNING: Reproductive Harmwww.P65Warnings.ca.gov

G 12/J5GHS

Lot No. XQ####

Spectrum Chemical Mfg Corp

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