

# SAFETY DATA SHEET



**NOTE: This Material Safety Data Sheet (SDS) is prepared for industrial / commercial use situations. The preparation of this MSDS may be required by law does not address consumer use; for any information relevant to consumer use or retail handling refer to the package label.**

## 1. IDENTIFICATION

**Product Name:** Capsaicin Cream 0.025% (2.1 oz-60 g)  
Capsaicin Cream 0.075% (2 oz-57 g)  
Capsaicin Cream 0.1%, (1.5 oz-42.5 g & 2 oz-56.6 g)

**Product NDC No.:** 50268-195-60 (Capsaicin Cream 0.025%, 2.1 oz, 60 g)  
50268-196-57 Capsaicin Cream (0.075%, 2 oz, 57 g)  
50268-198-42 (Capsaicin Cream 0.1%, 1.5 oz, 42.5 g)  
50268-197-56 (Capsaicin Cream 0.1%, 2 oz, 56.6 g)

**Product Type:** Finished Product - Consumer (Retail) Use Only

**Distributed by:** AvKARE, Pulaski, TN 38478

**Manufactured by:** Quality CDMO  
5000 South Freeway, Suite 106  
Fort Worth, TX 76115

## 2. HAZARD IDENTIFICATION

This is a personal care product that is safe for consumers and other users under normal and reasonably foreseeable use. This product has been evaluated according to Global Harmonized System (GHS) requirements. This safety data sheet was developed based on regulations applicable to bulk substances in an industrial/occupational setting.

**Classification of the substance or mixture:** Regulation (EC) No. 1272/2008

Based on available data, not classified as hazardous according to the criteria of the Globally Harmonized System.

**Label elements:**

Label elements Based on available data, not classified as hazardous according to the criteria of the Globally Harmonized System in accordance with 29 CFR 1910.1200 (OSHA HCS).

**OSHA Hazards:** No known OSHA hazards.

**GHS Hazards:** Not a dangerous or hazardous substance or preparation according to the Global Harmonized System (GHS).

**Signal Word:** No Signal Word Applicable.

**Hazard Statement(s):** Suspected of causing eye irritation or redness.

**Precautionary statement(s):** Do not handle until all safety precautions have been read and understood.

**Other Hazards:** Not determine

### 3. COMPOSITION/INFORMATION ON INGREDIENTS

Ingredients listed below are not classified as hazardous according to 29CFR 1910.1200 and the Globally Harmonized System

Chemical Name	CAS-No.
Capsaicin	404-86-4
Cetyl/Stearyl Alcohol	67762-30-5
Glyceryl Stearate SE	11099-07-3
White Petrolatum	8009-03-8
Mineral Oil	8042-47-5
PEG-100 Stearate	9004-99-3
Water	7732-18-5
Propylene Glycol	57-55-6
Xanthan Gum	11138-66-2
Peppermint oil	8006-90-4
Aloe Vera	85507-69-3
Phenoxyethanol	122-99-6

### 4. FIRST AID MEASURES

#### First aid measures for different exposure routes:

<b>Eye contact</b>	Flush eyes with copious amounts of water for a minimum of 15 minutes.
<b>Skin contact</b>	Flush exposed skin with copious amounts of water for a minimum of 15 minutes.
<b>Ingestion</b>	This product is used for external/topical use only. If swallowed, get medical help or contact a Poison Control Center right away.
<b>Inhalation</b>	Remove from source of exposure. If signs of toxicity occur, seek medical attention. Provide symptomatic/supportive care, as necessary.
<b>Protection of First aiders:</b>	Use personal protective equipment.

#### Most important symptoms and effects, both acute and delayed:

**Signs and Symptoms:** You may experience a burning sensation. The intensity varies among individuals and generally disappears with regular use.

**Indication of immediate medical attention and special treatment needed:** None.

**Notes To Physician:** Treat symptomatically

#### Other Health Warnings:

#### CONTRAINDICATIONS:

Do not use if you are allergic to capsicum or chili peppers.

#### WARNINGS:

For External use only. Read all warnings and directions before use. Test first on a small area of skin. Do not use on wounds or damaged skin. Do not use with heating pad or expose area to sunlight. Avoid contact with eyes, lips, nose and mucus membranes. Do not wrap or bandage the treatment area.

Stop use and ask a doctor if-

The condition worsens or does not improve with regular use, if severe burning persists or redness or blistering occurs. Keep out of reach of children. Wash hands thoroughly with soap and water immediately after application.

## 5. FIRE-FIGHTING MEASURES

No flammable properties are associated with this product.

### Extinguishing Media:

**Suitable Extinguishing Media:** Use extinguishing agent suitable for type of surrounding fire.  
Use water spray, dry chemical, or carbon dioxide.

**Unsuitable Extinguishing Media:** Not determined

### Special hazards arising from the substance or mixture:

**Special Exposure Hazards:** May be combustible at high temperatures.

### Advice for firefighters:

**Protective Equipment and Precautions for Firefighters:** In a fire, wear self-contained breathing apparatus and full protective gear if necessary.

## 6. ACCIDENTAL RELEASE MEASURES

### Personal precautions:

For personal protection, also see Section 8.

**Eye Protection** Wear safety goggles or a face shield when cleaning up spills.

**Skin Protection** Wear protective attire that prevents contamination of skin and personal clothing.

**Hand Protection** Wear nitrile or vinyl gloves that cover exposed skin.

**Other Protections** Avoid breathing mists, dusts, and aerosols.

**Environmental Controls:** Prevent spilled product from entering drains.

**Spill Clean-up Measures:** Contain the material to prevent it from becoming airborne.  
Place absorbent material on top of, and around the perimeter of the spill.  
Sweep up the spilled material and decontaminate the area with soap and water or an equivalent cleaner.

## 7. HANDLING AND STORAGE

### Precautions for safe handling:

Handle in accordance with product label information. Handle in accordance with good industrial hygiene and safety practice. Also see Section 8 for recommended protective equipment.

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

Store according to the product label instructions.

**Storage Conditions** Keep out of reach of children, For external use only.

**Storage Temperature** Store at room temperature, 15° - 30°C (59°-86 °F)

**Incompatible products** None in particular

### Specific end use(s):

**Recommended use:** Pharmaceuticals  
**Restrictions on use:** Use only as directed by physician. For Topical Use Only. Not For Ophthalmic Use. Ask a doctor for use in children below 18 years of age.

## 8. EXPOSURE CONTROLS/PERSONAL PROTECTION

None of the chemicals in this preparation are assigned occupational exposure limits. This product can be safely handled under normal conditions with no controls.

**Control parameters:** Not applicable

### **Exposure controls:**

**Engineering Controls** No special provisions are required under normal product use conditions.  
When handling bulk formulation, use in a well-ventilated area.

**Respiratory Protection** Respiratory protection is not needed during normal product use.  
When handling the bulk formulation, an approved respirator (i.e. NIOSH, EN, etc.) should be worn when exposures are expected to exceed the applicable limits.

**Eyes Protection** Eye protection not needed during typical product use conditions.  
Wear eye protection and face shield as appropriate when handling the bulk formulation.

**Skin and Body Protection** No special precaution must be adopted for normal use.

**Personal Protective Equipment** Gloves not required during normal product use conditions.  
Wear impervious gloves when handling the bulk formulation for prolonged skin contact.  
If the product is hot, wear thermal-insulated gloves to protect from burning skin.

**Other PPE Data** Wear appropriate body coverings if contact may occur.

**Environmental Exposure Controls** Not determined

## 9. PHYSICAL AND CHEMICAL PROPERTIES

Information on basic physical and chemical properties.

**Physical State:** Semi-solid  
**Appearance:** White-Off White color cream  
**Odor:** None  
**Odor Threshold:** Not determined

<b><u>Property:</u></b>	<b><u>Values</u></b>
<b>pH:</b>	5.0 – 7.0
<b>Density (g/mL):</b>	0.90 - 1.10
<b>Boiling Pt. @ 760 mm Hg (°C):</b>	Not determined
<b>Melting/Freezing Point (°C):</b>	Not determined
<b>Flash Point (°C):</b>	Not determined
<b>Evaporation Rate at 20°C:</b>	Not determined
<b>Flammability (Solid, Gas):</b>	Not determined
<b>Lower Explosive Limit:</b>	Not determined
<b>Upper Explosive Limit:</b>	Not determined
<b>Vapor Pressure (mm Hg):</b>	Not determined
<b>Vapor Density (Air = 1):</b>	Not determined
<b>Specific Gravity:</b>	Not determined
<b>Solubility(ies):</b>	Insoluble in water
<b>Partition coefficient (n-octanol/water):</b>	Not determined
<b>Autoignition temperature (°C):</b>	Not determined
<b>Decomposition temperature (°C):</b>	Not determined
<b>Viscosity (centipoise):</b>	Not determined
<b>Explosion Severity:</b>	Not determined
<b>Oxidizing Properties:</b>	Not determined

**Other information:**  
**Substance group relevant properties:** Not determined.  
**Miscibility:** Not determined  
**Fat solubility:** Not determined.  
**Conductivity:** Not determined

## 10. STABILITY AND REACTIVITY

<b>Reactivity</b>	Not determined.
<b>Chemical Stability</b>	Stable under recommended storage conditions. Avoid source of ignition.
<b>Hazardous Reactions</b>	Not determined.
<b>Conditions to Avoid</b>	Avoid extremely high or low temperatures, moisture, and sunlight.
<b>Incompatible Materials</b>	Strong oxidants.
<b>Hazardous Decomposition Products</b>	May produce toxic fumes of carbon monoxide, carbon dioxides and/or Nitrogen oxides.

## 11. TOXICOLOGICAL INFORMATION

The toxicological properties of this preparation have not been fully investigated.

### Acute effects of exposure:

Information on likely routes of exposure.

<b>Inhalation:</b>	Inhalation of mists may cause minor irritation of the mucous membranes and upper respiratory tract.
<b>Skin Irritation:</b>	Minor irritation/ burning sensation is possible.
<b>Ingestion:</b>	Swallowing may cause gastrointestinal distress.
<b>Eye Irritation:</b>	Contact may cause slight eye irritation with redness and tearing.

### Chronic effects of exposure:

This medication is to be used as directed by a physician and should not be used to treat any condition other than that for which it was prescribed.

<b>Skin Corrosivity:</b>	Not determined
<b>Skin Sensitization:</b>	Not determined but some allergic reactions are possible in sensitive individuals.
<b>Serious eye damage/ eye Irritation:</b>	Not determined but prolonged contact may cause eye irritation and damage.
<b>Toxicokinetic/Metabolism:</b>	Not determined
<b>Target Organ Effects:</b>	Not determined
<b>Reproductive Toxicity:</b>	Not determined
<b>Germ Cell Mutagenicity:</b>	Not determined.
<b>Carcinogenicity:</b>	Not determined
National Toxicology Program (NTP):	No data available
International Agency for Research on Cancer (IARC):	No data available
Occupational Safety and Health Administration (OSHA):	No data available
<b>Mutagenicity:</b>	Not determined
<b>Aspiration hazard:</b>	Not determined.

### Active Pharmaceutical Ingredient (API) Information:

Chemical Name	CAS-No	LD50 Oral	LD50 Dermal	LC50 Inhalation
Capsaicin	404-86-4	47.2 mg/kg (mouse)	-	-

## 12. ECOLOGICAL INFORMATION

<b><u>Toxicity:</u></b>	No information found.
<b><u>Persistence and degradability:</u></b>	Not determined.
<b><u>Bio-accumulative potential:</u></b>	Not determined.
<b><u>Mobility in soil:</u></b>	Not determined.
<b><u>Results of PBT or vPvB assessment:</u></b>	Chemical safety report is not required for this substance/product.
<b><u>Other adverse effects:</u></b>	Not determined.

## 13. DISPOSAL CONSIDERATIONS

<b><u>Waste Treatment Methods:</u></b>	Check regional waste requirements.
<b><u>Waste Treatment Options:</u></b>	Treatment options approved by local authorities.
<b><u>Sewage Disposal Options:</u></b>	Check with local authorities before discharge to the sewer.
<b><u>Other Disposal Recommendations:</u></b>	Dispose of according to local, state, and national regulatory requirements.
<b><u>U.S. Waste Classification:</u></b>	Non-RCRA Waste
<b><u>California Hazardous Waste Codes:</u> <u>(non-household setting)</u></b>	H132

## 14. TRANSPORT INFORMATION

Follow federal and local regulations.

### **ADR, DOT, ICAO/IATA, IMDG/IMO**

<b>Status:</b>	Not regulated as a dangerous good
<b>UN Number:</b>	Not applicable
<b>Proper shipping name:</b>	Not applicable
<b>Hazard class:</b>	Not applicable
<b>Packing group:</b>	Not applicable
<b>Environmental hazard:</b>	Not applicable
<b>Special Provisions:</b>	Not applicable
<b>Transport in bulk according to Annex II of MARPOL 73/78 and the IBC Code:</b>	Not applicable

## 15. REGULATORY INFORMATION

### **Safety, health, and environmental regulations/legislation specific for the substance or mixture:**

#### **U.S. Federal, State, and international Regulations:**

##### **US OSHA (United States Occupational Safety and Health Administration)**

Not regulated as a hazardous material in accordance with 29 CFR 1910.1200 (OSHA HCS).

##### **US EPA (United States Environmental Protection Agency)**

Non-hazardous material to the environment.

##### **European Union (EU) Regulations**

This material safety data sheet conforms to Regulation (EC) No 1272/2008, 1907/ 2006, and other requirements established by the European Union.

**Superfund Amendments and Reauthorization Act (SARA)**

**Under 311/312 of SARA Hazard Category:** Acute Health

**Under Section 313 of Title III of 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.

**Comprehensive Environmental Response Compensation and Liability Act (CERCLA)**

This product is not subject to the Comprehensive Environmental Response Compensation and Liability Act (CERCLA) (40 CFR 302) release reporting. Many states have more stringent release reporting requirements. Report spills as required under federal, state, and local regulations.

**Food and Drug Administration (FDA)**

The product described in this Safety Data Sheet is regulated under the Federal Food, Drug, and Cosmetics Act and is safe to use as per directions on container, box or accompanying literature (where applicable).

**Clean Air Act, Section 112 Hazardous Air Pollutants (HAPs) (see 40 CFR 61)**

This product does not contain any substances regulated as hazardous air pollutants (HAPS) under Section 112 of the Clean Air Act Amendments of 1990.

**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)

**California Proposition 65**

This product is not subject to warning labeling under California Proposition 65.

**Toxic Substances Control Act (TSCA)**

All the components of this product are listed on the Toxic Substances Control Act (TSCA) Chemical Substances Inventory.

**CANADA:**

**Canadian CEPA:** This product is a drug, and all the ingredients are listed on the Canadian Domestic Substances List.

**Chemical Safety Assessment:**

Chemical safety assessment has not been conducted on this substance/product.

## 16. OTHER INFORMATION

**Issuing Date:** 05-December-2022

**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 SDS**