

Scientific Documentation

Eugenol, USP

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 Eugenol, USP (EU110)

Item Number	EU110
Item	Eugenol, USP
CAS Number	97-53-0
Molecular Formula	C ₁₀ H ₁₂ O ₂
Molecular Weight	164.20
MDL Number	
Synonyms	4-Allylguaiacol ; 4-Allyl-2-methoxyphenol ; Eugenic Acid

Test	Specification			
	Min	Max		
SOLUBILITY IN 70% ALCOHOL		TO PASS TEST		
SPECIFIC GRAVITY @ 25°C	1.064	1.070		
DISTILLING RANGE (min. 95 %)	250°	255°C		
REFRACTIVE INDEX @ 20°C	1.540	1.542		
ELEMENTAL IMPURITIES		AS REPORTED		
HYDROCARBONS		TO PASS TEST		
PHENOLS		TO PASS TEST		
IDENTIFICATION		TO PASS TEST		
EXPIRATION DATE				
CERTIFIED HALAL				
DATE OF MANUFACTURE				
APPEARANCE				
RESIDUAL SOLVENTS		TO PASS TEST		

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	EU110	Lot Number	2NA0190
Item	Eugenol, USP	CAS Number	97-53-0
Molecular Formula	C ₁₀ H ₁₂ O ₂	Molecular Weight	164.20

TFCT	SPECIFICATION			
TEST	MIN	MAX	RESULT	
SOLUBILITY IN 70% ALCOHOL		TO PASS TEST	PASSES TEST	
SPECIFIC GRAVITY @ 25°C	1.064	1.070	1.0640	
DISTILLING RANGE (min. 95 %)	250°	255°C	250 255°C	
REFRACTIVE INDEX @ 20°C	1.540	1.542	1.5410	
ELEMENTAL IMPURITIES		AS REPORTED	NO ELEMENTAL IMPURITIES PRESENT	
HYDROCARBONS		TO PASS TEST	PASSES TEST	
PHENOLS		TO PASS TEST	PASSES TEST	
IDENTIFICATION		TO PASS TEST	PASSES TEST	
EXPIRATION DATE			16-DEC-2025	
CERTIFIED HALAL			CERTIFIED HALAL	
DATE OF MANUFACTURE			17-DEC-2023	
APPEARANCE			COLORLESS LIQUID	
RESIDUAL SOLVENTS		TO PASS TEST	NO RESIDUAL SOLVENT PRESENT	
MONOGRAPH EDITION			USP 2023	

Certificate of Analysis Results Entered By:

CMARIN Catherine Marin 26-FEB-24 13:18:27

Spectrum Chemical Mfg Corp 755 Jersey Avenue New Brunswick 08901 NJ



Certificate of Analysis Results Approved By:

MCAMACHO Matheu Camacho 26-FEB-24 13:32:43

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.

spectrum[®]



SAFETY DATA SHEET

Preparation Date: 03/05/2015

Revision Date: 06/25/2018

Revision Number: G2

1. IDENTIFICATION

|--|

Product code: **Product Name:** EU110 EUGENOL, USP

Other means of identification Synony

Other means of identification	
Synonyms:	4-Allylguaiacol
	4-Allyl-2-methoxyphenol
	4-Allylcatechol-2-methyl ether
	p-Allylguaiacol
	4-Allylguaiacol
	4-Allyl-1-hydroxy-2-methoxybenzene
	4-Allyl-2-methoxyphenol
	Caryophyllic acid
	Eugenic acid
	p-Eugenol
	1,3,4-Eugenol
	Hydroxy-1-methoxy-2-allyl-4-benzene
	1-Hydroxy-2-methoxy-4-allylbenzene
	4-Hydroxy-3-methoxyallylbenzene
	1-Hydroxy-2-methoxy-4-prop-2-enylbenzene
	2-Methoxy-4-allylphenol
	2-Methoxy-1-hydroxy-4-allylbenzene
	2-Methoxy-4-prop-2-enylphenol
	2-Methoxy-4-(2-propenyl)phenol
	2-Metoksy-4-allilofenol (Polish)
	Phenol, 4-ally-2-methoxy
	Phenol, 2-methoxy-4-(2-propenyl)-
CAS #:	97-53-0
RTECS #	SJ4375000
CI#:	Not available
Ci#.	
Recommended use of the chem	ical and restrictions on use
Recommended use:	Insecticide.
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 Borson:	Ibad Tirmiz (East Coast)

Martin LaBenz (West Coast) Ibad Tirmiz (East Coast)

2. HAZARDS IDENTIFICATION

Classification

Contact Person:

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)

Acute toxicity - Oral	Category 4
Serious eye damage/eye irritation	Category 2A
Skin sensitization	Category 1B

Label elements

Warning Hazard statements Harmful if swallowed Causes serious eye irritation May cause an allergic skin reaction



Hazards not otherwise classified (HNOC) Not Applicable

Other hazards Not available

Precautionary Statements - Prevention

Wash face, hands and any exposed skin thoroughly after handling Do not eat, drink or smoke when using this product Avoid breathing dust/fume/gas/mist/vapors/spray Contaminated work clothing must not be allowed out of the workplace Wear protective gloves/protective clothing/eye protection/face protection

Precautionary Statements - Response

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 If skin irritation or rash occurs: Get medical advice/attention Wash contaminated clothing before reuse IF SWALLOWED: Call a POISON CENTER or doctor/physician if you feel unwell Rinse mouth

Precautionary Statements - Disposal

Dispose of contents/container to an approved waste disposal plant

3. COMPOSITION/INFORMATION ON INGREDIENTS

Components	CAS-No.	Weight %
Eugenol	97-53-0	100

4. FIRST AID MEASURES

First aid measures

General Advice:		n Center in the United States can provide assistance if you
	1-800-222-1222.	ncy and need to talk to a poison specialist. Call
Skin Contact:		h soap and plenty of water removing all contaminated clothing and tion. If skin irritation persists, call a physician.
Eye Contact:	Flush eyes with water for	15 minutes. Get medical attention.
Inhalation:	Move to fresh air. If not b oxygen. Get medical atte	reathing, give artificial respiration. If breathing is difficult, give ntion.
Ingestion:	Do not induce vomiting w unconscious person. Obt	ithout medical advice. Never give anything by mouth to an ain medical attention.
Most important symptoms and effect	ts, both acute and delay	ed
Symptoms	Causes serious eye irrita Moderately irritating to th Eye contact may result in May cause an allergic ski May cause nausea and v gastroenteritis May cause central nervor Somnolence Ataxia	e eyes n redness or pain in reaction omiting
Indication of any immediate medica	l attention and special tr	eatment needed
Notes to Physician:	Treat symptomatically.	
Protection of first-aiders First-Aid Providers: Avoid exposure to contaminated clothing and equipment		ar gloves and other necessary protective clothing. Dispose of
	5. FIRE-FIGHT	ING MEASURES
Extinguishing Media Suitable Extinguishing Media:		Carbon dioxide (CO2). Dry chemical. Water spray mist or foam.
Unsuitable Extinguishing Media	:	Do not use a solid (straight) water stream as it may scatter and spread fire.
Specific hazards arising from	the chemical	
Hazardous Combustion Product	s:	Carbon Monoxide, Carbon Dioxide.
Specific hazards:		May be combustible at high temperatures. May be ignited by heat, sparks or flames. Container explosion may occur under fire conditions or when heated. When heated to decompositon it emits acrid smoke and irritating fumes.
Special Protective Actions for	r Firefighters	
Specific Methods:		Water mist may be used to cool closed containers. For larger fires, use water spray or fog. Cool containers with flooding quantities of water until well after fire is out. Dike fire-control water for later disposal; do not scatter the material.

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. Keep people away from and upwind of spill/leak. Avoid contact with skin, eyes and clothing. Use personal protective equipment. 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 contain	inment and cleaning up	
Methods for containment	Stop leak if you can do it without risk. Absorb spill with inert material (e.g. vermiculite, dry sand or earth). In case of large spill, dike if needed. Dike far ahead of liquid spill for later disposal.	
Methods for cleaning up	Use appropriate tools to put the spilled material in a suitable chemical waste disposal container. 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. Remove all sources of ignition. Keep away from incompatible materials.

Safe Handling Advice

Wear personal protective equipment. Use only in well-ventilated areas. Avoid contact with skin, eyes and clothing. Keep away from heat and sources of ignition. Do not breathe vapors or spray mist. Do not ingest. When using do not smoke. Handle in accordance with good industrial hygiene and safety practice.

Conditions for safe storage, including any incompatibilities

Technical Measures/Storage Conditions:

Keep container tightly closed in a dry and well-ventilated place. Store at room temperature in the original container. Store away from incompatible materials. Sensitive to light. Store in light-resistant containers.

Incompatible Materials:

Oxidizing agents

8. EXPOSURE CONTROLS/PERSONAL PROTECTION

Control parameters

National occupational exposure limits

United States

Components	CAS-No.	OSHA	NIOSH	ACGIH	AIHA WEEL
Eugenol	97-53-0	None	None	None	None

Canada

Components	CAS-No.	Canada - Alberta	Canada - British Columbia	Canada - Ontario	Canada - Quebec
Eugenol	97-53-0	None	None	None	None

Australia and Mexico

Components	CAS-No.	Australia	Mexico
Eugenol	97-53-0	None	None

Appropriate engineering controls

Engineering measures to reduce exposure:

Ensure adequate ventilation. Provide exhaust ventilation or other engineering controls to keep the airborne concentrations of vapors and mist below their respective threshold limit value.

Individual protection measures, such as personal protective equipment

Personal Protective Equipment

Eye protection:	Goggles			
Skin and body protection: Chemical resistant apron Gloves Long sleeved clothing				
Respiratory protection: Respiratory protection is not necessary for normal handling. Good room ventilation or use of local exhaust (fume hood) is sufficient. Use a vapor reunder conditions where exposure to the substance is apparent (e.g. general high concentrations of mist or vapor, inadequate ventilation, development or respiratory tract irritation), and engineering controls are not feasible. Be su use an approved/certified respirator or equivalent.				
Hygiene measures:	Avoid contact with skin, eyes and clothing immediately after handling the product. W			
9	. PHYSICAL AND CHEMICAL PROPE	RTIES		
Physical state:	Appearance:	Color:		
Liquid	No information available.	Colorless. Yellow.		
Odor:	Taste	Formula:		
Clove-like.	No information available.	C10H12O2		
Molecular/Formula weight: 164.20	Flammability: No information available	Flashpoint (°C/°F): 104°C/219.2°F		
Flash Point Tested according to	: Autoignition Temperature (°C/°F):	Lower Explosion Limit (%):		
Open cup	No information available	No information available		
Upper Explosion Limit (%):	Melting point/range(°C/°F):	Decomposition temperature(°C/°F):		
No information available	-7.5°C/18.5°F	No information available		
Boiling point/range(°C/°F):	Bulk density:	Density (g/cm3):		
253.2°C/487.8°F	No information available	No information available		
Specific gravity:	pH:	Vapor pressure @ 20°C (kPa):		
1.055	No information available	0.03 mmHg		

Evaporation rate: No information available	Vapor density: No information available
Odor threshold (ppm): No information available	Partition coefficient (n-octanol/water): No information available
Miscibility: No information available	Solubility: Insoluble in cold water
	10. STABILITY AND F
Reactivity Reactive with oxidizing agents	

VOC content (g/L): No information available

Viscosity: No information available

ND REACTIVITY

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. Exposure to light.
Incompatible Materials:	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.

Acute Toxicity

Component Information

Eugenol	
CAS-No.	97-53-0
LD50/oral/rat	1930 mg/kg Oral LD50 Rat
LD50/oral/mo	se = 3000 mg/kg
LD50/dermal/	bbit = No information available
LD50/dermal/	t = No information available
LC50/inhalati	n/rat = No information available
LC50/inhalati	n/mouse = No information available
Other LD50 o	LC50information = No information available
Product Informa	on

LD50/oral/rat =

VALUE- Acute Tox Oral = 1930	mg/kg
LD50/oral/mouse = Value - Acute Tox Oral = 3000 r	mg/kg
LD50/dermal/rabbit VALUE-Acute Tox Dermal = No	information available
LD50/dermal/rat VALUE -Acute Tox Dermal = No	o information available
LC50/inhalation/rat VALUE-Vapor = No information a VALUE-Gas = No information ava VALUE-Dust/Mist = No informati	ailable
LC50/Inhalation/mouse VALUE-Vapor = No information a VALUE - Gas = No information av VALUE - Dust/Mist = No information	vailable
<u>Symptoms</u>	
Skin Contact:	May cause skin irritation. May cause allergic skin reaction.
Eye Contact:	Causes serious eye irritation.
Inhalation	May cause irritation of respiratory tract.
Ingestion	Harmful if swallowed. May cause gastroenteritis. Ingestion may cause nausea, vomiting. May affect behavior/central nervous system (somnolence, ataxia). May affect respiration (dyspnea - difficulty breathing and shortness of breath).
Aspiration hazard	No information available.
Delayed and immediate effects a	as well as chronic effects from short and long-term exposure
Chronic Toxicity	Skin: Sensitizer. May cause allergic skin reaction (allergic contact dermatitis).
Sensitization:	May cause sensitization by skin contact.
Mutagenic Effects:	DNA damage - hamster ovary DNA damage - rat liver Mutations in microorganisms Experiments with bacteria and/or yeast have shown mutagenic effects Sister Chromatid Exchange (hamster embryo) Sister Chromatid Exchange - Hamster ovary Cytogenic analysis - hamster ovary Cytogenic Analysis: human lymphocyte

Carcinogenic effects: Not considered carcinogenic.

Components	CAS-No.	IARC	ACGIH - Carcinogens	NTP	OSHA HCS - Carcinogens	Australia - Notifiable Carcinogenic Substances	Australia - Prohibited Carcinogenic Substances
Eugenol		Supplement 7 [1987] Monograph 36 [1985]	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

<u>Ecotoxicity</u>	
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
Eugenol	97-53-0	None	None	None	None

14. TRANSPORT INFORMATION

• ·	
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	No information available
Number	
Marine Pollutant	No data available
DOT RQ (lbs):	No information available

Special Provisions Symbol(s): **Description:**

TDG (Canada)

UN-No: **Proper Shipping Name:** Hazard Class: Subsidiary Risk: Packing Group: **Marine Pollutant Description:**

ADR

UN-No: **Proper Shipping Name:** Hazard Class: Packing Group: Subsidiary Risk:

IMO / IMDG

UN-No: **Proper Shipping Name:** Hazard Class: Subsidiary Risk: Packing Group: Marine Pollutant

RID

UN-No:	No
Proper Shipping Name:	No
Hazard Class:	No
Subsidiary Risk:	No
Packing Group:	No

ICAO

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

ΙΑΤΑ

UN-No: **Proper Shipping Name:** Hazard Class: Subsidiary Risk: Packing Group: ERG Code: **Special Provisions**

No Information available No information available No information available

Not Regulated

No information available No information available

Not Regulated No information available No information available No information available No information available

Not Regulated No information available No information available No information available No information available No information available

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Not Regulated No information available 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.
Eugenol	97-53-0	PresentACTIV E	Present KE-23385	Present	Present (3)-637	Present	Present	Present 202-589-1

U.S. Regulations

Eugenol

California Directors List of Hazardous Substances: Present

FDA - Food Additives Generally Recognized as Safe (GRAS): 21 CFR 184.1257

FDA - 21 CFR - Total Food Additives 177.2800, 184.1257

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	Female
		-		Reproductive	Reproductive
				Toxicity	Toxicity:
Eugenol	97-53-0	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
Eugenol	97-53-0	None	None	None	None	None

U.S. TSCA

Components		TSCA Section 5(a)2 - Chemicals With Significant New Use Rules (SNURS)	()
Eugenol	97-53-0	Not Applicable	Not Applicable

Canada

WHIMIS 2015 - GHS Classifications

WHMIS 2015 Hazard Classification The WHMIS 2015 classification of this product has not been validated or reviewed yet. Information:

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

D2B Toxic materials

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)
Eugenol	97-53-0	Present	Not Listed
Components	Components CAS-No.		CEPA Schedule I - Toxic Substances
Eugenol	97-53-0		Not listed
Components		CAS-No.	CEPA - 2010 Greenhouse Gases Subject

		to Mandatory Reporting
Eugenol	97-53-0	Not listed

EU Classification

EU GHS - SV - CLP 1272/2008

Components	CAS-No.	EU GHS - SV - CLP (1272/2008)
Eugenol	97-53-0	No information

EU - CLP (1272/2008)

R-phrase(s)

R22 - Harmful if swallowed.

R36 - Irritating to eyes.

R38 - Irritating to skin.

R43 - May cause sensitization by skin contact.

S -phrase(s)

S24 - Avoid contact with skin.

S26 - In case of contact with eyes, rinse immediately with plenty of water and seek medical advice.

Components	CAS-No.	Classification	Concentration Limits:	Safety Phrases
Eugenol	97-53-0		No information	

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

Indication of danger:

Xn - Harmful. Xi - Irritant.

16. OTHER INFORMATION

Preparation Date:	03/05/2015
Revision Date:	06/25/2018
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

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
EU110	Eugenol, USP

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 <u>gualityassurance@spectrumchemical.com</u>

Sincerely,

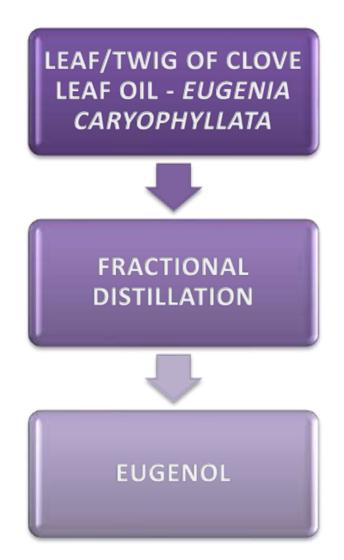
Oulu Clamy

Oralia Chavez Quality Assurance Specialist



Manufacturing Process Flowchart

Eugenol, USP (Cat# EU110)



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

EU110, Eugenol, USP

Source Statement

The above mentioned catalog item is manufactured by using plant derived material (Clove leaf 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 contain one of the 26 EU fragrance allergens listed in Annex III lines 67-92 (Eugenol).

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

RE: Elemental Impurities - Eugenol, USP (Cat# EU110)

To Whom It May Concern:

Thank you for your interest in Spectrum high quality chemicals.

The above mentioned material complies with the USP<232>, <233> Elemental Impurities and the ICH Q3D Elemental Impurities Guideline. No Class 1, Class 2A, Class 2B or Class 3 elemental impurities are likely to be present. These substances are not used in the production process, are not intentionally added or known to be present in the above mentioned material.

This information is subject to change and is intended for risk assessment only. It is 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 <u>TechServices@spectrumchemical.com.</u>

Sincerely,

Technical Services Spectrum Chemical Mfg. Corp.

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

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

RE: Residual Solvents - Eugenol, USP (Cat# EU110)

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 the USP <467> Residual Solvents and the ICH Q3C Residual Solvents Guideline. No Class 1, Class 2, Class 3 or other solvents are used or produced in the manufacture of this product.

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

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

Sincerely,

Technical Services Spectrum Chemical Mfg. Corp.

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

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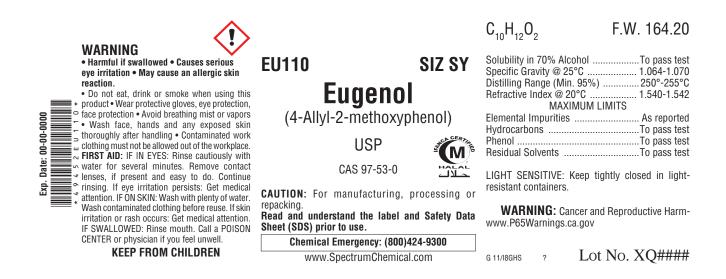
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Label Information

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.



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