

# **Scientific Documentation**

## Isopropyl Myristate, 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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Product Specification Certificate of Analysis Safety Data Sheet (SDS) Certification of Current Good Manufacturing Practices (cGMP) Manufacturing Process Flowchart Technical Statements Elemental Impurities Statement Residual Solvents Statement General Label Information – Sample Label



## **Specification for Isopropyl Myristate, NF (IS145)**

Item Number	IS145
Item	Isopropyl Myristate, NF
CAS Number	110-27-0
Molecular Formula	C <sub>17</sub> H <sub>34</sub> O <sub>2</sub>
Molecular Weight	270.45
MDL Number	
Synonyms	Tetradecanoic Acid 1-Methylethyl Ester ; Tetradecanoic Acid 1-Methylethyl Ester ; Myristic Acid Isopropyl Ester ; Isopropyl Tetradecanoate

Test	Specific	ation
	Min	Max
ASSAY (C <sub>17</sub> H <sub>34</sub> O <sub>2</sub> )	90.0 %	
SPECIFIC GRAVITY @ 25º/25ºC	0.846	0.854
REFRACTIVE INDEX @ 20°C	1.432	1.436
SAPONIFICATION VALUE	202	212
ACID VALUE		1
IODINE VALUE		1
RESIDUE ON IGNITION		0.1 %
ELEMENTAL IMPURITIES:	AS REPORTED	
IDENTIFICATION		TO PASS TEST
CERTIFIED HALAL		
APPEARANCE		
RETEST DATE		
DATE OF MANUFACTURE		
RESIDUAL SOLVENTS	AS REPORTED	
MONOGRAPH EDITION		

#### Spectrum Chemical Mfg Corp

Corporate Headquarters:	West Coast Facility:
769 Jersey Ave.	14422 S. San Pedro St.
New Brunswick, NJ 08901	Gardena, CA 90248

#### Spectrum Chemical Mfg Corp

 Corporate Headquarters:
 West Coast Facility:

 732.214.1300
 310.516.8000



### **Certificate Of Analysis**

Item Number	IS145	Lot Number	1NB0285
Item	Isopropyl Myristate, NF	CAS Number	110-27-0
Molecular Formula	C <sub>17</sub> H <sub>34</sub> O <sub>2</sub>	Molecular Weight	270.45

тгст	SPECIFICATION		DECLUIT
TEST	MIN	MAX	RESULT
ASSAY (C <sub>17</sub> H <sub>34</sub> O <sub>2</sub> )	90.0 %		98.5 %
SPECIFIC GRAVITY @ 25º/25ºC	0.846	0.854	0.852
REFRACTIVE INDEX @ 20 <sup>0</sup> C	1.432	1.436	1.435
SAPONIFICATION VALUE	202	212	208
ACID VALUE		1	0.01
IODINE VALUE		1	0.1
RESIDUE ON IGNITION		0.1 %	<0.0 %
ELEMENTAL IMPURITIES:	AS REPORTED		NO ELEMENTAL IMPURITIES PRESENT
IDENTIFICATION		TO PASS TEST	PASSES TEST
CERTIFIED HALAL			CERTIFIED HALAL
APPEARANCE			CLEAR COLORLESS LIQUID
RETEST DATE			15-FEB-2026
DATE OF MANUFACTURE			15-FEB-2024
RESIDUAL SOLVENTS	AS REPORTED		NO RESIDUAL SOLVENTS PRESENT
MONOGRAPH EDITION			(USP-NF) 2023

Certificate of Analysis Results Entered By:

HBERMUDEZ Hernan Bermudez 05-APR-24 10:04:17

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



Certificate of Analysis Results Approved By:

SHANSEN Selin Hansen 05-APR-24 15:15:57 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

Revision date 06-July-2022

1. Identification	
Product identifier	
Product Name	ISOPROPYL MYRISTATE, NF
Other means of identification	
Product Code(s)	IS145
Synonyms	None
Recommended use of the chemical	and restrictions on use
Recommended use	In pharmaceuticals. Cosmetic additive
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).

Appearance Clear

Physical state Oily liquid

Odor No information available



Revision Number 2

#### **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-%	Trade secret
Isopropyl Myristate	110-27-0	100	*

\*The exact percentage (concentration) of composition has been withheld as a trade secret.

#### 4. First-aid measures

#### **Description of first aid measures**

General advice	Show this safety data sheet to the doctor in attendance. Immediate medical attention is required.
Inhalation	Remove to fresh air.
Eye contact	Get immediate medical advice/attention. Rinse immediately with plenty of water, also under the eyelids, for at least 15 minutes. Keep eye wide open while rinsing.
Skin contact	Get immediate medical advice/attention. Wash off immediately with soap and plenty of water while removing all contaminated clothes and shoes.
Ingestion	Do NOT induce vomiting. Clean mouth with water and drink afterwards plenty of water. Never give anything by mouth to an unconscious person. Get immediate medical advice/attention.
Self-protection of the first aider	Ensure that medical personnel are aware of the material(s) involved, take precautions to protect themselves and prevent spread of contamination. Wear personal protective clothing (see section 8). Avoid direct contact with skin. Use barrier to give mouth-to-mouth resuscitation.
Most important symptoms and effects, both acute and delayed	
Symptoms	No information available.
Indication of any immediate medica	al attention and special treatment needed
Note to physicians	Treat symptomatically.

#### 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 (CO2).		
Explosion data Sensitivity to mechanical impac	t 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 meas	6. Accidental release measures		
Personal precautions, protective equipment and emergency procedures			
Personal precautions	Avoid contact with skin, eyes or clothing. Ensure adequate ventilation. Use personal protective equipment as required. Evacuate personnel to safe areas.		
Other information	Refer to protective measures listed in Sections 7 and 8.		
Methods and material for containme	ent 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, includi	ng any incompatibilities
Storage Conditions	Keep containers tightly closed in a dry, cool and well-ventilated place. 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	Wear safety glasses with side shields (or goggles).
Hand protection	Wear suitable gloves. Impervious gloves.

Skin and body protection	Impervious clothing. Wear suitable protective clothing. Long sleeved clothing. Chemical resistant apron.
Respiratory protection	No protective equipment is needed under normal use conditions. If exposure limits are exceeded or irritation is experienced, ventilation and evacuation may be required.
General hygiene considerations	Avoid contact with skin, eyes or clothing. Wear suitable gloves and eye/face protection. Do not eat, drink or smoke when using this product. Remove and wash contaminated clothing and gloves, including the inside, before re-use. Regular cleaning of equipment, work area and clothing is recommended. Wash hands before breaks and immediately after handling the product.

#### 9. Physical and chemical properties

Information on basic physical and o		
Physical state	Oily liquid	
Appearance	Clear	
Color	Colorless	
Odor	No information available	
Odor threshold	No information available	
Property	Values	Remarks • Method
рН	no data available	None known
Melting point / freezing point	3 °C / 37.4 °F	None known
Boiling point / boiling range	191 °C / 375.8 °F	None known
Flash point	143 °C / 289.4 °F	CC (closed cup)
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 pressure	<0.1	None known
Vapor density	no data available	None known
Relative density	0.85	None known
Water solubility	Insoluble in water	None known
Solubility(ies)	Very soluble in Acetone	None known
	Soluble in Oils	
	Soluble in ethyl acetate	
	Soluble in Ethanol	
	Soluble in Chloroform	
	Insoluble in Propylene Glycol	
	Insoluble in Glycerol	
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
-		
Other information		
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		

#### 10. Stability and reactivity

No information available.

Chemical stability	Stable under normal conditions.
Possibility of hazardous reactions	None under normal processing.
Conditions to avoid	None known based on information supplied.
Incompatible materials	None known based on information supplied.

Hazardous decomposition products None known based on information supplied.

#### 11. Toxicological information

#### Information on likely routes of exposure

Product Information	
Inhalation	May be harmful if inhaled.
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. Fatal in contact with skin. (based on components).
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

#### **Component Information**

Chemical name	Oral LD50	Dermal LD50	Inhalation LC50
Isopropyl Myristate 110-27-0	> 10000 mg/kg (Rat)	= 5 g/kg (Rabbit)	41 mg/l (Rat)1 h

#### 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. No information available.
Reproductive toxicity	No information available.
STOT - single exposure STOT - repeated exposure Aspiration hazard	No information available. No information available. No information available.
Other adverse effects	No information available.
Interactive effects	No information available.

40	Easteriast information	

12.	. Eco	logical	informa	ation

Ecotoxicity

Harmful to aquatic life with long lasting effects.

Chemical name	Algae/aquatic plants	Fish	Toxicity to microorganisms	Crustacea
Isopropyl Myristate 110-27-0	EC50: >100mg/L (72h, Desmodesmus subspicatus)	LC50: =8400mg/L (96h, Brachydanio rerio)	-	EC50: =100mg/L (48h, Daphnia magna)

#### Persistence and degradability Bioaccumulation

No information available. Inherently biodegradable.

#### **Component Information**

Chemical name	Partition coefficient
Isopropyl Myristate 110-27-0	>6

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
IATA	not regulated
IMDG_	not regulated
RID	not regulated
ADR	not regulated
ADN	not regulated

#### 15. Regulatory information

#### International Inventories

TSCA

Complies

Complies Complies This product complies with ENCS: This product complies with China: Complies Complies All the constituents of this material are listed on the Australian Inventory of Chemical
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

#### <u>SARA 313</u>

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 2 Flammability 1 Instability 0 Physical and chemical properties -<u>HMIS\_</u> 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 Ceiling	TWA (time-weighted average) Maximum limit value	STEL	STEL (Short Term Exposure Limit)
	e references and sources for data used to	•	

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 Revision Note** Disclaimer

06-July-2022

No information available.

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
IS145	Isopropyl Myristate, 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

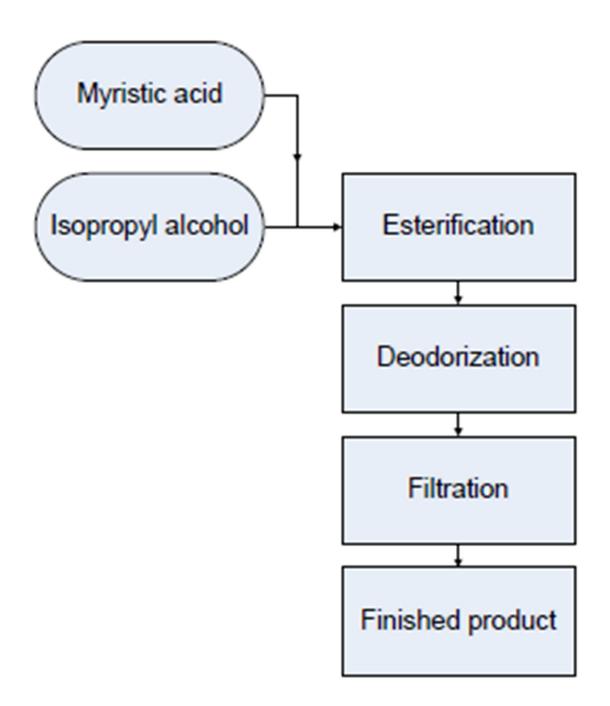
Thank you for your interest in Spectrum products. If we may be of further assistance, please feel free to contact the Quality Assurance department at 310-516-8000 or via email at qualityassurance@spectrumchemical.com

Sincerely, Quality Assurance Spectrum Chemical Mfg. Corp.

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



Manufacturing Process Flowchart - Isopropyl Myristate, NF (Catalog No. IS145)





#### 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

#### 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 the above-mentioned material.

#### Animal Testing Statement

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

Celery

Cereals containing Gluten

- Mustard
- Sesame Seed
- Corn
- Latex
- Sulfites > 10 ppm





#### **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 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
- Antibiotics
- Bisphenol A (BPA)
- CMR Substances

- Parabens
- Pesticides
- Phthalates
- Preservatives



# Elemental Impurities - Isopropyl Myristate, NF (Catalog No. IS145)

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. 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 the 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.



# Residual Solvents - Isopropyl Myristate, NF (Catalog No. IS145)

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. No Class 1, Class 2, Class 3 or other solvents are used or produced in the manufacture of this product.

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.

# **spectrum**<sup>®</sup>

F.W. 270.45

#### 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.



#### Lot No. XQ#### G 7/G10GHS

 $C_{17}H_{24}O_{2}$ 

#### Spectrum Chemical Mfg Corp

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