



Scientific Documentation

CE120, Cetyl Alcohol, NF

Not appropriate for regulatory submission.
Please visit www.spectrumchemical.com or
contact Tech Services for the most up-to-date
information contained in this information
package.

Spectrum Chemical Mfg Corp

769 Jersey Avenue
New Brunswick, NJ 08901
Phone 732.214.1300

Ver4.04 17.September.2018



Dear Customer,

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

Spectrum has been proudly serving the scientific community for over 45 years. It is our mission to manufacture and distribute fine chemicals and laboratory products with Quality and delivery you can count on every time.

To accomplish our mission, Spectrum utilizes our sourcing leverage and supplier qualification expertise in offering one of the industry's most comprehensive line of fine chemical products under one brand, in packaging configurations designed to meet your research and production requirements. Our product grades include: USP, NF, BP, EP, JP, FCC, ACS, KSA, Reagent grade, as well as DEA controlled substances. We operate facilities in the United States on the East Coast, West Coast, as well as in Shanghai, China in order to provide the best logistical support for our customers.

At Spectrum, Quality is priority number one. Suppliers with the best qualifications are preferred and we employ full-functioning in-house analytical laboratories at each of our facilities. Our facilities and systems are USFDA registered and ISO certified. We frequently host customer audits and cherish opportunities for improvements. Quality is engrained into our culture. Quality is priority number one.

In the following pages, we have designed and prepared documented scientific information to aid you in your initial qualification or your continual use of our products. Please do not hesitate to contact us if further information or the most up-to-date documentation is desired from any of the covered areas.

We appreciate your business and we look forward to hearing from you.

Sincerely,

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

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

CE120, Cetyl Alcohol, NF

Table of Contents

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

Spectrum[®]
CHEMICAL MFG CORP



Specification for Cetyl Alcohol, NF (CE120)

Item Number	CE120
Item	Cetyl Alcohol, NF
CAS Number	36653-82-4
Molecular Formula	C ₁₆ H ₃₄ O
Molecular Weight	242.44
MDL Number	
Synonyms	1-Hexadecanol

Test	Specification	
	Min	Max
ASSAY	90.0	102.0 %
HYDROXYL VALUE	218	238
ACID VALUE		2
IODINE VALUE		5
RESIDUE ON IGNITION		0.1 %
WATER DETERMINATION		0.5 %
RELATED FATTY ALCOHOLS	TO PASS TEST	
ELEMENTAL IMPURITIES	AS REPORTED	
IDENTIFICATION	TO PASS TEST	
EXPIRATION DATE		
MANUFACTURE DATE		
APPEARANCE		
RESIDUAL SOLVENTS	TO PASS TEST	

Spectrum Chemical Mfg Corp

Corporate Headquarters:
769 Jersey Ave.
New Brunswick, NJ 08901
732.214.1300

West Coast Facility:
14422 S. San Pedro St.
Gardena, CA 90248
310.516.8000

SAFETY DATA SHEET

Preparation Date: 01/19/2015

Revision Date: 1/15/2018

Revision Number: G2

1. IDENTIFICATION

Product identifier

Product code: CE120
Product Name: CETYL ALCOHOL, NF

Other means of identification

Synonyms: Cetanol; Hexadecyl Alcohol; Adol; Cetaffine; 1-Hexadecanol; Ethal; Ethol
CAS #: 36653-82-4
RTECS # MM0225000
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 considered hazardous according to the 2012 OSHA Hazard Communication Standard (29 CFR 1910.1200)

Considered a dangerous substance or mixture according to the Globally Harmonized System (GHS)

Serious eye damage/eye irritation	Category 2A
-----------------------------------	-------------

Label elements

Warning

Hazard statements
 Causes serious eye irritation



Hazards not otherwise classified (HNOC)

Not Applicable

Other hazards

May be harmful if swallowed

May be harmful in contact with skin

Precautionary Statements - Prevention

Wash face, hands and any exposed skin thoroughly after handling

Wear eye/face protection

Wear protective gloves

IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing. If eye irritation persists: Get medical advice/attention.

3. COMPOSITION/INFORMATION ON INGREDIENTS

Components	CAS-No.	Weight %
Cetyl Alcohol	36653-82-4	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

Causes eye irritation
Eye contact may result in redness or pain
Causes skin irritation
Skin contact may result in redness, pain, inflammation, itching, scaling
May be harmful in contact with skin
May be harmful if swallowed

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. Alcohol-resistant foam.

Unsuitable Extinguishing Media: No information available.

Specific hazards arising from the chemical

Hazardous Combustion Products: Carbon oxides

Hazardous Combustion Products: No information available.

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. Avoid dust formation. 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. 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. Avoid dust formation. 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. Avoid dust formation. 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:

Acids
Strong oxidizing agents

8. EXPOSURE CONTROLS/PERSONAL PROTECTION

Control parameters**National occupational exposure limits****United States**

Components	CAS-No.	OSHA	NIOSH	ACGIH	AIHA WEEL
Cetyl Alcohol	36653-82-4	None	None	None	None

Canada

Components	CAS-No.	Canada - Alberta	Canada - British Columbia	Canada - Ontario	Canada - Quebec
Cetyl Alcohol	36653-82-4	None	None	None	None

Australia and Mexico

Components	CAS-No.	Australia	Mexico
Cetyl Alcohol	36653-82-4	None	None

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 Safety glasses with side-shields
Skin and body protection:	Long sleeved clothing Chemical resistant apron Gloves
Respiratory protection:	Effective dust mask. Wear respirator with dust filter.
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: Crystals. Powder.	Color: White.
Odor: No information available.	Taste: Mild.	Formula: C16H34O

Molecular/Formula weight: 242.44	Flammability: No information available	Flashpoint (°C/°F): 160°C/320°F
Flash Point Tested according to: Closed cup	Autoignition Temperature (°C/°F): 251°C/484°F	Lower Explosion Limit (%): 1
Upper Explosion Limit (%): 8	Melting point/range(°C/°F): 49.3°C/120.7°F	Decomposition temperature(°C/°F): No information available
Boiling point/range(°C/°F): 344°C/651.2°F	Bulk density: No information available	Density (g/cm3): No information available
Specific gravity: No information available	pH: No information available	Vapor pressure @ 20°C (kPa): No information available
Evaporation rate: No information available	Vapor density: 8.36	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: Soluble in Acetone Soluble in Chloroform Soluble in diethyl ether Insoluble in water Slightly soluble in alcohol	

10. STABILITY AND REACTIVITY

Reactivity

Reactive with acids
Reactive with oxidizing agents

Chemical stability

Stability: Stable under recommended storage conditions.

Possibility of Hazardous Reactions: Hazardous polymerization does not occur

Conditions to avoid: Heat. Ignition sources. Incompatible materials. Avoid dust formation.

Incompatible Materials: Acids
Strong 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. Ingestion. Inhalation. Skin.

Acute Toxicity

Component Information

Cetyl Alcohol	
CAS-No.	36653-82-4

LD50/oral/rat = > 5 g/kg Oral LD50 Rat
LD50/oral/mouse = 3200 mg/kg (RTECS)
LD50/dermal/rabbit = >2600 mg/kg
LD50/dermal/rat = No information available
LC50/inhalation/rat = No information available
LC50/inhalation/mouse = No information available
Other LD50 or LC50 information = 1600 mg/kg, intraperitoneal, mouse

Product Information

LD50/oral/rat =
VALUE- Acute Tox Oral = 5 g/kg

LD50/oral/mouse =
Value - Acute Tox Oral = 3200

LD50/dermal/rabbit
VALUE-Acute Tox Dermal = >2600 mg/kg

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: Causes skin irritation. May be harmful in contact with skin.

Eye Contact: Causes eye irritation.

Inhalation May cause irritation of respiratory tract.

Ingestion May be harmful if swallowed.

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
Cetyl Alcohol	36653-82-4	Not listed	Not listed	Not listed	Not listed	Not listed	Not listed

ACGIH (American Conference of Governmental Industrial Hygienists)

IARC (International Agency for Research on Cancer)

NTP (National Toxicology Program)

OSHA (Occupational Safety and Health Administration of the US Department of Labor)

Reproductive toxicity No data is available

Reproductive Effects: No information available

Developmental Effects: No information available

Teratogenic Effects: No information available

Specific Target Organ Toxicity

STOT - single exposure No information available.

STOT - repeated exposure No information available.

Target Organs: No information available.

12. ECOLOGICAL INFORMATION

Ecotoxicity

Ecotoxicity effects: No data available.

Persistence and degradability: No information available

Bioaccumulative potential: No information available.

Mobility: No information available.

13. DISPOSAL CONSIDERATIONS

Disposal Methods

Waste from residues / unused products:

Waste must be disposed of in accordance with Federal, State and Local regulation.

Contaminated packaging:

Empty containers should be taken for local recycling, recovery or waste disposal

Components	CAS-No.	RCRA - F Series Wastes	RCRA - K Series Wastes	RCRA - P Series Wastes	RCRA - U Series Wastes
Cetyl Alcohol	36653-82-4	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 Number	No information available
Marine Pollutant	No data available
DOT RQ (lbs):	No information available
Special Provisions	No Information available
Symbol(s):	No information available
Description:	No information available

TDG (Canada)

UN-No:	Not Regulated
Proper Shipping Name:	No information available
Hazard Class:	No information available
Subsidiary Risk:	No information available
Packing Group:	No information available
Marine Pollutant	No Information available
Description:	No information available

ADR

UN-No:	Not Regulated
Proper Shipping Name:	No information available
Hazard Class:	No information available
Packing Group:	No information available
Subsidiary Risk:	No information available

IMO / IMDG

UN-No:	Not Regulated
Proper Shipping Name:	No information available
Hazard Class:	No information available
Subsidiary Risk:	No information available
Packing Group:	No information available
Marine Pollutant	No information available

RID

UN-No:	Not Regulated
Proper Shipping Name:	No information available
Hazard Class:	No information available
Subsidiary Risk:	No information available
Packing Group:	No information available

ICAO

UN-No:	Not Regulated
Proper Shipping Name:	No information available
Hazard Class:	No information available
Subsidiary Risk:	No information available
Packing Group:	No information available

IATA

UN-No:	Not Regulated
Proper Shipping Name:	No information available
Hazard Class:	No information available
Subsidiary Risk:	No information available
Packing Group:	No information available
ERG Code:	No information available
Special Provisions	No information available

15. REGULATORY INFORMATION

International Inventories

Components	CAS-No.	U.S. TSCA	KOREA KECL	Philippines (PICCS)	Japan ENCS	CHINA	Australia (AICS)	EINECS-No.
<i>Cetyl Alcohol</i>	36653-82-4	PresentACTIVE	Present KE-18460	Present	Present (2)-3704,(2)-2 17	Present	Present	Present 253-149-0

U.S. Regulations

Cetyl Alcohol

FDA - Direct Food Additives 21 CFR 172.515

FDA - 21 CFR - Total Food Additives 172.515, 172.864, 175.105, 175.300, 176.200, 177.1200, 73.1, 73.1001

California Prop. 65: Safe Drinking Water and Toxic Enforcement Act of 1986.

Chemicals Known to the State of California to Cause Cancer:

This product does not contain a chemical requiring a warning under California Prop. 65. (See table below)

Chemicals Known to the State of California to Cause Reproductive Toxicity:

This product does not contain a chemical requiring a warning under California Prop. 65. (See table below)

Components	CAS-No.	Carcinogen	Developmental Toxicity	Male Reproductive Toxicity	Female Reproductive Toxicity:
<i>Cetyl Alcohol</i>	36653-82-4	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
<i>Cetyl Alcohol</i>	36653-82-4	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
<i>Cetyl Alcohol</i>	36653-82-4	Not Applicable	Not Applicable

Canada

WHMIS 2015 - GHS Classifications

WHMIS 2015 Hazard Classification Information:

Component
Cetyl Alcohol
36653-82-4 (100)

WHMIS 2015 Hazard Classification
Combustible Dust - Category 1: May form combustible dust concentrations in air (factors such as combustibility and explosiveness of dusts including composition and shape and size of particles could cause substance to belong to 'Combustible dust' hazard class)

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

Product code: CE120

Product name: CETYL ALCOHOL, NF

D2B Toxic materials

Components

Cetyl Alcohol

WHMIS 1988

D2B

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)
Cetyl Alcohol	36653-82-4	Present	Not Listed

Components	CAS-No.	CEPA Schedule I - Toxic Substances
Cetyl Alcohol	36653-82-4	Not listed
Components	CAS-No.	CEPA - 2010 Greenhouse Gases Subject to Mandatory Reporting
Cetyl Alcohol	36653-82-4	Not listed

EU Classification

EU GHS - SV - CLP 1272/2008

Components	CAS-No.	EU GHS - SV - CLP (1272/2008)
Cetyl Alcohol	36653-82-4	No information

EU - CLP (1272/2008)

R-phrase(s)

Not determined

S -phrase(s)

none

Components	CAS-No.	Classification	Concentration Limits:	Safety Phrases
Cetyl Alcohol	36653-82-4		No information	

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

Indication of danger:

not determined

16. OTHER INFORMATION

Preparation Date: 01/19/2015
Revision Date: 1/15/2018
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



Manufacturer

Product Covered: CE120, Cetyl Alcohol, NF

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

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

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

Sincerely,

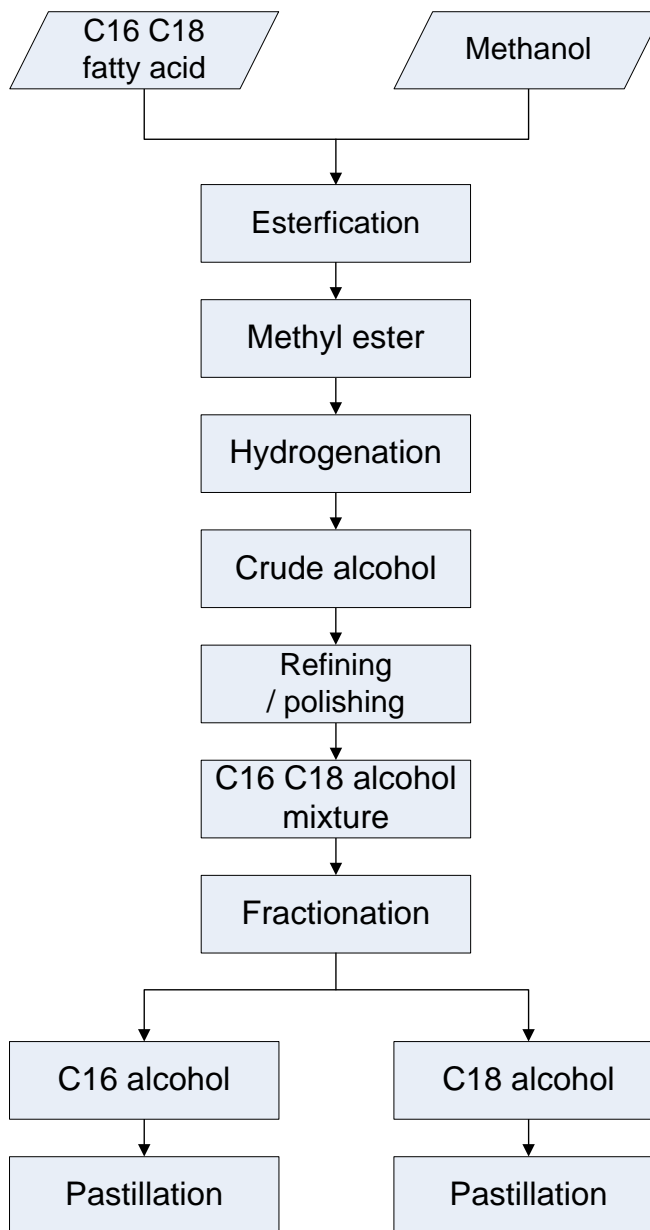
A handwritten signature in blue ink, appearing to read "Michael Dang", with a long horizontal flourish extending to the right.

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

17.September.2018

Manufacturing Process Flowchart

Cetyl Alcohol, NF - CE120



Spectrum Chemical Mfg Corp

Corporate Headquarters:

769 Jersey Ave.
New Brunswick, NJ 08901
732.214.1300

West Coast Facility:

14422 S. San Pedro St.
Gardena, CA 90248
310.516.8000

CERTIFICATE OF REGISTRATION

This is to certify that the quality management system of:

Spectrum Chemicals and Laboratory Products, Inc.

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

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

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

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

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

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

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

ISO 9001:2015

The quality management system is applicable to:

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

Certificate Number:

94-316m-03

Initial Certification Date:

27 December 1994

Certificate Issue Date:

31 July 2017

Certificate Expiry Date:

28 January 2019



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

Authorized Signature

Calin Moldovean

President Business Assurance

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



APPENDIX TO CERTIFICATE OF REGISTRATION

This appendix identifies the locations by the management system of

Spectrum Chemicals and Laboratory Products, Inc.

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

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

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



管理体系认证 注册证书

兹证明，以下组织：

斯百全化学（上海） 有限公司

上海市松江区申港路3802弄A20

的管理体系，符合以下标准要求并予以注册：

ISO 9001:2015

此管理体系适用于：

药用辅料销售，化学品销售

统一社会信用代码：

91310000777627048K

证书编号：

111310001

首次认证日期：

2015年11月17日

认证决定日期：

2017年12月26日

签发日期：

2017年12月26日

有效期至：

2018年11月10日



014

Calin Moldovean

President, Business Assurance

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

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



CERTIFICATE OF REGISTRATION

This is to certify that the management system of:

Spectrum China Ltd.

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

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

ISO 9001:2015

The management system is applicable to:

Sales for Pharmaceutical Excipients, Sales for Chemicals

Unified Social Credit Identifier:

91310000777627048K

Certificate Number:

111310001

Initial Certification Date:

17 November 2015

Date of Certification Decision:

26 December 2017

Issuing Date:

26 December 2017

Valid Until:

10 November 2018



014

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

Calin Moldovean

President, Business Assurance

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

Intertek Certification Limited is a UKAS accredited body under schedule of accreditation no. 014.



July 13, 2017

Certification of Compliance with current Good Manufacturing Practices

Dear Valued Customer:

Spectrum Chemical Mfg Corp certifies that our USP, NF, FCC, EP, BP, JP and food grade products are produced, processed, packaged and held in compliance with current Good Manufacturing Practices (cGMP) in accordance with the applicable parts of 21 CFR, parts 210 and 211 of the Code of Federal Regulations.

Spectrum is an FDA registered and inspected Drug Establishment. Our United States Food and Drug Administration (USFDA) Registration numbers are as follows:

Spectrum-Gardena, CA:	<u>2020632</u>
Spectrum-New Brunswick, NJ:	<u>2246824</u>
Spectrum-Shanghai, China:	<u>3006174778</u>

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

Sincerely,



Oralia Chavez
Quality Assurance Specialist

September 17, 2018

Certification of Compliance with current Good Manufacturing Practices

Dear Valued Customer:

Spectrum Chemical Mfg Corp certifies that the following product(s) is produced, processed, packaged and held in compliance with current Good Manufacturing Practices (cGMP) in accordance with the applicable parts of 21 CFR, parts 210 and 211 of the Code of Federal Regulations.

Catalog Number	Product Name
CE120	Cetyl Alcohol, NF

Spectrum is an FDA registered and inspected Drug Establishment. Our United States Food and Drug Administration (USFDA) Registration numbers are as follows:

Spectrum-Gardena, CA: 2020632
Spectrum-New Brunswick, NJ: 2246824
Spectrum-Shanghai, China: 03006174778

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

Sincerely,



Oralia Chavez
Quality Assurance Specialist



May 23, 2016

Re: Cetyl Alcohol, NF- CE120

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

Cetyl Alcohol, NF- CE120

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



May 23, 2016

Re: Cetyl Alcohol, NF- CE120

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; Lupin; Tree nuts; Mollusks; Wheat; Peanuts; Soy; Cereals containing Gluten; Celery; Mustard; Sesame Seed).

Cetyl Alcohol, NF- CE120

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



May 23, 2016

Re: Cetyl Alcohol, NF- CE120

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.

Cetyl Alcohol, NF- CE120

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

Item Number	CE120	Lot Number	1HF0336
Item	Cetyl Alcohol, NF		
CAS Number	36653-82-4		
Molecular Formula	C ₁₆ H ₃₄ O	Molecular Weight	242.44

Test	Specification		Result
	min	max	
ASSAY	90.0	102.0 %	100.4 %
HYDROXYL VALUE	218	238	230.0
ACID VALUE		2	0.01
IODINE VALUE		5	0.02
RESIDUE ON IGNITION		0.1 %	0.01 %
WATER DETERMINATION		0.5 %	0.09 %
RELATED FATTY ALCOHOLS	TO PASS TEST		PASSES TEST
ELEMENTAL IMPURITIES	AS REPORTED		NO ELEMENTAL IMPURITIES PRESENT
IDENTIFICATION	TO PASS TEST		PASSES TEST
EXPIRATION DATE			30-APR-2021
MANUFACTURE DATE			30-APR-2018
APPEARANCE			WHITE PELLETS
RESIDUAL SOLVENTS	TO PASS TEST		NO RESIDUAL SOLVENTS USED

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

Certificate of Analysis Results Certified By:



Adan Hernandez
 Quality Control Manager
 Spectrum Chemicals & Laboratory Products



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

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

Item Number	CE120	Lot Number	2HF0018
Item	Cetyl Alcohol, NF		
CAS Number	36653-82-4		
Molecular Formula	$C_{16}H_{34}O$	Molecular Weight	242.44

Test	Specification		Result
	min	max	
ASSAY	90.0	102.0 %	98.6 %
HYDROXYL VALUE	218	238	230
ACID VALUE		2	0.01
IODINE VALUE		5	0.01
RESIDUE ON IGNITION		0.1 %	0.01 %
WATER DETERMINATION		0.5 %	0.1 %
RELATED FATTY ALCOHOLS	TO PASS TEST		PASSES TEST
ELEMENTAL IMPURITIES	AS REPORTED		NO ELEMENTAL IMPURITIES PRESENT
IDENTIFICATION	TO PASS TEST		PASSES TEST
EXPIRATION DATE			10-JAN-2021
MANUFACTURE DATE			10-JAN-2018
APPEARANCE			UNCTUOUS WHITE PELLETS
RESIDUAL SOLVENTS	TO PASS TEST		NO RESIDUAL SOLVENTS USED

Spectrum Chemical Mfg Corp
755 Jersey Avenue
New Brunswick 08901 NJ



Certificate Of Analysis Results Certified by



Ibad Tirmizi
Director of Quality
Spectrum Chemical Mfg. Corp.

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


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

Label Information

The Spectrum label presents technical and safety information in an easily understood format. Our technical specialists stay abreast of the latest requirements of the Globally Harmonized System for Classification and Labelling of Chemicals (GHS), as well as the Occupational Safety and Health Administration (OSHA), the Food and Drug Administration (FDA) and other government regulatory agencies in order to ensure compliance, accuracy and concise hazard communication.

A **WARNING**

C • Causes skin and eye irritation • May be harmful if swallowed or in contact with skin.
• Wear protective gloves • Wash face, hands and any exposed skin thoroughly after handling.

B 

E **FIRST AID:** IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing. If eye irritation persists: Get medical attention. IF ON SKIN: Wash with plenty of water. Take off contaminated clothing and wash it before reuse. If skin irritation occurs: Get medical attention. Call a POISON CENTER or physician if you feel unwell.

L **KEEP FROM CHILDREN**

SPECTRUM[®]

D **CE120** **F** **2.5 KG**

E **Cetyl Alcohol**

E **(1-Hexadecanol)**

N.F.

G **CAS 36653-82-4**

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

J **Chemical Emergency: (800)424-9300**
www.SpectrumChemical.com

K **C₁₆H₃₄O** **F.W. 242.44**

Vegetable origin.

Assay 90.0-102.0%
Hydroxyl Value 218-238

MAXIMUM LIMITS

Acid Value 2
Iodine Value 5
Residue on Ignition 0.1%
Water 0.5%
Related Fatty Alcohols To pass test
Residual Solvents To pass test

M **Lot No. 062233**

O **Storage Color Band: A**

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

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

This color-coded band indicates the hazard most likely to be posed by that material under storage conditions. The criteria used to assign band colors have been established by the Storage Code working group of the Society for Chemical Hazard Communication (SCHC). It is recommended that like colors be stored together, unless otherwise stated, based on the color codes indicated to the right. However, it is the responsibility of the customer to check with their local fire department for possible conflicts with our recommendations when storing hazardous chemicals.

- YELLOW:** Oxidizer
- RED:** Flammable
- GREEN:** General Storage
- BLUE:** Health Hazard
- WHITE:** Corrosive

Spectrum Chemical Mfg Corp

Corporate Headquarters:

769 Jersey Ave.
New Brunswick, NJ 08901

732.214.1300

West Coast Facility:

14422 S. San Pedro St.
Gardena, CA 90248

310.516.8000

June 15, 2018

RE: Lot Numbering System

Dear Valued Customer:

This letter is to inform you of Spectrum Chemicals and Laboratory Products' Lot Numbering System. The system is based on an alpha-numerical sequence which provides the month, year and location of production.

The lot numbering system utilized until 2010 is a sequence of **six characters**, two letters followed by four numbers. The first letter represents the year, for example, Y denotes 2009 and Z denotes 2010. The second letter represents the month and site, for example, A-L denotes January through December at Spectrum's Gardena, CA facility, while M-X denotes January through December at the New Brunswick, NJ facility. The following four numbers are sequentially assigned.

Example: Z10928 = The 928th material produced in California in September 2010

The lot numbering system utilized for 2011 and forward, is a sequence of **seven characters**. The first character, a number, represents the production facility:

- 1 = Gardena, CA Facility
- 2 = New Brunswick, NJ Facility
- 3 = China Facility

The second character, a letter, represents the year. For example, A denotes 2011 and B denotes 2012. The third character, a letter, represents the month, with A denoting January and L denoting December. The following four numbers are sequentially assigned.

Example: 2AA0706 = The 706th material produced in New Jersey in January 2011

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

Sincerely,



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



Stability – Shelf Life Guidance

Product Covered: CE120, Cetyl Alcohol, NF

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

The product, CE120, Cetyl Alcohol, NF, 60 Percent, USP, 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

A handwritten signature in black ink, appearing to read "Adan R. Hernandez".

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

17.September.2018