

Scientific Documentation

Cetyl Esters Wax, Synthetic, 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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Specification for Cetyl Esters Wax, Synthetic, NF (SP310)

Item Number	SP310
Item	Cetyl Esters Wax, Synthetic, NF
CAS Number	
Molecular Formula	
Molecular Weight	
MDL Number	
Synonyms	Spermaceti ; Cetyl Esters Wax

Test	Specification	
	Min	Max
TOTAL FATTY ESTERS AND CETYL PALMITATE	90.0 %	
FATTY ESTERS WITH CARBON-CHAIN LENGTH, %:		
C26	AS REPORTED	
C28	AS REPORTED	
C30	AS REPORTED	
C32	AS REPORTED	
C34	AS REPORTED	
C36	AS REPORTED	
MELTING RANGE	43°	47°C
TOTAL FREE FATTY ALCOHOLS AND FREE FATTY ACIDS		10.0 %
IODINE VALUE		1
ACID VALUE		5
PARAFFIN AND FREE ACIDS	SAMPLE DISSOLVES COMPLETELY AND IS NEUTRAL OR ACIDIC	
ELEMENTAL IMPURITIES	AS REPORTED	
IDENTIFICATION (A)	RETENTION TIME OF SAMPLE PEAKS CORRESPONDS TO STANDARD D	
IDENTIFICATION (B)	109	120

Test	Specification	
	Min	Max
EXPIRATION DATE		
DATE OF MANUFACTURE		
APPEARANCE		
RESIDUAL SOLVENTS	AS REPORTED	

Spectrum Chemical Mfg Corp

<i>Corporate Headquarters:</i>	<i>West Coast Facility:</i>
769 Jersey Ave.	14422 S. San Pedro St.
New Brunswick, NJ 08901	Gardena, CA 90248
732.214.1300	310.516.8000

Certificate Of Analysis

Item Number	SP310	Lot Number	2LK0178
Item	Cetyl Esters Wax, Synthetic, NF		

TEST	SPECIFICATION		RESULT
	MIN	MAX	
TOTAL FATTY ESTERS AND CETYL PALMITATE	90.0 %		98.66 %
FATTY ESTERS WITH CARBON-CHAIN LENGTH, %:			.
C26	AS REPORTED		0.0 %
C28	AS REPORTED		23.31 %
C30	AS REPORTED		26.27 %
C32	AS REPORTED		39.19 %
C34	AS REPORTED		0.0 %
C36	AS REPORTED		0.0 %
MELTING RANGE	43°	47°C	44°C
TOTAL FREE FATTY ALCOHOLS AND FREE FATTY ACIDS		10.0 %	1.34 %
IODINE VALUE		1	1
ACID VALUE		5	5
PARAFFIN AND FREE ACIDS	SAMPLE DISSOLVES COMPLETELY AND IS NEUTRAL OR ACIDIC		SAMPLE DISSOLVES COMPLETELY AND IS NEUTRAL OR ACIDIC
ELEMENTAL IMPURITIES	AS REPORTED		COMPLIES WITH STANDARD
IDENTIFICATION (A)	RETENTION TIME OF SAMPLE PEAKS CORRESPONDS TO STANDARD D		RETENTION TIME OF SAMPLE PEAKS CORRESPONDS TO STANDARD D

TEST	SPECIFICATION		RESULT
	MIN	MAX	
IDENTIFICATION (B)	109	120	109.23
EXPIRATION DATE			24-MAY-2024
DATE OF MANUFACTURE			25-MAY-2022
APPEARANCE			WHITE FLAKES
RESIDUAL SOLVENTS	AS REPORTED		.
CLASS 2 (solvent) TOLUENE			<890 ppm

Certificate of Analysis Results Entered By:

SVANGOOR
Swetha Vangoor
12-DEC-22 06:04:08

Spectrum Chemical Mfg Corp
755 Jersey Avenue
New Brunswick 08901 NJ



Certificate of Analysis Results Approved By:

AWILLIAMS
Allison Williams
12-DEC-22 15:06:38

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

Preparation Date: 9/11/2018

Revision Date: 9/11/2018

Revision Number: G1

1. IDENTIFICATION

Product identifier

Product code: SP310
Product Name: CETYL ESTERS WAX, SYNTHETIC, NF

Other means of identification

Synonyms: This product is a mixture consisting primarily of esters of saturated fatty alcohols (C14 to C18) and saturated fatty acids (C14 to C18)

CAS #: Mixture
RTECS # Not available
CI#: Not available

Recommended use of the chemical and restrictions on use

Recommended use: No information available.
Uses advised against No information available

Supplier: Spectrum Chemical Mfg. Corp
 14422 South San Pedro St.
 Gardena, CA 90248
 (310) 516-8000

Order Online At: <https://www.spectrumchemical.com>

Emergency telephone number Chemtrec 1-800-424-9300

Contact Person: Martin LaBenz (West Coast)

Contact Person: Ibad Tirmiz (East Coast)

2. HAZARDS IDENTIFICATION

Classification

This chemical is not considered hazardous according to the 2012 OSHA Hazard Communication Standard (29 CFR 1910.1200)

Not a dangerous substance or mixture according to the Globally Harmonized System (GHS)

Label elements

Not classified

Hazards not otherwise classified (HNOC)

Not Applicable

Other hazards

Not available

3. COMPOSITION/INFORMATION ON INGREDIENTS

Components	CAS-No.	Weight %
Cetyl Esters Wax (Spermaceti)	NCAS	100

4. FIRST AID MEASURES

First aid measures

General Advice:	National Capital Poison Center in the United States can provide assistance if you have a poison emergency and need to talk to a poison specialist. Call 1-800-222-1222.
Skin Contact:	Wash off immediately with soap and plenty of water removing all contaminated clothing and shoes. Get medical attention if irritation develops. Consult a physician if necessary.
Eye Contact:	Flush eyes with water for 15 minutes. Get medical attention if irritation occurs. If symptoms persist, call a physician.
Inhalation:	Move to fresh air. If not breathing, give artificial respiration. If breathing is difficult, give oxygen. Get medical attention.
Ingestion:	Do not induce vomiting without medical advice. Never give anything by mouth to an unconscious person. Consult a physician if necessary.

Most important symptoms and effects, both acute and delayed

Symptoms	Health injuries are not known or expected under normal use
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Indication of any immediate medical attention and special treatment needed

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

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

5. FIRE-FIGHTING MEASURES

Extinguishing Media

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

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

Special Protective Actions for Firefighters

Specific Methods:	No information available.
Special Protective Equipment for Firefighters:	As in any fire, wear self-contained breathing apparatus pressure-demand, MSHA/NIOSH (approved or equivalent)

and full protective gear

6. ACCIDENTAL RELEASE MEASURES

Personal precautions, protective equipment and emergency procedures

Personal Precautions: Use personal protective equipment. Avoid contact with skin, eyes and clothing. Remove all sources of ignition.

Environmental precautions Prevent further leakage or spillage if safe to do so. Prevent product from entering drains.

Methods and material for containment and cleaning up

Methods for containment Stop leak if you can do it without risk. Cover with plastic sheet to prevent spreading.

Methods for cleaning up Sweep up and shovel into suitable containers for disposal. Clean contaminated surface thoroughly.

7. HANDLING AND STORAGE

Precautions for safe handling

Technical Measures/Precautions:

Provide sufficient air exchange and/or exhaust in work rooms. 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:

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 Esters Wax (Spermaceti)	NCAS	None	None	None	None

Canada

Components	CAS-No.	Canada - Alberta	Canada - British Columbia	Canada - Ontario	Canada - Quebec
Cetyl Esters Wax (Spermaceti)	NCAS	None	None	None	None

Australia and Mexico

Components	CAS-No.	Australia	Mexico
Cetyl Esters Wax (Spermaceti)	NCAS	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 with side-shields.

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

Respiratory protection: Respiratory protection is not necessary for normal handling. Good room ventilation or use of local exhaust (fume hood) is sufficient.

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: Flakes.	Color: White.
Odor: No information available.	Taste: Mild.	Formula: No information available
Molecular/Formula weight (g/mole): No information available	Flammability: No information available	Flashpoint (°C/°F): 165.6°C/330°F
Flash Point Tested according to: Closed cup	Autoignition Temperature (°C/°F): 251°C/484°F	Lower Explosion Limit (%): No information available
Upper Explosion Limit (%): No information available	Melting point/range(°C/°F): 43-47 °C/109.4-116.6 °F	Decomposition temperature(°C/°F): No information available
Boiling point/range(°C/°F): No information available	Bulk density: No information available	Density (g/cm3): No information available
Specific gravity: 0.897	pH: No information available	Vapor pressure @ 20°C (kPa): No information available
Evaporation rate: No information available	Vapor density: No information available	VOC content (g/L): No information available
Odor threshold (ppm):	Partition coefficient	

Product code: SP310

Product name: CETYL ESTERS
WAX, SYNTHETIC, NF

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No information available

(n-octanol/water):
No information available

Viscosity:
No information available

Miscibility:
No information available

Solubility:
Insoluble in water

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: Strong oxidizing agents

Hazardous decomposition products: No information available.

Other Information

Corrosivity: No information available

Special Remarks on Corrosivity: No information available

11. TOXICOLOGICAL INFORMATION

Information on likely routes of exposure

Principal Routes of Exposure:
Ingestion. Inhalation.

Acute Toxicity

Component Information

Cetyl Esters Wax (Spermaceti)	
CAS-No.	NCAS

LD50/oral/rat = No information available

LD50/oral/mouse = No information available

LD50/dermal/rabbit = No information available

LD50/dermal/rat = No information available

LC50/inhalation/rat = No information available

LC50/inhalation/mouse = No information available

Other LD50 or LC50 information = No information available

Product Information

LD50/oral/rat =

VALUE- Acute Tox Oral = No information available

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

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

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

LC50/inhalation/rat
VALUE-Vapor = No information available
VALUE-Gas = No information available
VALUE-Dust/Mist = No information available

LC50/Inhalation/mouse
VALUE-Vapor = No information available
VALUE - Gas = No information available
VALUE - Dust/Mist = No information available

Symptoms

Skin Contact: May cause skin irritation.
Eye Contact: May cause eye irritation.
Inhalation May cause irritation of respiratory tract.
Ingestion Health injuries are not known or expected under normal use.
Aspiration hazard No information available.

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

Chronic Toxicity No information available.
Sensitization: No information available.
Mutagenic Effects: No information available

Carcinogenic effects: Not considered carcinogenic.

Components	CAS-No.	IARC	ACGIH - Carcinogens	NTP	OSHA HCS - Carcinogens	Australia - Notifiable Carcinogenic Substances	Australia - Prohibited Carcinogenic Substances
Cetyl Esters Wax (Spermaceti)	NCAS	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

Product code: SP310

Product name: CETYL ESTERS
WAX, SYNTHETIC, NF

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 Esters Wax (Spermaceti)	NCAS	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

Product code: SP310

Product name: CETYL ESTERS
WAX, SYNTHETIC, NF

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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 Esters Wax (Spermaceti)</i>	NCAS	Not Listed	Not present	Not present	Not present	Not present	Not present	Not present

U.S. Regulations

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)

Product code: SP310

Product name: CETYL ESTERS
WAX, SYNTHETIC, NF

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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:
Cetyl Esters Wax (Spermaceti)	NCAS	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
Cetyl Esters Wax (Spermaceti)	NCAS	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
Cetyl Esters Wax (Spermaceti)	NCAS	Not Applicable	Not Applicable

Canada**WHMIS 2015 - GHS Classifications**

WHMIS 2015 Hazard Classification Information:

Not a dangerous product according to HPR classification criteria.

Canada Hazardous Products Regulation This product has been classified according to the hazard criteria of the HPR (Hazardous Products Regulation) and the SDS contains all of the information required by the HPR

Inventory

Components	CAS-No.	Canada (DSL)	Canada (NDSL)
Cetyl Esters Wax (Spermaceti)	NCAS	Not Listed	Not Listed

Components	CAS-No.	CEPA Schedule I - Toxic Substances
Cetyl Esters Wax (Spermaceti)	NCAS	Not listed
Components	CAS-No.	CEPA - 2010 Greenhouse Gases Subject to Mandatory Reporting
Cetyl Esters Wax (Spermaceti)	NCAS	Not listed

EU Classification**EU GHS - SV - CLP 1272/2008**

Components	CAS-No.	EU GHS - SV - CLP (1272/2008)
Cetyl Esters Wax (Spermaceti)	NCAS	No information

EU - CLP (1272/2008)**R-phrases(s)**

not determined (not applicable)

S -phrase(s)

none

Components	CAS-No.	Classification	Concentration Limits:	Safety Phrases
Cetyl Esters Wax (Spermaceti)	NCAS		No information	

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

Not dangerous

16. OTHER INFORMATION

Preparation Date: 9/11/2018
Revision Date: 9/11/2018
Prepared by: Sonia Owen

Disclaimer:

All chemicals may pose unknown hazards and should be used with caution. This Safety Data Sheet (SDS) applies only to the material as packaged. If this product is combined with other materials, deteriorates, or becomes contaminated, it may pose hazards not mentioned in this SDS. The physical properties reported in this SDS are obtained from the literature and do not constitute product specifications. Information contained herein does not constitute a warranty, whether expressed or implied, as to the safety, merchantability or fitness of the goods for a particular purpose. Spectrum Chemicals & Laboratory Products, Inc. assumes no responsibility for results obtained or for incidental or consequential damages, including lost profits, arising from the use of these data. No warranty against infringement of any patent, copyright or trademark is made or implied. It shall be the user's responsibility to develop proper methods of handling and personal protection based on the actual conditions of use. While this SDS is based on technical data judged to be reliable, Spectrum assumes no responsibility for the completeness or accuracy of the information contained herein.

End of Safety Data Sheet



Certification of Compliance with current Good Manufacturing Practices

Dear Valued Customer:

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

Catalog Number	Product Name
SP310	Cetyl Esters Wax, Synthetic, 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,

A handwritten signature in black ink, appearing to read "Oralia Chavez", written in a cursive style.

Oralia Chavez
Quality Assurance Specialist

Manufacturing Process Flowchart **Cetyl Esters Wax, Synthetic, NF (Cat# SP310)**

Cetyl Alcohol + Fatty Acids (C12 - C18)

Heat, catalyst



Esterification Reaction



Cetyl Esters



Filter and Fill

CORPORATE HEADQUARTERS

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WEST COAST FACILITY

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Gardena, California 90248

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SP310, Cetyl Esters Wax, Synthetic, NF

Source Statement

The above mentioned catalog item is manufactured by using plant derived material (Palm Oil). No animal derived products are used in the manufacturing process.

BSE/TSE Statement

The above mentioned catalog item does not contain nor is manufactured using any animal derived products and is therefore, BSE/TSE free.

Allergen Statement

The above mentioned catalog item does not contain any of the following:

- Milk
- Egg
- Fish
- Shellfish
- Tree Nuts
- Wheat
- Peanuts
- Soy
- Cereals containing Gluten
- Celery
- Mustard
- Sesame Seed
- Corn
- Latex
- Sulfites > 10 ppm

EU Fragrance Allergen Statement

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

GMO Statement

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

Melamine Statement

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

Nitrosamine Statement

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

Animal Testing Statement

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

Organic Compliance Statement

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

Shelf Life Statement

The above mentioned catalog item is typically assigned a shelf life of 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 | • Parabens |
| • Antibiotics | • Pesticides |
| • Bisphenol A (BPA) | • Phthalates |
| • CMR Substances | • Preservatives |



RE: Elemental Impurities - Cetyl Esters Wax, Synthetic, NF (Cat# SP310)

To Whom It May Concern:

Thank you for your interest in Spectrum high quality chemicals.

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

Elemental Impurity		Class	Expected Concentration
Cadmium	Cd	1	< 0.5 ppm
Lead	Pb	1	< 0.5 ppm
Arsenic	As	1	< 1.5 ppm
Mercury	Hg	1	< 3 ppm
Cobalt	Co	2A	< 5 ppm
Vanadium	V	2A	< 10 ppm
Nickel	Ni	2A	< 20 ppm
Thallium	Tl	2B	< 0.8 ppm
Gold	Au	2B	< 10 ppm
Palladium	Pd	2B	< 10 ppm
Iridium	Ir	2B	< 10 ppm
Osmium	Os	2B	< 10 ppm
Rhodium	Rh	2B	< 10 ppm
Ruthenium	Ru	2B	< 10 ppm
Selenium	Se	2B	< 15 ppm
Silver	Ag	2B	< 15 ppm
Platinum	Pt	2B	< 10 ppm
Lithium	Li	3	< 55 ppm
Antimony	Sb	3	< 120 ppm
Barium	Ba	3	< 140 ppm
Molybdenum	Mo	3	< 300 ppm
Copper	Cu	3	< 300 ppm
Tin	Sn	3	< 600 ppm
Chromium	Cr	3	< 1100 ppm

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

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Gardena, California 90248

PHONE 310.516.8000

FAX 310.516.9843



substances are not used in the production process, are not intentionally added or known to be present in the above mentioned material.

This information is subject to change and is intended for risk assessment only. It is responsibility of the end user to evaluate suitability of any chemical for the intended use as well as to assess compound-specific limits of daily intake of metal impurities. For lot-specific information, please refer to the respective Certificate of Analysis.

If you have any further questions, please contact us by telephone at 1(800)772-8786 Option 2, or by email at TechServices@spectrumchemical.com.

Sincerely,

Technical Services
Spectrum Chemical Mfg. Corp.

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

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WEST COAST FACILITY

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Gardena, California 90248
PHONE 310.516.8000
FAX 310.516.9843



RE: Residual Solvents - Cetyl Esters Wax, Synthetic, NF (Cat# SP310)

To Whom It May Concern:

Thank you for your interest in Spectrum high quality chemicals.

The above mentioned catalog item complies with the requirements of USP <467> Residual Solvents and ICH Q3C Residual Solvents Guideline. The following solvents are likely to be present:

Residual Solvent	Class	Expected Concentration
Toluene	2	< 890 ppm

No Class 1, Class 3 or other solvents are used or produced in the manufacturing process of this material.

For lot-specific information, please refer to the respective Certificate of Analysis.

If you have any further questions, please contact us by telephone at 1(800)772-8786 Option 2, or by email at TechServices@spectrumchemical.com.

Sincerely,

Technical Services
Spectrum Chemical Mfg. Corp.

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WEST COAST FACILITY

14422 South San Pedro Street
Gardena, California 90248
PHONE 310.516.8000
FAX 310.516.9843

Label Information

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

USE CARE: This material has been evaluated per GHS/OSHA criteria and is not classified as hazardous. All chemicals may pose unknown hazards and must be used with caution. Use personal protection and safe handling methods consistent with proper workplace safety practices. Consult SDS for additional properties and precautions. If adverse reaction occurs seek medical attention.

KEEP FROM CHILDREN

SP310

SIZ SY

Cetyl Esters Wax

(Spermaceti)

Synthetic

NF

CAUTION: For manufacturing, processing or repacking.

Read and understand the label and Safety Data Sheet (SDS) prior to use.

Chemical Emergency: (800)424-9300

www.SpectrumChemical.com

This product is a mixture consisting primarily of esters of saturated fatty alcohols (C₁₂ to C₁₈) and saturated fatty acids (C₁₂ to C₁₈).

Total Fatty Esters and Cetyl Palmitate To pass test
Fatty Esters with Carbon-Chain Length, %:

C26	?
C28	?
C30	?
C32	?
C34	?
C36	?
Melting Range	43°-47°C

MAXIMUM LIMITS

Total Free Fatty Alcohols and Free Fatty Acids	10.0%
Iodine Value	1
Acid Value	5
Paraffin and Free Acids	To pass test
Elemental Impurities	As reported
Residual Solvents	To pass test

G 10/H10GHS

?

Lot No. XQ####

Spectrum Chemical Mfg Corp

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New Brunswick, NJ 08901
732.214.1300

West Coast Facility:

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