

Scientific Documentation

Capsaicin, 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



Table of Contents

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

Specification for Capsaicin, USP (C1869)

Item Number	C1869
Item	Capsaicin, USP
CAS Number	404-86-4
Molecular Formula	C ₁₈ H ₂₇ NO ₃
Molecular Weight	305.41
MDL Number	
Synonyms	

Test	Specification	
	Min	Max
TOTAL CAPSAICINOIDS	90.0	110.0 %
CAPSAICIN (C ₁₈ H ₂₇ NO ₃)	55 %	
DIHYDROCAPSAICIN (C ₁₈ H ₂₉ NO ₃)	20 %	
MELTING RANGE	57°	66°C
LOSS ON DRYING		1.0 %
OTHER CAPSAICINOIDS		15 %
RESIDUE ON IGNITION		1.0 %
ELEMENTAL IMPURITIES	AS REPORTED	
IDENTIFICATION	COLOR AND Rf VALUE CORRESPONDS TO STANDARD	
EXPIRATION DATE		
DATE OF MANUFACTURE		
APPEARANCE		
RESIDUAL SOLVENTS	AS REPORTED	

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	C1869	Lot Number	4MG0049
Item	Capsaicin, USP	Manufacturer Lot	API-04/A1/23-24
CAS Number	404-86-4	Manufacturer Code	15265
Molecular Formula	C ₁₈ H ₂₇ NO ₃	Molecular Weight	305.41

TEST	SPECIFICATION		RESULT
	MIN	MAX	
TOTAL CAPSAICINOIDS	90.0	110.0 %	90.7 %
CAPSAICIN (C ₁₈ H ₂₇ NO ₃)	55 %		62.3 %
DIHYDROCAPSAICIN (C ₁₈ H ₂₉ NO ₃)	20 %		23.7 %
MELTING RANGE	57°	66°C	63.2 - 65.7°C
LOSS ON DRYING		1.0 %	0.02 %
OTHER CAPSAICINOIDS		15 %	4.7 %
RESIDUE ON IGNITION		1.0 %	0.3 %
ELEMENTAL IMPURITIES	AS REPORTED		COMPLIES WITH STANDARD
IDENTIFICATION	COLOR AND Rf VALUE CORRESPONDS TO STANDARD		COLOR AND Rf VALUE CORRESPOND TO STANDARD
EXPIRATION DATE			01-JUL-2026
DATE OF MANUFACTURE			01-JUL-2023
APPEARANCE			OFF-WHITE POWDER
RESIDUAL SOLVENTS	AS REPORTED		.
CLASS 2 (solvent) / HEXANE			<290 ppm
CLASS 2 (SOLVENT) / METHANOL			<3000 ppm

Certificate of Analysis Results Entered By:

MCAMACHO
Matheu Camacho
09-NOV-23 08:36:06

Certificate of Analysis Results Approved By:

BPATEL
Bhargavi Patel
13-NOV-23 07:46:30

Spectrum Chemical Mfg Corp
777 Jersey Avenue
New Brunswick 08901 NJ



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 Chemical Mfg. Corp. repackages Active Pharmaceutical Ingredient chemicals provided by other manufacturers and suppliers. For traceability purposes, Spectrum's Certificate of Analysis contains an identifier code unique to each manufacturer or supplier, as well as the chemical's lot number provided on the original manufacturer Certificate of Analysis. This material is manufactured by AUDI PHARMA INGREDIENTS at D9/B, Gem Apartments 27th Cross Street, Maharajanagar, Tirunelveli, TAMIL NADU 627011, India (IND). Copies of the original Certificate of Analysis are available upon request from your Spectrum Sales Representative or by calling Spectrum's Quality Department at 1-800-772-8786.

SAFETY DATA SHEET

Preparation Date: 03/31/2016

Revision Date: 06/27/2018

Revision Number: G2

1. IDENTIFICATION

Product identifier

Product code: C1869
Product Name: CAPSAICIN, USP

Other means of identification

Synonyms: (E)-8-Methyl-N-vanillyl-6-nonenamide
 6-Nonenamide, 8-methyl-N-vanillyl-, (E)- (8CI)
 8-Methyl-N-vanillyl-6-nonenamide
 Capsaicine
 N-((4-Hydroxy-3-methoxyphenyl)methyl)-8-methyl-6-nonenamide
 trans-8-Methyl-N-vanillyl-6-nonenamide
 trans-N-((4-Hydroxy-3-methoxyphenyl)methyl)-8-methyl-6-nonenamide

CAS #: 404-86-4
RTECS # RA8530000
CI#: Not available

Recommended use of the chemical and restrictions on use

Recommended use: Topical analgesic. Animal and insect repellent.
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)

Acute toxicity - Oral	Category 3
Skin corrosion/irritation	Category 2
Serious eye damage/eye irritation	Category 2A
Respiratory sensitization	Category 1
Skin sensitization	Category 1
Specific target organ toxicity (single exposure)	Category 3

Label elements

Danger

Hazard statements

Toxic if swallowed
Causes skin irritation
Causes serious eye irritation
May cause allergy or asthma symptoms or breathing difficulties if inhaled
May cause an allergic skin reaction
May cause respiratory irritation



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
In case of inadequate ventilation wear respiratory protection
Contaminated work clothing must not be allowed out of the workplace
Use only outdoors or in a well-ventilated area
Wear protective gloves

Precautionary Statements - Response

Specific treatment (see .? on this label)

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

Take off contaminated clothing and wash it before reuse

If skin irritation or rash occurs: Get medical advice/attention

If experiencing respiratory symptoms: Call a POISON CENTER or doctor/physician. IF INHALED: Remove person to fresh air and keep comfortable for breathing.

IF SWALLOWED: Immediately call a POISON CENTER or doctor/physician

Rinse mouth

Precautionary Statements - Storage

Store locked up

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

Precautionary Statements - Disposal

Dispose of contents/container to an approved waste disposal plant

3. COMPOSITION/INFORMATION ON INGREDIENTS

Components	CAS-No.	Weight %
Capsaicin, natural	404-86-4	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. Ensure that medical personnel are aware of the material(s) involved and take precautions to protect themselves. First aider needs to protect himself.
Skin Contact:	Wash off immediately with soap and plenty of water removing all contaminated clothing and shoes. Get medical attention. 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 breathing, give artificial respiration. If breathing is difficult, give oxygen. WARNING! It may be hazardous to the person providing aid to give mouth-to-mouth resuscitation when the inhaled or ingested material is toxic, infectious or corrosive. Do not use mouth-to-mouth resuscitation if victim ingested or inhaled the substance; induce artificial respiration with the aid of a pocket mask equipped with a one-way valve or other proper respiratory medical device. Get medical attention.
Ingestion:	Do not induce vomiting without medical advice. Never give anything by mouth to an unconscious person. Obtain medical attention. Call a physician or Poison Control Center immediately.

Most important symptoms and effects, both acute and delayed

Symptoms	<p>Toxic if swallowed</p> <p>Irritating to eyes and skin</p> <p>Redness and burning sensation on skin</p> <p>Lacrimation</p> <p>Causes conjunctivitis</p> <p>Burning sensation or pain of the eyes</p> <p>Irritating to respiratory system</p> <p>Sensitizing</p> <p>May cause an allergic skin reaction</p> <p>May cause allergic respiratory reaction</p> <p>Causes digestive (gastrointestinal) tract irritation</p> <p>May cause gastritis</p> <p>May cause abdominal pain, nausea, vomiting, diarrhea</p> <p>May affect behavior/central nervous system (tremor, convulsions)</p>
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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:	Dry chemical. Carbon dioxide (CO ₂). Water spray mist or foam.
Unsuitable Extinguishing Media:	No information available.

Specific hazards arising from the chemical

Hazardous Combustion Products: Carbon Monoxide, Carbon Dioxide. Nitrogen Oxides.

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. Keep people away from and upwind of spill/leak. Avoid contact with skin, eyes and clothing. Do not touch damaged containers or spilled material unless wearing appropriate protective clothing. Use personal protective equipment. Avoid dust formation. 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. All equipment used when handling the product must be grounded. Keep away from incompatible materials.

Safe Handling Advice

Wear personal protective equipment. Avoid contact with skin, eyes and clothing. Avoid dust formation. Do not ingest. Do not breathe dust. Keep away from heat and sources of ignition. Handle in accordance with good industrial hygiene and safety practice.

Conditions for safe storage, including any incompatibilities

Technical Measures/Storage Conditions:

Keep containers tightly closed in a cool, well-ventilated place. Keep refrigerated. Store at 2-8 deg. C. Store away from incompatible materials.

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
Capsaicin, natural	404-86-4	None	None	None	None

Canada

Components	CAS-No.	Canada - Alberta	Canada - British Columbia	Canada - Ontario	Canada - Quebec
Capsaicin, natural	404-86-4	None	None	None	None

Australia and Mexico

Components	CAS-No.	Australia	Mexico
Capsaicin, natural	404-86-4	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: Goggles

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

Respiratory protection: Wear respirator with dust filter. Be sure to use an approved/certified respirator or equivalent.

Hygiene measures: Avoid contact with skin, eyes and clothing. Wash hands before breaks and immediately after handling the product. When using, do not eat, drink or smoke.

9. PHYSICAL AND CHEMICAL PROPERTIES

Physical state:
Solid

Appearance:
Powder.

Color:
Off-white.

Odor:
Pungent.

Taste
Burning.

Formula:
C18H27NO3

Molecular/Formula weight:
305.41

Flammability:
No information available

Flashpoint (°C/°F):
No information available.

Flash Point Tested according to:
Not available

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

Lower Explosion Limit (%):
No information available

Upper Explosion Limit (%):

No information available

Melting point/range(°C/°F):

65 °C/149 °F

Decomposition temperature(°C/°F):

No information available

Boiling point/range(°C/°F):

210-220 °C/410-428 °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:

No information available

VOC content (g/L):

No information available

Odor threshold (ppm):

No information available

**Partition coefficient
(n-octanol/water):**

3.04

Viscosity:

No information available

Miscibility:

No information available

Solubility:

Practically insoluble in cold water
Freely soluble in alcohol
Freely soluble in Benzene
Freely soluble in Ether
Soluble in carbon tetrachloride
Soluble in Petroleum Ether

10. STABILITY AND REACTIVITY

Reactivity

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. Avoid dust formation. Incompatible materials.

Incompatible Materials:

Oxidizing agents

**Hazardous decomposition
products:**

When heated to decomposition it emits toxic fumes. Nitrogen oxides (NOx).
Carbon monoxide.

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. Skin.

Acute Toxicity

Component Information

Product code: C1869

Product name: CAPSAICIN, USP

6 / 12

Capsaicin, natural	
CAS-No.	404-86-4

LD50/oral/rat = 148.1 mg/kg Oral LD50 Rat; 161.2 mg/kg Oral LD50 Rat
LD50/oral/mouse = 47.2 mg/kg (RTECS)
60 - 294mg/kg (LOLI)
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 LC50information = > 512 mg/kg Dermal LD50 dermal Mouse

Product Information

LD50/oral/rat =
VALUE- Acute Tox Oral = No information available

LD50/oral/mouse =
Value - Acute Tox Oral = 47.2 mg/kg

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:	Causes skin irritation. Moderately irritating to the skin. Causes burning or stinging pain and redness without blistering.
Eye Contact:	Causes serious eye irritation. Moderately irritating to the eyes. Causes intense tearing. Causes blepharospasm (forcible closure of the eyelids). Causes a burning sensation or pain. Causes conjunctival irritation.
Inhalation	Irritating to respiratory system.
Ingestion	Toxic if swallowed. May cause salivation. May cause cyanosis. May affect behavior/central nervous system (tremor, convulsions). Causes digestive (gastrointestinal) tract irritation. May cause gastritis. May cause abdominal pain, nausea, vomiting, diarrhea.
Aspiration hazard	No information available.

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

Chronic Toxicity Prolonged or repeated exposure may cause allergic respiratory and skin reactions. Prolonged or repeated inhalation may cause allergic reaction. Skin: Prolonged or repeated skin contact may cause allergic skin reaction.

Sensitization: May cause sensitization by inhalation and skin contact.

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
Capsaicin, natural	404-86-4	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 Respiratory system.

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
Capsaicin, natural	404-86-4	None	None	None	None

14. TRANSPORT INFORMATION

DOT

UN-No: Not Regulated
Proper Shipping Name: Toxic solids, organic, n.o.s. (capsaicin)
Hazard Class: 6.1
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): [DOT]: (G) - Identifies proper shipping names for which one or more technical names of the hazardous material must be entered in parentheses, in association with the basic description.
Description: UN2811, Toxic solids, organic, n.o.s. ,6.1,PG III

TDG (Canada)

UN-No: UN2811
Proper Shipping Name: Toxic solid, organic, n.o.s.
Hazard Class: 6.1
Subsidiary Risk: No information available
Packing Group: III
Marine Pollutant: No Information available
Description: UN2811, TOXIC SOLID, ORGANIC, N.O.S.,6.1,PG III

ADR

UN-No: UN2811
Proper Shipping Name: Toxic solid, organic, n.o.s.
Hazard Class: 6.1
Packing Group: III
Subsidiary Risk: No information available
Description: UN2811 Toxic solid, organic, n.o.s.,6.1,III

IMO / IMDG

UN-No: UN2811
Proper Shipping Name: Toxic solid, organic, n.o.s.
Hazard Class: 6.1
Subsidiary Risk: No information available
Packing Group: III
Marine Pollutant: No information available
EMS: F-A

RID

UN-No: UN2811
Proper Shipping Name: Toxic solid, organic, n.o.s.
Hazard Class: 6.1
Subsidiary Risk: No information available
Packing Group: III
Description: UN2811 Toxic solid, organic, n.o.s.,6.1,III

ICAO

UN-No: UN2811
Proper Shipping Name: Toxic solid, organic, n.o.s.
Hazard Class: 6.1
Subsidiary Risk: No information available
Packing Group: III
Description: UN2811, Toxic solid, organic, n.o.s.,6.1,PG III

IATA

UN-No: UN2811
Proper Shipping Name: Toxic solid, organic, n.o.s.
Hazard Class: 6.1
Subsidiary Risk: No information available
Packing Group: III
ERG Code: 6L
Special Provisions No information available
Description: UN2811, Toxic solid, organic, n.o.s., 6.1, PG III

15. REGULATORY INFORMATION

International Inventories

Components	CAS-No.	U.S. TSCA	KOREA KECL	Philippines (PICCS)	Japan ENCS	CHINA	Australia (AICS)	EINECS-No.
<i>Capsaicin, natural</i>	404-86-4	Present(ACTI VE)	Not present	Not present	Present (3)-711	Not present	Present	Present 206-969-8

U.S. Regulations*Capsaicin, natural***FDA - 21 CFR - Total Food Additives** Present (not regulated under 21 CFR)**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:
Capsaicin, natural	404-86-4	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>Capsaicin, natural</i>	404-86-4	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
Capsaicin, natural	404-86-4	Not Applicable	Not Applicable

Canada**WHMIS 2015 - GHS Classifications**

WHMIS 2015 Hazard Classification Information:

Component
 Capsaicin, natural

WHMIS 2015 Hazard Classification
 Acute toxicity - Oral - Category 3: H301 Toxic if swallowed.

Product code: C1869**Product name:** CAPSAICIN, USP**10 / 12**

404-86-4 (100)

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

D1B Toxic materials

D2B Toxic materials

Components

Capsaicin, natural

WHMIS 1988

D1B,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)
Capsaicin, natural	404-86-4	Not Listed	Present

Components	CAS-No.	CEPA Schedule I - Toxic Substances
Capsaicin, natural	404-86-4	Not listed
Components	CAS-No.	CEPA - 2010 Greenhouse Gases Subject to Mandatory Reporting
Capsaicin, natural	404-86-4	Not listed

EU Classification

EU GHS - SV - CLP 1272/2008

Components	CAS-No.	EU GHS - SV - CLP (1272/2008)
Capsaicin, natural	404-86-4	No information

EU - CLP (1272/2008)

R-phrases(s)

R25 - Toxic if swallowed.

R38 - Irritating to skin.

R41 - Risk of serious damage to eyes.

S -phrase(s)

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

S28 - After contact with skin, wash immediately with plenty of water

S45 - In case of accident or if you feel unwell, seek medical advice immediately (show the label where possible).

S36/37 - Wear suitable protective clothing and gloves.

Components	CAS-No.	Classification	Concentration Limits:	Safety Phrases
Capsaicin, natural	404-86-4		No information	

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

Indication of danger:

T - Toxic

Xi - Irritant.

T**Xi****16. OTHER INFORMATION**

Preparation Date: 03/31/2016
Revision Date: 06/27/2018
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
C1869	Capsaicin, USP

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

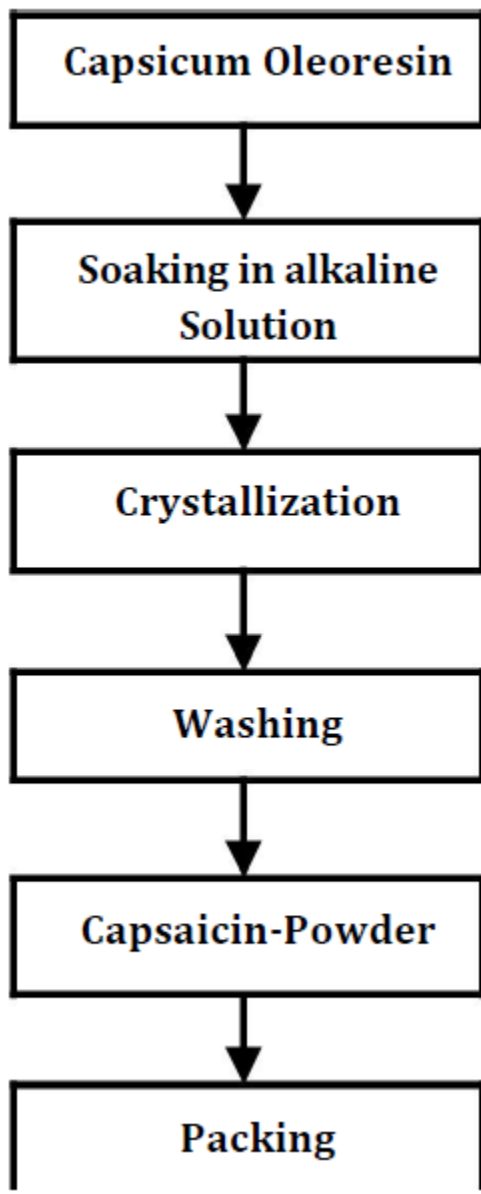
Spectrum-Gardena, CA: 2020632
Spectrum-New Brunswick, NJ: 2246824

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 qualityassurance@spectrumchemical.com

Sincerely,

Oralia Chavez
Quality Assurance Specialist

Manufacturing Process Flowchart Capsaicin, USP (Cat# C1869)



CORPORATE HEADQUARTERS

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New Brunswick, NJ 08901

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FAX 732.246.7132

WEST COAST FACILITY

14422 South San Pedro Street

Gardena, California 90248

PHONE 310.516.8000

FAX 310.516.9843

C1869, Capsaicin, USP

Source Statement

The above mentioned catalog item is manufactured from Red Chilies. 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 | • Cereals containing Gluten |
| • Egg | • Celery |
| • Fish | • Mustard |
| • Shellfish | • Sesame Seed |
| • Tree Nuts | • Corn |
| • Wheat | • Latex |
| • Peanuts | • Sulfites > 10 ppm |
| • Soy | |

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 60 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 - Capsaicin, USP (Cat# C1869)

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 TechServices@spectrumchemical.com.

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



RE: Residual Solvents - Capsaicin, USP (Cat# C1869)

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
Hexane	2	< 290 ppm
Methanol	2	< 3000 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,

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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.

DANGER

- Toxic if swallowed • Causes serious eye irritation • Causes skin irritation • May cause respiratory irritation • May cause an allergic skin reaction • May cause allergy or asthma symptoms or breathing difficulties if inhaled.

• Do not eat, drink or smoke when using this product • Wear respiratory protection, protective gloves, eye protection, face protection • Avoid breathing dust • Use only outdoors or in a well-ventilated area • Wash face, hands and any exposed skin thoroughly after handling • Contaminated work clothing must not be allowed out of the workplace.

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 or rash occurs: Get medical attention. IF INHALED: If breathing is difficult, remove person to fresh air and keep comfortable for breathing. If experiencing respiratory symptoms: Call a POISON CENTER or physician. IF SWALLOWED: Immediately call a POISON CENTER or physician. Rinse mouth.

KEEP FROM CHILDREN

C1869

SIZ SY

Capsaicin

USP

CAS 404-86-4

CAUTION: For manufacturing, laboratory or other authorized use only.
Read and understand the label and Safety Data Sheet (SDS) prior to use.

DOT: UN2811, Toxic solid, organic, n.o.s. (capsaicin), 6.1, PG III

Chemical Emergency: (800)424-9300

www.SpectrumChemical.com

REFRIGERATE

$C_{18}H_{27}NO_3$ F.W. 305.41

Manufacturer/Supplier Code ?
Manufacturer Lot Number..... ?

Total Capsaicinoids 90.0% - 110.0%
Capsaicin ($C_{18}H_{27}NO_3$) Min. 55%
Dihydrocapsaicin ($C_{18}H_{29}NO_3$) Min. 20%
Melting Range..... 57°-66°C


MAXIMUM LIMITS

Loss on Drying..... 1.0%
Other Capsaicinoids 15%
Residue on Ignition..... 1.0%
Elemental Impurities As reported
Residual Solvents To pass test

Keep tightly closed.

Repackaged by Spectrum as:
Lot No. XQ####

Exp. Date: 00-00-0000



Spectrum Chemical Mfg Corp

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West Coast Facility:

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