


## SAFETY DATA SHEET

Section 1: Identification	
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<b>Product</b>	Capsaicin Topical Patch 0.025%
<b>Distributor</b>	SOLA Pharmaceuticals 655 Highlandia Drive, Ste B Baton Rouge, LA. 70810 Tel: 866.747.7365 Fax: 800.754.9550 <a href="http://www.solameds.us">www.solameds.us</a> info@solameds.us
<b>NDC Number</b>	70512-016-10
Section 2: Hazard(s) Identification	
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<b>Classification of the Substance or Mixture</b>	
<b>GHS Classification in Accordance with 29 CFR 1910 (OSHA HCS)</b>	
<p>Acute toxicity, Oral (Category 2), H300            Skin irritation (Category 2), H315            Serious eye damage (Category 1), H318            Respiratory sensitization (Category 1), H334            Skin sensitization (Category 1), H317            Specific target organ toxicity – single exposure (Category 3), Respiratory system, H335</p> <p>For the full text of the H-Statements mentioned in this Section, see Section 16.</p>	
<b>GHS Label Elements, Including Precautionary Statements</b>	
Pictogram	
	
<b>Signal Word</b>	Danger
<b>Hazard Statements(s)</b>	
H300	Fatal if swallowed.
H315	Causes skin irritation.
H317	May cause an allergic skin reaction
H318	Causes serious eye damage.
H334	May cause allergy or asthma symptoms or breathing difficulties if inhaled.
H335	May cause respiratory irritation.
<b>Precautionary Statement(s)</b>	
P261	Avoid breathing dust.

P264	Wash skin thoroughly after handling.
P270	Do not eat, drink or smoke when using this product.
P271	Use only outdoors or in a well-ventilated area.
P272	Contaminated work clothing must not be allowed out of the workplace.
P280	Wear protective gloves/eye protection/face protection.
P285	In case of inadequate ventilation, wear respiratory protection.
P301/P310/P330	IF SWALLOWED: Immediately call a POISON CENTER/doctor. Rinse mouth.
P304/P340/P312	IF INHALED: Remove person to fresh air and keep comfortable for breathing. Call a POISON CENTER/doctor if you feel unwell.
P302/P352	IF ON SKIN: Wash with plenty of soap and water.
P305/P351/P338/P310	IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing. Immediately call a POISON CENTER/doctor.
P333/P313	If skin irritation or rash occurs: Get medical advice/attention.
P342/P311	If experiencing respiratory symptoms: Call a POISON CENTER/doctor.
P362	Take off contaminated clothing and wash before reuse.
P403/P233	Store in a well-ventilated place. Keep container tightly closed.
P405	Store locked up.
P501	Dispose of contents/container to an approved waste disposal plant.

**Hazards Not Otherwise Classified (NOC) or Not Covered by GHS**

Lachrymator, Sternutator

**Section 3: Composition/Information on Ingredients**

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**Substances**

<b>Synonyms</b>	8-Methyl-N-vanillyl-trans-6-nonenamide
<b>Formula</b>	C18H27NO3
<b>Molecular Weight</b>	305.41g/mol
<b>CAS No.</b>	404-86-4
<b>EC No.</b>	206-969-8

Component	Classification	Concentration
Capsaicine	Acute Tox. 2; Skin Irrit. 2; Eye dam. 1; Resp. Sens. 1; Skin Sens. 1; STOT SE 3; H300, H315, H318, H334, H317, H335	<=100%

For the full text of the H-Statements mentioned in this Section, See Section 16.

**Section 4: First-Aid Measures**

**Section 4, First-Aid Measures**

**Description of First-Aid Measures**

**General Advise**

First aiders need to protect themselves. Show this material safety data sheet to the doctor in attendance.

**If Inhaled**

After inhalation: fresh air. Call in physician.

**In Case of Skin Contact**

Take off immediately all contaminated clothing. Rinse skin with water/shower. Consult a Physician.

**In Case of Eye Contact**

Rinse out with plenty of water. Immediately call in ophthalmologist. Remove contact lenses.

**If Swallowed**

Give water to drink (two glasses at most). Seek medical advice immediately. In exceptional cases only, if medical care is not available within one hour, induce vomiting (only in persons who are wide awake and fully conscious), administered activated charcoal (20 – 40g in a 10% slurry), and consult a doctor as quickly as possible.

**Most Important Symptoms and Effects, Both Acute and Delayed**

The most important known symptoms and effects are described in the labeling (see Section 2.2) and/or in Section 11.

**Indication of Any Immediate Medical Attention and Special Treatment Needed**

No data available.

**Section 5: Fire-Fighting Measures****Section 5, Fire-Fighting Measures****Extinguishing Media****Suitable Extinguishing Media**

Water Foam Carbon dioxide (CO<sub>2</sub>) Dry Powder

**Unsuitable Extinguishing Media**

For this substance/mixture, no limitations of extinguishing agents are given.

**Special Hazards Arising From The Substance or Mixture**

Carbon oxides

Nitrogen oxides (NO<sub>x</sub>)

Combustible

Vapors are heavier than air and may spread along floors

Forms explosive mixtures with air on intense heating

Development of hazardous combustion gases or vapors possible in the event of fire

**Advice for Firefighters**

Stay in danger area only with self-contained breathing apparatus. Prevent skin contact by keeping a safe distance or by wearing suitable protective clothing.

**Further Information**

Suppress (knock down) gases/vapors/mists with a water spray jet. Prevent fire extinguishing water from contaminating surface water or the ground water system.

**Section 6: Accidental Release Measures****Section 6, Accidental Release Measures****Personal Precautions, Protective Equipment and Emergency Procedures**

Advise for non-emergency personnel: Avoid inhalation of dusts. Avoid substance contact. Ensure adequate ventilation. Evacuate the danger area, observe emergency procedures, consult an expert. For personal protection, see Section 8.

**Environmental Precautions**

Do not let product enter drains.

**Methods and materials for Containment and Cleaning Up**

Cover drains. Collect, bind, and pump off spills. Observe possible material restrictions (see Sections 7 and 10). Take up carefully. Dispose of properly. Clean up affected area. Avoid generation of dusts.

**Reference to Other Sections**

For disposal, see Section 13.

**Section 7: Handling and Storage****Section 7, Handling and Storage****Precautions for Safe Handling****Advice on Safe Handling**

Work under hood. Do not inhale substance/mixture.

**Hygiene Measures**

Immediately change contaminated clothing. Apply preventive skin protection. Wash hands and face after working with substance. For precautions, see Section 2.

**Conditions for Safe Storage, Including Any Incompatibilities****Storage Conditions**

Tightly closed. Dry. Keep in a well-ventilated place. Keep locked up or in an area accessible only to qualified or authorized persons.

**Storage Stability**

Recommended storage temperature

2 – 8°C

**Storage Class**

Storage class (TRGS 510): 6.1A: Combustible, acute toxic Cat. 1 and 2 / very toxic hazardous materials

**Specific End Use(s)**

Apart from the uses mentioned in Section 1, no other specific uses are stipulated.

**Section 8: Exposure Controls / Personal Protection****Section 8, Exposure Controls / Personal Protection****Control Parameters****Ingredients With Workplace Control Parameters**

Contains no substances with occupational exposure limit values.

**Exposure Controls**

Appropriate Engineering Controls

Immediately change contaminated clothing. Apply preventive skin protection. Wash hands and face after working with substance.

**Personal Protective Equipment**

**Eye/Face Protection**

Use equipment for eye protection tested and approved under appropriate government standards such as NIOSH (US) or EN 166 (EU). Tightly fitting safety goggles.

**Skin Protection**

This recommendation applies only to the product stated in the safety data sheet, supplied by us and for the designated use. When dissolving in or mixing with other substances and under conditions deviating from those stated in EN 374, please contact the supplier of CE-approved gloves. Material: Nitrile rubber; Minimum layer thickness: 0.11mm; Break-through time: 480 mins; Material tested: KCL 741 Dermatrill® L.

**Body Protection**

Protective clothing.

**Respiratory Protection**

Required when dusts are generated.

**Control of the Environmental Exposure**

Do not let product enter drains.

**Section 9: Physical and Chemical Properties**

**Section 9, Physical and Chemical Properties**

**Information on Basic Physical and Chemical Properties**

Appearance	Form: Crystalline; Color: White
Odor	No data available
Odor Threshold	No data available
pH	No data available
Melting/Freezing Point	Melting point/range: 62 – 65°C (144 – 149°F) – lit.
Initial Boiling Point/Range	210 – 220°C/410 – 428°F at 0.013 hPa
Flash Point	113°C (235°F) – closed cup
Evaporation Rate	No data available
Flammability (solid/gas)	No data available
Upper/Lower Flammability	No data available
Or Explosive Limits	
Vapor Pressure	No data available
Vapor Density	No data available
Density	No data available
Relative Density	No data available
Water Solubility	Insoluble
Partition Coefficient: n-octanol/water	No data available
Autoignition Temperature	No data available
Decomposition Temperature	No data available
Viscosity	No data available
Oxidizing Properties	None

**Other Safety Information**

Solubility in Other Solvents      Benzene – soluble

Ether – soluble  
Chloroform - soluble

**Section 10: Stability and Reactivity**

**Section 10, Stability and Reactivity**

**Reactivity**

Forms explosive mixtures with air on intense heating.

A range from approximately 15 Kelvin below the flash point is to be rated as critical. The following applies in general to flammable organic substances and mixtures: in correspondingly fine distribution, when whirled up a dust explosion potential may generally be assumed.

**Chemical Stability**

The product is chemically stable under standard ambient conditions (room temperature).

**Possibility of Hazardous Reactions**

Violent reactions possible with: strong oxidizing agents

**Conditions to Avoid**

Strong heating.

**Incompatible Materials**

No data available

**Hazardous Decomposition Products**

In the event of fire, see Section 5.

**Section 11: Toxicological Information**

**Section 11, Toxicological Information**

**Acute Toxicity**

LD50 Oral – Mouse – 47.2mg/kg

Remarks: (RTECS)

Inhalation: No data available

LD50 Dermal – Mouse - .512mg/kg

Remarks (RTECS)

No data available

**Skin Corrosion/Irritation**

Remarks: No data available

**Serious Eye Damage/Eye Irritation**

Remarks: No data available

**Respiratory or Skin Sensitization**

No Data Available

**Germ Cell Mutagenicity**

No data available

**Carcinogenicity**

IARC: No ingredient of this product present at levels greater than or equal to 0.1% is identified as probable, possible, or confirmed human carcinogen by IARC.

NTP: No ingredient of this product present at levels greater than or equal to 0.1% is identified as a known or anticipated carcinogen by NTP.

OSHA: No component of this product present at levels greater than or equal to 0.1% is on OSHA’s list of regulated carcinogens.

**Reproductive Toxicity**

No data available

**Specific Target Organ Toxicity – Single Exposure**

May cause respiratory irritation.

**Specific Target Organ Toxicity – Repeated Exposure**

No data available

**Aspiration Hazard**

No data Available

**Additional Information**

RTECS: RA8530000

Burning sensation, cough, sneezing, wheezing, laryngitis, shortness of breath, headache, nausea, vomiting  
To the best of our knowledge, the chemical, physical, and toxicological properties have not been thoroughly investigated.

Liver – Irregularities – Based on Human Evidence

**Section 12: Ecological Information**

**Section 12, Ecological Information**

<b>Toxicity</b>	No data available
<b>Persistence and Degradability</b>	No data available
<b>Bioaccumulative Potential</b>	No data available
<b>Mobility in Soil</b>	No data available
<b>Results of PBT and vPvB Assessment</b>	PBT/vPvB assessment not available as chemical safety assessment not required/not conducted.
<b>Endocrine Disrupting Properties</b>	No data available
<b>Other Adverse Effects</b>	No data available

**Section 13: Disposal Considerations**

**Section 13, Disposal Considerations**

**Waste Treatment Methods**

**Product**

Waste material must be disposed of in accordance with the national and local regulations. Leave chemicals in original containers. No mixing with other waste. Handle uncleaned containers like the product itself.

**Section 14: Transport Information****Section 14, Transport Information****DOT (US)**

UN No.: 3462

Class 6.1

Packing Group III

Proper Shipping Name: Toxins, extracted from living sources, solid, n.o.s. (capsaicine)

Reportable Quantity (RQ): Poison Inhalation Hazard: No

**IMDG**

UN No.: 3462

Class 6.1

Packing Group II

EMS-No: F-A, S-A

Proper Shipping Name: Toxins, extracted from living sources, solid, n.o.s. (capsaicine)

**IATA**

UN No.: 3462

Class 6.1

Packing Group II

Proper Shipping Name: Toxins, extracted from living sources, solid, n.o.s. (capsaicine)

**Section 15: Regulatory Information****Section 15, Regulatory Information****SARA 302 Components**

This material does not contain any components with a section 302 EHS TPQ.

**SARA 313 Components**

This material does not contain any chemical components with known CAS numbers that exceed the threshold (De Minimis) reporting levels established by SARA Title III, Section 313.

**SARA 311/312 Hazards**

Acute Health Hazard, Chronic Health Hazard

**Massachusetts Right To Know Components**

No components are subject to the Massachusetts Right To Know Act.

**Section 16: Other Information****Section 16, Other Information**

The above information is believed to be correct but does not purport to be all-inclusive and shall be used only as a guide. Nothing herein shall be deemed to create any warranty, express or implied. It is the responsibility of the user to determine the applicability of this information and the suitability of the material or product for any particular purpose.

**SOLA** shall not be held liable for any damage resulting from handling or from contact with the above product. SOLA reserves the right to revise this Safety Data Sheet.