

## **Scientific Documentation**

## **Clove Oil, FCC**

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

Spectrum Chemical Mfg Corp 769 Jersey Avenue New Brunswick, NJ 08901 Phone 732.214.1300





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Product Specification Certificate of Analysis Safety Data Sheet (SDS) Certification of Current Good Manufacturing Practices (cGMP) Manufacturing Process Flowchart Technical Statements General Label Information – Sample Label



## **Specification for Clove Oil, FCC (CL130)**

Item Number	CL130
Item	Clove Oil, FCC
CAS Number	8000-34-8
Molecular Formula	
Molecular Weight	
MDL Number	
Synonyms	Caryophylli Floris Aetheroleum ; Clove Bud Oil ; Eugenia Caryophyllus (Clove) Flower Oil

Test	Specification		
	Min	Max	
ASSAY (PHENOLS)	85.0 %		
ANGULAR ROTATION	$-1.5^{\circ}$ to $0^{\circ}$		
PHENOLS	NO BLUE OR VIOLET COLOR		
REFRACTIVE INDEX @ 20°C	1.527	1.535	
SOLUBILITY IN 70% ALCOHOL	1 ml SAMPLE DISSOLVES IN 2 ml 70% ALCOHOL		
SPECIFIC GRAVITY @ 25°C	1.038	1.060	
IDENTIFICATION (FTIR)	SPECTRUM MATCHES REFERENCE		
CERTIFIED HALAL			
EXPIRATION DATE			
DATE OF MANUFACTURE			
APPEARANCE			

#### Spectrum Chemical Mfg Corp

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



### **Certificate Of Analysis**

Item Number	CL130	Lot Number	2MK0167
Item	Clove Oil, FCC	CAS Number	8000-34-8

тест	SPECIFICATION		DECLUZ	
TEST	MIN	MAX	RESULT	
ASSAY (PHENOLS)	85.0 %		86.0 %	
ANGULAR ROTATION	-1.5° to 0°		-0.8°	
PHENOLS	NO BLUE OR VIOLET COLOR		NO BLUE OR VIOLET COLOR	
REFRACTIVE INDEX @ 20 <sup>0</sup> C	1.527	1.535	1.5334	
SOLUBILITY IN 70% ALCOHOL	1 ml SAMPLE DISSOLVES IN 2 ml 70% ALCOHOL		1 ml SAMPLE DISSOLVES IN 2 ml 70% ALCOHOL	
SPECIFIC GRAVITY @ 25 <sup>0</sup> C	1.038	1.060	1.0462	
	SPECTRUM MATCHES REFERENCE		SPECTRUM MATCHES REFERENCE	
CERTIFIED HALAL			CERTIFIED HALAL	
EXPIRATION DATE			04-OCT-2025	
DATE OF MANUFACTURE			04-OCT-2023	
APPEARANCE			PALE YELLOW LIQUID	
MONOGRAPH EDITION			FCC 13TH	

Certificate of Analysis Results Entered By:

MCAMACHO Matheu Camacho 05-DEC-23 11:27:21

Spectrum Chemical Mfg Corp 755 Jersey Avenue New Brunswick 08901 NJ



Certificate of Analysis Results Approved By:

GHERRERA Genaro Herrera 08-DEC-23 06:04:33 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.

## SAFETY DATA SHEET

Revision date 18-August-2022

1. Identification	
Product identifier	
Product Name	CLOVE OIL, FCC
Other means of identification	
Product Code(s)	CL130
Synonyms	None
Recommended use of the chemical	and restrictions on use
Recommended use	No information available
Restrictions on use	No information available
Details of the supplier of the safety	data sheet
<u>Supplier Address</u> Spectrum Chemical Mfg. Corp. 14422 South San Pedro St. Gardena, CA 90248 (310) 516-8000	

Emergency telephone number

**Emergency Telephone** 

Chemtrec 1-800-424-9300

#### 2. Hazard(s) identification

#### **Classification**

Skin corrosion/irritation	Category 2
Serious eye damage/eye irritation	Category 2A
Skin sensitization	Category 1A
Specific target organ toxicity (single exposure)	Category 3
Flammable liquids	Category 4

#### Hazards not otherwise classified (HNOC)

Not applicable

#### Label elements

Warning

#### Hazard statements

Causes skin irritation Causes serious eye irritation May cause an allergic skin reaction May cause respiratory irritation



Revision Number 2

# Combustible liquid Appearance Clear viscous Physical state Oily liquid Odor No information available

#### **Precautionary Statements - Prevention**

Wash face, hands and any exposed skin thoroughly after handling Avoid breathing dust/fume/gas/mist/vapors/spray Contaminated work clothing must not be allowed out of the workplace Use only outdoors or in a well-ventilated area Keep away from flames and hot surfaces. - No smoking Keep cool Wear protective gloves/protective clothing/eye protection/face protection

#### **Precautionary Statements - Response**

Specific treatment (see .? on this label) 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 IF ON SKIN: Wash with plenty of water and soap Call a POISON CENTER or doctor if you feel unwell Take off contaminated clothing and wash it before reuse If skin irritation or rash occurs: Get medical advice/attention IF INHALED: Remove person to fresh air and keep comfortable for breathing Call a POISON CENTER or doctor if you feel unwell In case of fire: Use CO2, dry chemical, or foam to extinguish

#### **Precautionary Statements - Storage**

Store in a well-ventilated place. Keep container tightly closed Store locked up.

#### **Precautionary Statements - Disposal**

Dispose of contents/container to an approved waste disposal plant

#### Unknown acute toxicity

#### Other information

May be harmful if swallowed.

#### 3. Composition/information on ingredients

#### Substance

Chemical name	CAS No	Weight-%	Trade secret
Clove Oil	8000-34-8	100	*

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

#### 4. First-aid measures

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

**General advice** 

Show this safety data sheet to the doctor in attendance.

Inhalation

Remove to fresh air. IF exposed or concerned: Get medical advice/attention. Get medical attention immediately if symptoms occur.

Eye contact	Rinse immediately with plenty of water, also under the eyelids, for at least 15 minutes. Keep eye wide open while rinsing. Do not rub affected area. Remove contact lenses, if present and easy to do. Continue rinsing. Get medical attention if irritation develops and persists.	
Skin contact	Wash off immediately with soap and plenty of water while removing all contaminated clothes and shoes. May cause an allergic skin reaction. If symptoms persist, call a physician.	
Ingestion	Do NOT induce vomiting. Clean mouth with water and drink afterwards plenty of water. Never give anything by mouth to an unconscious person. Call a physician.	
Self-protection of the first aider	Remove all sources of ignition. Ensure that medical personnel are aware of the material(s) involved, take precautions to protect themselves and prevent spread of contamination. Wear personal protective clothing (see section 8). Avoid contact with skin, eyes or clothing.	
Most important symptoms and effects, both acute and delayed		
Symptoms	Itching. Rashes. Hives. May cause redness and tearing of the eyes. Burning sensation.	
Indication of any immediate medical attention and special treatment needed		
Note to physicians	May cause sensitization in susceptible persons. Treat symptomatically.	

5. Fire-fighting measure	es
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Suitable Extinguishing Media Large Fire	Dry chemical. Carbon dioxide (CO2). water spray. Alcohol resistant foam. CAUTION: Use of water spray when fighting fire may be inefficient.
Unsuitable extinguishing media	Do not scatter spilled material with high pressure water streams.
Specific hazards arising from the chemical	Keep product and empty container away from heat and sources of ignition. In the event of fire, cool tanks with water spray. Product is or contains a sensitizer. May cause sensitization by skin contact.
Hazardous combustion products	Burns rapidly, releasing dense, white, irritating fumes.
Explosion data Sensitivity to mechanical impac	ct none.
Sensitivity to static discharge	yes.
Special protective equipment for fire-fighters	Firefighters should wear self-contained breathing apparatus and full firefighting turnout gear. Use personal protection equipment.

#### 6. Accidental release measures

Personal precautions, protective equipment and emergency procedures

Personal precautions	Evacuate personnel to safe areas. Use personal protective equipment as required. See section 8 for more information. Take precautionary measures against static discharges. Do not touch or walk through spilled material. Avoid contact with skin, eyes or clothing. Ensure adequate ventilation. Keep people away from and upwind of spill/leak.
Other information	Refer to protective measures listed in Sections 7 and 8.
Methods and material for containn	nent and cleaning up
Methods for containment	Stop leak if you can do it without risk. Do not touch or walk through spilled material. Dike far ahead of liquid spill for later disposal.
Methods for cleaning up	Take precautionary measures against static discharges. Dam up. Soak up with inert absorbent material. Pick up and transfer to properly labeled containers.

#### 7. Handling and storage

#### Precautions for safe handling

Advice on safe handling Use personal protection equipment. Do not breathe vapor or mist. Keep away from heat, hot surfaces, sparks, open flames and other ignition sources. No smoking. Take precautionary measures against static discharges. Use with local exhaust ventilation. Handle in accordance with good industrial hygiene and safety practice. Avoid contact with skin, eyes or clothing. In case of insufficient ventilation, wear suitable respiratory equipment. Do not eat, drink or smoke when using this product. Take off contaminated clothing and wash before reuse.

#### Conditions for safe storage, including any incompatibilities

**Storage Conditions** Keep containers tightly closed in a dry, cool and well-ventilated place. Keep away from heat, sparks, flame and other sources of ignition (i.e., pilot lights, electric motors and static electricity). Keep in properly labeled containers. Store in accordance with the particular national regulations. Store in accordance with local regulations. Store locked up. Keep out of the reach of children.

#### 8. Exposure controls/personal protection

#### Control parameters

Exposure Limits	The following ingredients are the only ingredients of the product above the cut-off level (or level that contributes to the hazard classification of the mixture) which have an exposure limit applicable in the region for which this safety data sheet is intended or other recommended limit. At this time, the other relevant constituents have no known exposure limits from the sources listed here.
Appropriate engineering controls	
Engineering controls	Showers Eyewash stations Ventilation systems.
Individual protection measures, suc	ch as personal protective equipment
Eye/face protection	Tight sealing safety goggles.
Hand protection	Wear suitable gloves. Impervious gloves.
Skin and body protection	Wear suitable protective clothing. Long sleeved clothing.
Respiratory protection	No protective equipment is needed under normal use conditions. If exposure limits are exceeded or irritation is experienced, ventilation and evacuation may be required.
General hygiene considerations	Do not eat, drink or smoke when using this product. Contaminated work clothing should not be allowed out of the workplace. Regular cleaning of equipment, work area and clothing is recommended. Wash hands before breaks and immediately after handling the product. Avoid contact with skin, eyes or clothing. Wear suitable gloves and eye/face protection.

#### 9. Physical and chemical properties

Information on basic physical and chemical properties

Physical state Appearance Color Odor Odor threshold Oily liquid Clear viscous Colorless to pale yellow or brown No information available No information available

<u>Property</u> pH Melting point / freezing point Boiling point / boiling range	<u>Values</u> no data available no data available 251 °C / 483.8 °F	Remarks • Method None known None known None known
Flash point	no data available	None known
Evaporation rate	no data available	None known
Flammability (solid, gas)	no data available	None known
Flammability Limit in Air		None known
Upper flammability or explosive	No data available	
limits		
Lower flammability or explosive	No data available	
limits		
Vapor pressure	No data available	None known
Vapor density	no data available	None known
Relative density	1.04	None known
Water solubility	Insoluble in water	None known
Solubility(ies)	Soluble in Alcohol	None known
Partition coefficient	No data available	None known
Autoignition temperature	no data available	None known
Decomposition temperature		None known
Kinematic viscosity	no data available	None known
Dynamic viscosity	No data available	None known
Other information		
Explosive properties	No information available	
Oxidizing properties	No information available	
Softening point	No information available	
Molecular weight	No information available	
VOC Content (%)	No information available	
Liquid Density	No information available	

#### 10. Stability and reactivity

Bulk density

Reactivity	No information available.
Chemical stability	Stable under normal conditions.
Possibility of hazardous reactions	None under normal processing.
Conditions to avoid	Heat, flames and sparks.
Incompatible materials	Strong acids. Strong bases. Strong oxidizing agents.

No information available

Hazardous decomposition products None known based on information supplied.

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#### 11. Toxicological information

Information on likely routes of exposure

#### **Product Information**

Inhalation	Specific test data for the substance or mixture is not available. May cause irritation of respiratory tract.
Eye contact	Specific test data for the substance or mixture is not available. Irritating to eyes. (based on components). Causes serious eye irritation.

Skin contact	May cause sensitization by skin contact. Specific test data for the substance or mixture is not available. Repeated or prolonged skin contact may cause allergic reactions with susceptible persons. (based on components). Causes skin irritation.
Ingestion	Specific test data for the substance or mixture is not available. Ingestion may cause gastrointestinal irritation, nausea, vomiting and diarrhea. May be harmful if swallowed.
Symptoms related to the physical,	chemical and toxicological characteristics
Symptoms	Itching. Rashes. Hives. Redness. May cause redness and tearing of the eyes.
Acute toxicity	

Numerical measures of toxicity

#### Unknown acute toxicity

Chemical name	Oral LD50	Dermal LD50	Inhalation LC50
Clove Oil	= 1370 mg/kg (Rat)	= 1200 mg/kg (Rabbit)	-
8000-34-8			

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

Skin corrosion/irritation Serious eye damage/eye irritation Respiratory or skin sensitization Germ cell mutagenicity	Classification based on data available for ingredients. Irritating to skin. Classification based on data available for ingredients. Causes serious eye irritation. May cause sensitization by skin contact. No information available.
Reproductive toxicity	No information available.
STOT - single exposure STOT - repeated exposure Aspiration hazard	No information available. No information available. No information available.
Other adverse effects	No information available.
Interactive effects	No information available.

#### 12. Ecological information

Ecotoxicity	The environmental impact of this product has not been fully investigated.
Persistence and degradability Bioaccumulation	No information available. Inherently biodegradable.
Other adverse effects	No information available.

#### 13. Disposal considerations

#### Waste treatment methods

Waste from residues/unused products	Dispose of in accordance with local regulations. Dispose of waste in accordance with environmental legislation.
Contaminated packaging	Do not reuse empty containers.

#### 14. Transport information

DOT	not regulated
TDG	not regulated
MEX	not regulated
ICAO (air)	not regulated
IATA	not regulated
IMDG_	not regulated
RID	not regulated
ADR	not regulated
ADN	not regulated

#### 15. Regulatory information

#### International Inventories

TSCA

Complies

DSL/NDSL	Complies
EINECS/ELINCS	Does not Comply
ENCS	This product complies with ENCS:
IECSC	This product complies with China:
KECL	Complies
PICCS	Complies
AICS	All the constituents of this material are listed on the Australian Inventory of Chemical Substances (AICS).

Legend:

**TSCA** - United States Toxic Substances Control Act Section 8(b) Inventory

DSL/NDSL - Canadian Domestic Substances List/Non-Domestic Substances List

EINECS/ELINCS - European Inventory of Existing Chemical Substances/European List of Notified Chemical Substances

ENCS - Japan Existing and New Chemical Substances

**IECSC** - China Inventory of Existing Chemical Substances

KECL - Korean Existing and Evaluated Chemical Substances

PICCS - Philippines Inventory of Chemicals and Chemical Substances

#### US Federal Regulations

#### **SARA 313**

Section 313 of Title III of the Superfund Amendments and Reauthorization Act of 1986 (SARA). This product does not contain any chemicals which are subject to the reporting requirements of the Act and Title 40 of the Code of Federal Regulations, Part 372.

#### SARA 311/312 Hazard Categories

Should this product meet EPCRA 311/312 Tier reporting criteria at 40 CFR 370, refer to Section 2 of this SDS for appropriate classifications.

#### CWA (Clean Water Act)

This product does not contain any substances regulated as pollutants pursuant to the Clean Water Act (40 CFR 122.21 and 40 CFR 122.42).

#### **CERCLA**

This material, as supplied, does not contain any substances regulated as hazardous substances under the Comprehensive

Environmental Response Compensation and Liability Act (CERCLA) (40 CFR 302) or the Superfund Amendments and Reauthorization Act (SARA) (40 CFR 355). There may be specific reporting requirements at the local, regional, or state level pertaining to releases of this material.

#### US State Regulations

#### **California Proposition 65**

This product does not contain any Proposition 65 chemicals.

#### U.S. State Right-to-Know Regulations

This product does not contain any substances regulated under applicable state right-to-know regulations

#### U.S. EPA Label Information

EPA Pesticide Registration Number Not applicable

#### 16. Other information

#### NFPA Health hazards 2 Flammability 0 Instability 0 Physical and chemical properties -HMIS Health hazards 2 Flammability 0 Physical hazards 0 Personal protection X Key or legend to abbreviations and acronyms used in the safety data sheet Legend Section 8: EXPOSURE CONTROLS/PERSONAL PROTECTION TWA (time-weighted average) STEL (Short Term Exposure Limit) TWA STEL Ceiling Maximum limit value Key literature references and sources for data used to compile the SDS Agency for Toxic Substances and Disease Registry (ATSDR) U.S. Environmental Protection Agency ChemView Database European Food Safety Authority (EFSA) EPA (Environmental Protection Agency) Acute Exposure Guideline Level(s) (AEGL(s)) U.S. Environmental Protection Agency Federal Insecticide, Fungicide, and Rodenticide Act U.S. Environmental Protection Agency High Production Volume Chemicals Food Research Journal Hazardous Substance Database International Uniform Chemical Information Database (IUCLID) Japan GHS Classification Australia National Industrial Chemicals Notification and Assessment Scheme (NICNAS) NIOSH (National Institute for Occupational Safety and Health) National Library of Medicine's ChemID Plus (NLM CIP) National Library of Medicine's PubMed database (NLM PUBMED) National Toxicology Program (NTP) New Zealand's Chemical Classification and Information Database (CCID) Organization for Economic Co-operation and Development Environment, Health, and Safety Publications Organization for Economic Co-operation and Development High Production Volume Chemicals Program Organization for Economic Co-operation and Development Screening Information Data Set World Health Organization **Revision date** 18-August-2022

Revision date18-August-2022Revision NoteNo information available.Disclaimer

The information provided in this Safety Data Sheet is correct to the best of our knowledge, information and belief at the date of its publication. The information given is designed only as a guidance for safe handling, use, processing, storage, transportation, disposal and release and is not to be considered a warranty or quality specification. The information relates only to the specific material designated and may not be valid for such material used in combination with any other materials or in any process, unless specified in the text.

#### End of Safety Data Sheet

## spectrum

#### 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
CL130	Clove Oil, FCC

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: Spectrum-New Brunswick, NJ: 2020632 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 <u>qualityassurance@spectrumchemical.com</u>

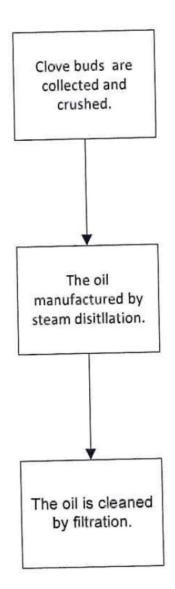
Sincerely,

Oulu Umy

Oralia Chavez Quality Assurance Specialist



#### Manufacturing Process Flowchart Clove Oil, FCC (Cat# CL130)



#### CORPORATE HEADQUARTERS

769 Jersey Avenue New Brunswick, NJ 08901 PHONE 732.214.1300 FAX 732.246.7132

#### WEST COAST FACILITY

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

AN ISO 9001:2015 REGISTERED COMPANY

www.spectrumchemical.com

## spectrum

#### CL130 - Clove Oil, FCC

#### **Source Statement**

The above-mentioned catalog item is a plant derived material (bud of *Eugenia*). 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 contains the following substances found among the 26 EU fragrance allergens listed in Annex III lines 67-92: Benzyl Alcohol, approximately 0.5% and Eugenol, present as at least 85% by volume of the oil. These substances are not intentionally or externally added to the clove oil.

#### **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:

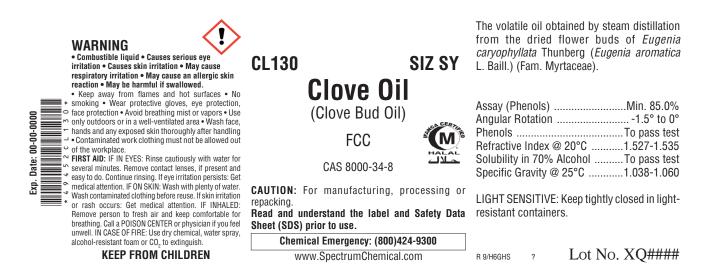
- Aflatoxins
- Antibiotics
- Bisphenol A (BPA)
- CMR Substances

- Parabens
- Pesticides
- Phthalates
- Preservatives

## spectrum®

#### **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.



#### Spectrum Chemical Mfg Corp

#### Corporate Headquarters:

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