Scientific Documentation

IS145, 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

Ver4.01 22.April.2016

Dear Customer,

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

Spectrum has been proudly serving our 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,

Alan Wang, MSQA, ASQ CQA
Senior Manager, Global Supplier Quality Assurance
qualityassurance@spectrumchemical.com

22.Apr.2016

IS145, Isopropyl Myristate, NF

Table of Contents

- Product Specification
- Safety Data Sheet (SDS)
- Manufacturer
- Manufacturing Process Flowchart
- Certification of Quality Mangement System (QMS)
- Certification of current Good Manufacturing Practices (cGMP)
- Product BSE/TSE Statement
- Product Allergen Statement
- Product Aflatoxin Statement
- General Label Information – Sample Label
- Product Certificate of Analysis Sample(s)
- General Lot Numbering System Guidance
- Stability – Shelf Life Guidance

spectrum® CHEMICAL MFG CORP

Specification for Isopropyl Myristate, NF (IS145)

Item Number	IS145
Item	Isopropyl Myristate, NF
CAS Number	110-27-0
Molecular Formula	$C_{17}H_{34}O_2$
Molecular Weight	270.45
MDL Number	
Synonyms	Tetradecanoic Acid 1-Methylethyl Ester; Isopropyl Tetradecanoate; Myristic Acid Isopropyl

Test	Specification	
	Min	Max
ASSAY ($C_{17}H_{34}O_2$)	90.0 %	
SPECIFIC GRAVITY @ 25°/25	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 %
IDENTIFICATION		TO PASS TEST
RETEST DATE		
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: No data available **Revision Date:** 05/22/2015 **Revision Number:** G1

Product identifier

Product code: IS145
Product Name: ISOPROPYL MYRISTATE, NF

Other means of identification

Synonyms: Tetradecanoic acid, isopropyl ester; 1-Tridecanecarboxylic acid, isopropyl ester; Isopropyl tetradecanoate; Myristic acid, isopropyl ester; Tetradecanoic acid, isopropyl
CAS #: 110-27-0
RTECS # XB8600000
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 Chemicals and Laboratory Products, Inc.
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 by 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 %	Trade Secret
Isopropyl Myristate 110-27-0	110-27-0	100	*

4. FIRST AID MEASURES

First aid measures

General Advice: Poison information centers in each State capital city can provide additional assistance for scheduled poisons (13 1126)

Skin Contact: Wash off immediately with soap and plenty of water removing all contaminated clothes and shoes. Get medical attention if irritation develops. Consult a physician if necessary.

Eye Contact: Flush eye 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.

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 oxides

Specific hazards: May be combustible at high temperatures
When heated to decomposition it emits toxic fumes

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. Keep people away from and upwind of spill/leak. Do not touch damaged containers or spilled material unless wearing appropriate protective clothing. Remove all sources of ignition.

Environmental precautions Prevent further leakage or spillage if safe to do so. Prevent product from entering drains. Prevent entry into waterways, sewers, basements or confined areas.

Methods and material for containment and cleaning up

Methods for containment Stop leak if you can do it without risk. In case of large spill, dike if needed. Dike far ahead of liquid spill for later disposal.

Methods for cleaning up Absorb spill with inert material (e.g. vermiculite, dry sand or earth). Use appropriate tools to put the spilled material in a suitable chemical waste disposal container.

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 vapors or spray mist. 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. Sensitive to light. Store in light-resistant containers.

Incompatible Materials:
Alkalis. Oxidizing agents.

8. EXPOSURE CONTROLS/PERSONAL PROTECTION

Control parameters

National occupational exposure limits

United States

Components	OSHA	NIOSH	ACGIH	AIHA WHEEL
Isopropyl Myristate - 110-27-0	None	None	None	None

Canada

Components	Alberta	British Columbia	Ontario	Quebec
Isopropyl Myristate - 110-27-0	None	None	None	None

Australia and Mexico

Components	Australia	Mexico
Isopropyl Myristate 110-27-0	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. Safety glasses with side-shields.

Skin and body protection: Chemical resistant apron. Gloves. Long sleeved clothing.

Respiratory protection: Vapor respirator. 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

9. PHYSICAL AND CHEMICAL PROPERTIES

Physical state:
Liquid

Appearance:
No information available

Color:
Clear. Colorless.

Odor:
Odorless.

Taste
No information available

Molecular/Formula weight:
270.45

Formula:
C17H34O2

Flash point (°C):
No data available

Flashpoint (°C/°F):
Closed Cup: 143.33°C/290°F; Open Cup: 152°C/305.6°F

Flash Point Tested according to:
Not available

Lower Explosion Limit (%):
No information available

Upper Explosion Limit (%):
No information available

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

pH:
No information available

Melting point/range(°C/°F):
3°C/37.4°F

Boiling point/range(°C/°F):
191°-193°C/375.8°-379.4°F

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

Bulk density:
No information available

Specific gravity:
0.846-0.854

Density (g/cm3):
No information available

Vapor pressure @ 20°C (kPa):
<0.1

Evaporation rate:
No information available

Vapor density:
9.32

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:
Easily soluble in acetone
Insoluble in cold water
Insoluble in hot water
Practically insoluble in Glycerol
Practically insoluble in propylene glycol
Soluble in castor oil
Soluble in Chloroform
Soluble in cottonseed oil
Soluble in diethyl ether
Soluble in Ethanol
Soluble in ethyl acetate
Soluble in mineral oil
Soluble in Toluene

10. STABILITY AND REACTIVITY

Reactivity
Reactive with alkalis
Reactive with oxidizing agents

Chemical stability

Stability: Sensitive to light. Exposure to light accelerates decomposition. Stable at normal conditions.

Possibility of Hazardous Reactions: Hazardous polymerization does not occur

Conditions to avoid: Heat. Ignition sources. Incompatible materials.

Incompatible Materials: Alkalis. Oxidizing agents.

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:
Eyes. Skin.

Acute Toxicity

Component Information

Isopropyl Myristate - 110-27-0

LD50/oral/rat = > 16000 mg/kg Oral LDL Rat
LD50/oral/mouse = 49700 mg/kg Oral LD50 Mouse
LD50/dermal/rat = No information available
LD50/dermal/rabbit = 5 g/kg Dermal LD50Rabbit
LC50/inhalation/rat = 41 mg/L Inhalation LC50 Rat
LC50/inhalation/mouse = No infomation available
Other LD50 or LC50information = >79500 mg/kg Intraperitoneal LD50 Rat;
>25 mL/kg Oral LD50 Guinea Pig;
>50200 mg/kg Subcutaneous LD50 Mouse

Product Information

LD50/oral/rat =
VALUE- Acute Tox Oral = >16000mg/kg

LD50/oral/mouse =
Value - Acute Tox Oral = 49700mg/kg

LD50/dermal/rabbit
VALUE-Acute Tox Dermal = 5g/kg

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

LC50/inhalation/rat
VALUE-Vapor = 41g/m^3 (1-hr)
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 respiratory tract irritation.
Ingestion May cause digestive/gastrointestinal tract irritation.

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	ACGIH - Carcinogens	IARC	NTP	OSHA HCS - Carcinogens	Australia - Prohibited Carcinogenic Substances	Australia - Notifiable Carcinogenic Substances
Isopropyl Myristate	Not listed	Not listed	Not listed	Not listed	Not listed	Not listed

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.

Isopropyl Myristate - 110-27-0
Freshwater Algae Data: 100 mg/L EC50 Desmodesmus subspicatus 72 h
Freshwater Fish Species Data: 8400 mg/L LC50 Brachydanio rerio 96 h 1
8400 mg/L LC50 Brachydanio rerio 96 h semi-static 1
Water Flea Data: 100 mg/L EC50 Daphnia magna 48 h

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	RCRA - F Series Wastes	RCRA - K Series Wastes	RCRA - P Series Wastes	RCRA - U Series Wastes
Isopropyl Myristate	None	None	None	None

14. TRANSPORT INFORMATION

DOT

UN-No:	Not Regulated
Proper Shipping Name:	No information available
Hazard Class:	No information available
Subsidiary Risk:	No information available
Packing Group:	None
ERG No:	No information available
Marine Pollutant	No data available
DOT RQ (lbs):	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
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
Classification Code:	No information available
Description:	No information available
CEFIC Tremcard No:	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
Description:	No information available
IMDG Page:	No information available
Marine Pollutant	No information available
MFAG:	No information available

14. TRANSPORT INFORMATION

Maximum Quantity: 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
Classification Code: No information available
Description: 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
Description: 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
Description: No information available

15. REGULATORY INFORMATION

International Inventories

Components	U.S. TSCA	KOREA KECL	Philippines (PICCS)	Japan ENCS	CHINA	Australia (AICS)	EINECS-No.
Isopropyl Myristate	Present	Present KE-33355	Present	Present (2)-798	Present	Present	Present 203-751-4

U.S. Regulations

Isopropyl Myristate
FDA - 21 CFR - Total Food Additives Present

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	Carcinogen	Developmental Toxicity	Male Reproductive Toxicity	Female Reproductive Toxicity:
Isopropyl Myristate	Not Listed	Not Listed	Not Listed	Not Listed

CERCLA/SARA

Components	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*
Isopropyl Myristate	None	None	None	None	None

U.S. TSCA

Components	TSCA Section 5(a)2 - Chemicals With Significant New Use Rules (SNURS)	TSCA 8(d) -Health and Safety Reporting
Isopropyl Myristate	Not Applicable	Not Applicable

Canada

WHMIS 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	Canada (DSL)	Canada (NDSL)
Isopropyl Myristate	Present	Not Listed

Components	CEPA Schedule I - Toxic Substances	CEPA - 2010 Greenhouse Gases Subject to Manditory Reporting
Isopropyl Myristate	Not listed	Not listed

EU Classification

R-phrase(s)
not determined (not applicable)

S -phrase(s)
none

Components	Classification	Concentration Limits:	Safety Phrases
Isopropyl Myristate		No information	

The product is classified in accordance with Annex VI to Directive 67/548/EEC

Indication of danger:
None.

16. OTHER INFORMATION

Revision Date: 05/22/2015
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: IS145, Isopropyl Myristate, 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.

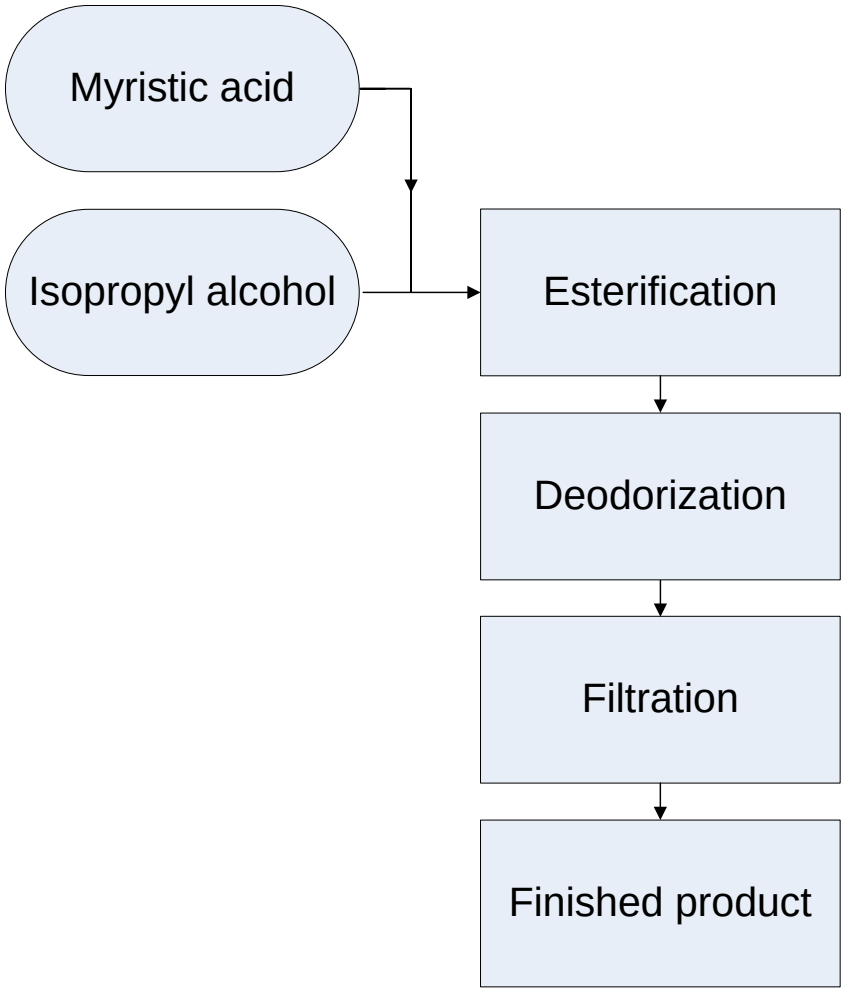
Sincerely,

Alan Wang, MSQA, ASQ CQA
Senior Manager, Global Supplier Quality Assurance
qualityassurance@spectrumchemical.com

22.Apr.2016

Manufacturing Process Flowchart

Isopropyl Myristate, NF - IS145



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
755 Jersey Avenue, New Brunswick, New Jersey, 08901, USA
769 Jersey Avenue, New Brunswick, New Jersey, 08901, USA
7400 North Oracle Road, Suite 221, Tucson, Arizona, 85704, USA

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

ISO 9001:2008

The quality management system is applicable to

California and New Jersey sites: 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.

Arizona site: Supporting Spectrum's two manufacturing facilitates by: selecting and qualifying distributors of Laboratory and Safety Equipment; processing bids and quotes to generate new sales opportunities; sourcing bulk chemicals in support of bulk bids and quotes; assisting production operations through order expediting and IT infrastructure support.

Certificate Number: 94-316m-01
Initial Certification Date: 27 December 1994
Certificate Issue Date: 29 January 2016
Certificate Expiry Date: 14 September 2018

Calin Moldovean, President
Intertek Testing Services NA, Inc.
900 Chelmsford Street, Suite 301-3, Lowell, MA, USA

ANAB ACCREDITED ISO/IEC 17021 MANAGEMENT SYSTEMS CERTIFICATION BODY

In the issuance of this certificate, Intertek assumes no liability to any party other than to the Client, and then only in accordance with the agreed upon Certification Agreement. This certificate's validity is subject to the organization maintaining their system in accordance with Intertek's requirements for systems certification. Validity may be confirmed via email at certificate.validation@intertek.com or by scanning the code to the right with a smartphone.

The certificate remains the property of Intertek, to whom it must be returned upon request.

Certificate of Registration

This is to certify that the quality management system of

Spectrum China Ltd.

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

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

ISO 9001: 2008

The quality management system is applicable to:

Provision of service of purchase, testing and sales for chemical products, repacking of non-hazardous chemical products.

Organization Code:	77762704-8
Certificate Number:	111310001-01
Certificate Issue Date:	17 November 2015
Certificate Expiry Date:	14 September 2018

UKAS MANAGEMENT SYSTEMS
014

Authorised Signature: 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.

In the issuance of this certificate, Intertek assumes no liability to any party other than to the client, and then only in accordance with the agreed upon Certification Agreement. This certificate's validity is subject to the organization maintaining their system in accordance with Intertek's requirements for systems certification. Validity may be confirmed via email at certificate.validation@intertek.com or by scanning the code to the right with a smartphone.
The annual validity of the certificate can also be checked through the website http://www.cnca.gov.cn of CNCA in China.

The certificate remains the property of Intertek, to whom it must be returned upon request.

Intertek Intertek Intertek Intertek Intertek

March 28, 2016

Certificate of cGMP

Dear Valued Customer:

Spectrum Chemicals and Laboratory Products certify 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:	2020632
Spectrum-New Brunswick, NJ:	2246824
Spectrum -Shanghai, China:	3006174778

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

Sincerely,

Michelle Weston

Michelle Weston
Quality Assurance Specialist

April 13, 2016

Certificate of cGMP

Dear Valued Customer:

Spectrum Chemicals and Laboratory Products certify 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
Spectrum-Shanghai, China: 3006174778

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

Sincerely,

Michelle Weston

Michelle Weston
Quality Assurance Specialist

April 21, 2016

Re: Isopropyl Myristate, NF- IS145

To Whom It May Concern:

Thank you for your interest in Spectrum high quality chemicals.

We at Spectrum Chemical Mfr. Corp. understand the concern regarding Bovine Spongiform Encephalopathy (BSE). Please be assured that the chemical

Isopropyl Myristate, NF-IS145

is BSE/TSE free.

If you have any further questions, please contact Tech Services at (310) 516-8000 Extension 5471, or by email at techservices@spectrumchemical.com.

Sincerely,

Darlene Dagdag-Lyudmirskiy
Technical Services
Spectrum Chemical Mfr. Corp.

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

April 21, 2016

Re: Isopropyl Myristate, NF-IS145

To Whom It May Concern:

Thank you for your interest in Spectrum high quality chemicals.

We at Spectrum Chemical Mfr. 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; Sulfur dioxide and sulfites at concentrations of more than 10 mg/kg or 10 mg/liter expressed as SO_2; Tree nuts; Wheat; Peanuts; Soy; Cereals containing Gluten; Celery; Mustard; Sesame Seed).

Isopropyl Myristate, NF-IS145

If you have any further questions, please contact Tech Services at (310) 516-8000 Extension 5471, or by email at techservices@spectrumchemical.com.

Sincerely,

Darlene Dagdag-Lyudmirskiy
Technical Services
Spectrum Chemical Mfr. Corp.

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

April 21, 2016

Re: Isopropyl Myristate, NF-IS145

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 Aflatoxins in raw materials. To the best of our knowledge, the product listed below is not contaminated with Aflatoxins. Aflatoxins are not used in production. The following product does not come in contact with Aflatoxins at any stage of production.

Isopropyl Myristate, NF-IS145

If you have any further questions, please contact Tech Services at (310) 516-8000 Extension 5471, or by email at techservices@spectrumchemical.com.

Sincerely,

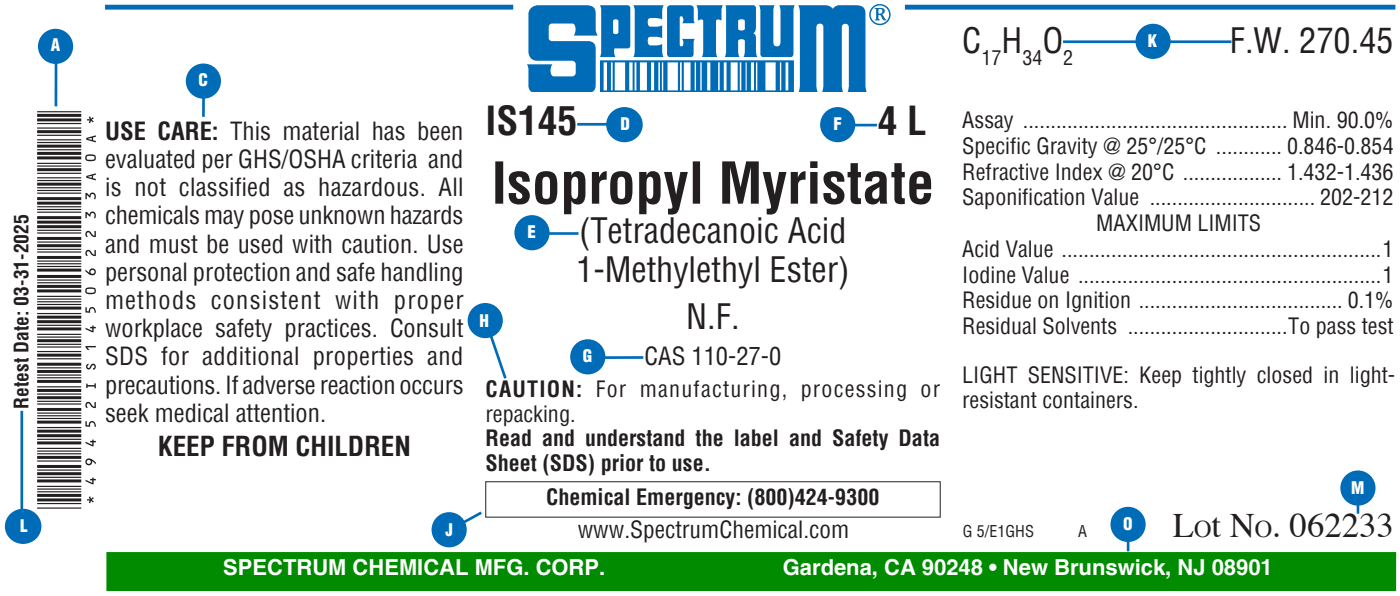
Darlene Dagdag-Lyudmirskiy
Technical Services
Spectrum Chemical Mfr. Corp.

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

spectrum®
CHEMICAL MFG CORP

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.



- **A** Bar Code
- **B** GHS Hazard Pictograms
- **C** Warning, Safety Data and Precautionary Information
- **D** Product Catalog Number
- **E** Item Name, Form, Grade
- **O** Storage Color Band
- **F** Size/Quantity
- **G** Chemical Abstracts Service (CAS) Registry Number
- **H** Caution Information
- **I** DOT Shipping Information
- **J** Toll-Free 24-Hour Chemical Emergency Telephone Number
- **K** Empirical Formula, Formula Weight and Technical Specifications Panel
- **L** Expiration Information
- **M** Lot Number
- **N** Kosher Certified by Kosher Supervision of America (KSA).

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

Certificate Of Analysis

Item Number	IS145	Lot Number	1FB0468
Item	Isopropyl Myristate, NF		
CAS Number	110-27-0		
Molecular Formula	$C_{17}H_{34}O_2$	Molecular Weight	270.45

Test	Specification		Result
	min	max	
ASSAY ($C_{17}H_{34}O_2$)	90.0 %		99.6 %
SPECIFIC GRAVITY @ 25°/25	0.846 - 0.854		0.853
REFRACTIVE INDEX @ 20°C	1.432 - 1.436		1.4348
SAPONIFICATION VALUE	202 - 212		210.5
ACID VALUE		1	0.06
IODINE VALUE		1	0.06
RESIDUE ON IGNITION		0.1 %	<0.1 %
IDENTIFICATION		TO PASS TEST	PASSES TEST
RETEST DATE			03-JUL-2018
RESIDUAL SOLVENTS		TO PASS TEST	NO RESIDUAL SOLVENTS USED
APPEARANCE			CLEAR COLORLESS OILY LIQUID
MANUFACTURE DATE			03-JUL-2015

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.

Certificate Of Analysis

Item Number	IS145	Lot Number	2EL0282
Item	Isopropyl Myristate, NF		
CAS Number	110-27-0		
Molecular Formula	$C_{17}H_{34}O_2$	Molecular Weight	270.45

Test	Specification		Result
	min	max	
ASSAY ($C_{17}H_{34}O_2$)	90.0 %		98.5 %
SPECIFIC GRAVITY @ 25°/25	0.846 - 0.854		0.850
REFRACTIVE INDEX @ 20°C	1.432 - 1.436		1.434
SAPONIFICATION VALUE	202 - 212		209.0
ACID VALUE		1	0.03
IODINE VALUE		1	0.30
RESIDUE ON IGNITION		0.1 %	<0.10 %
IDENTIFICATION		TO PASS TEST	PASSES TEST
RETEST DATE			09-MAY-2018
RESIDUAL SOLVENTS		TO PASS TEST	.
CLASS 3 (solvent) / 2-PROPANOL			<5000 ppm
APPEARANCE			CLEAR OILY LIQUID
DATE OF MANUFACTURE			09-MAY-2015

Spectrum Chemical Mfg Corp
755 Jersey Avenue
New Brunswick 08901 NJ

Certificate of Analysis Results Certified By:

Mulbah F. Dwanah
Laboratory Supervisor
Spectrum Chemicals & Laboratory Products

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

January 26, 2016

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: ZI0928 = 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
Manager, GMP Compliance

Stability – Shelf Life Guidance

Product Covered: IS145, Isopropyl Myristate, NF

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

The product, IS145, Isopropyl Myristate, NF, is assigned a 36 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

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

22.Apr.2016