

# HDA Standard Pharmaceutical Product and Medical Device Information (Rx Product Only)

Version 2021

Introduction Type:  New Item

Final Version

Date: 1/12/2023

PRODUCT INFORMATION		SPECIAL HANDLING AND STORAGE REQUIREMENTS*																													
Company Name: SOLA Pharmaceuticals Application Number for NDA/ANDA/BLA (drug); PMA/510(k)(med device): Medical Device Class, if applicable: DUNS: 080121345 Proprietary Name (if Applicable) and Established Name: Capsaicin Topical Patch Selling Unit NDC: 70512-016-10 Unit of Use NDC: CVX Code: MVX Code: 070512016103 Description: Capsaicin 0.025% Topical Patch Active Ingredient(s): Capsaicin 0.025% URL for Additional Product Information: Address: 655 Highlandia Dr. City: Baton Rouge State: LA Address 2: Zip: 70810 Key Contact: Email: info@solameds.us Phone Number: 866-747-7365 Fax: 800-754-9550 Product Therapeutic Classification: Topical Analgesic		a. Temperature – Indicate the USP temperature range for this product. Temperature Range: Other Temperature Range Requirement (write in): Store in a clean, dry place outside of direct sunlight. Protect from excessive moisture. Notes: Is this product to be shipped to customers on ice? <input type="checkbox"/> No Is this product to be shipped to customers on dry ice? <input type="checkbox"/> No																													
ADDITIONAL PRODUCT INFORMATION The product is? a legend device? <input type="checkbox"/> No if yes, enter class # if yes, list NDCs of component parts reverse numbered? co-licensed? latex-free? preservative-free? correctional institution block? oploid? Cannabinoid? If Unit Dose, is item bar coded to unit dose for hospital scanning? If Unit Dose, indicate NDC here:		b. Contact for temperature excursion questions: Name: Number: 866-747-7365 Group E-mail: info@solameds.us c. Special regulations for product in any states? Special returns requirements for this product? <input type="checkbox"/> No d. Store product (unit of sale) upright? Protect product (unit of sale) from light? <input type="checkbox"/> No e. Shelf life: Initial shelf life at launch (if different): 24 Months																													
PRODUCT DESCRIPTION INFORMATION Is the Product... Direct-Ship Only Is the Product... Orphan Drug Status FDA Approval Status Allergens Present Country of Origin: China Is this product covered under the Trade Agreements Act (TAA)? <input type="checkbox"/> No		ORDER INFORMATION Unit of Sale: <input checked="" type="checkbox"/> Bottle <input checked="" type="checkbox"/> Box/Carton <input type="checkbox"/> Ampule <input type="checkbox"/> Glass <input type="checkbox"/> Tube <input type="checkbox"/> Vial Liquid Sgl <input type="checkbox"/> Vial Liquid Multi <input type="checkbox"/> Vial Powder Sgl <input type="checkbox"/> Vial Power Multi <input type="checkbox"/> Other: Write In What is the NDC selling unit? 1 box of 10 patches (Write-in, e.g. 1 Box of 10 Vials) Minimum order quantity? <input type="checkbox"/> Yes If Yes, how many of which package type? 24 Each Inner/Carton/Pack Case																													
FOR GENERIC DRUG PRODUCTS I. Orange Book Rating: II. Generic Equivalent to What Brand?:		PHARMACY ORDER / BILL UNIT Rec. sell unit to customer? 1 box (Write-in, e.g. 1 Vial) Rx billing unit to pharmacy: <input checked="" type="checkbox"/> Each <input type="checkbox"/> Gram <input type="checkbox"/> Milliliter																													
DRUG SUPPLY CHAIN SECURITY ACT (DSCSA) INFORMATION Does supplier meet DSCSA definition of manufacturer? <input type="checkbox"/> Yes Is product exempt from DSCSA? If yes, select exemption: Other exemption - Write in: Is product repackaged? Is product sold by manufacturer's exclusive distributor? Has FDA granted waiver/exception/exemption for product? If yes, attach documentation from FDA.		ITEM AND PACKING INFORMATION <table border="1" style="width:100%; border-collapse: collapse;"> <thead> <tr> <th>Item/Each:</th> <th>Weight Lbs.</th> <th>Dimensions (US msmts.) Depth</th> <th>Width</th> <th>Height</th> <th>Volume (Cube)</th> <th>Saleable # Pieces</th> </tr> </thead> <tbody> <tr> <td>Box/Carton/Bundle/ Inner Pack:</td> <td>0.4</td> <td>1.5</td> <td>6.5</td> <td>7.7</td> <td>75.075</td> <td>1</td> </tr> <tr> <td>Case:</td> <td>10.8</td> <td>17.5</td> <td>13</td> <td>8</td> <td>1820</td> <td>24</td> </tr> <tr> <td>Pallet:</td> <td>518.4</td> <td>47.8</td> <td>38</td> <td>49</td> <td>89003.6</td> <td>1152</td> </tr> </tbody> </table>		Item/Each:	Weight Lbs.	Dimensions (US msmts.) Depth	Width	Height	Volume (Cube)	Saleable # Pieces	Box/Carton/Bundle/ Inner Pack:	0.4	1.5	6.5	7.7	75.075	1	Case:	10.8	17.5	13	8	1820	24	Pallet:	518.4	47.8	38	49	89003.6	1152
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*Please provide any additional information on page 2. Attach copy of SAFETY DATA SHEET (SDS) or non hazard letter, PACKAGE INSERT, LABEL AND PHOTO OF PRODUCT PACKAGING and BARCODE. See new p. 3 for Designated Drop Ship Only. Signature:																															



# Standard Pharmaceutical Product and Medical Device Information (Rx Product Only)

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For Designated Drop Ship Only Products, Please Use Page 3

## MATERIAL HAZARD CLASSIFICATION and TRANSPORTATION

Is this product (check all that apply):

a. Cytotoxic?  No

b. CA Prop. 65 Carcinogen or Reproductive Toxicant?  
 Is the product a CA Prop 65 carcinogen?  No  
 Is the product a CA Prop 65 reproductive toxicant?  No  
 Does the product label bear a CA Prop 65 warning?  No

c. Contact Hazard?  No

d. Does this product require special clean-up instructions?  
 (If yes, attach SDS with special instructions.)  No

e. Does the product contain DEHP?  No

Is this product regulated for shipment by DOT?  
 (if yes, answer a-e below and provide SDS)  Yes

a. UN/Identification Number

b. Proper Shipping Name

c. DOT Hazard Class

d. Packing Group

e. Inhalation Hazard?  No

Is this product regulated for shipment by IATA?  
 (if yes, answer a-e below and provide SDS)  Yes

a. UN/Identification Number

b. Proper Shipping Name

c. DOT Hazard Class

d. Packing Group

e. Inhalation Hazard?  No

Is the product restricted for air shipment? If so, indicate restriction:  No

Passenger

Cargo

Passenger & Cargo

Is this a reportable quantity?  No

RQ Threshold:

Is this a marine pollutant?  No

Is this product shipped utilizing an authorized DOT exception or Special Permit?  
 No (if yes, identify method below)

Limited Quantity

Consumer Commodity, ORM-D

Small Quantity (49 CFR 173.4)

Special Permit; DOT-SP

Special Provision (listed in Column 7 of 49 CFR 172.101);  
 SP#

### ADD'L STORAGE INFORMATION

Is the Product...

Controlled Substance?  No  Yes      Controlled Substance Code

Controlled by State(s)?  No  Yes      Listed Chemical (List I or II)  No  Yes

ARCOS Reportable?  No  Yes      If yes, indicate which:

Schedule No.       Is it a scheduled listed chemical product?:  No  Yes

### CLASS OF TRADE RESTRICTION:

No restriction: Select YES if sold to retail pharmacy, hospitals, clinics and physician offices  Yes

Restricted to retail pharmacy only:  No

Restricted to hospital, clinics, and physician offices only:  No

Restricted from US territories? (explain in comments)  No

Comments:

### SDS Hazard Classification

Organic       Corrosive

Inorganic       Oxidizer

Steroid/Androgen       Contact Hazard

Does the product have an Aerosol class? If yes,  No

identify NFPA Storage Level:

NFPA Storage Level:

Is the product a NIOSH hazardous drug?  
 If yes, indicate which:  No

### Hazardous Waste Identification

EPA Hazardous Waste Code:       Waste Characteristics

### REMS or REGISTRY RESTRICTIONS

Is there a REMS on this product?  No  Yes

If Yes, is it managed with a pharmacy registry?  No  Yes

Website URL:

Med Guide Required  No  Yes

Limited Distribution Requirement  No  Yes

Comments / Details: (For example, iPledge program?)

**REMS:**  No  Yes

REMS Program Manager Name:       Phone:

Supplier Manages REMS registry exclusively:  No  Yes

Wholesale distributor support:  No  Yes

Provider Name:       DEA #:

Site Enrollment Number assigned by Supplier:       NCPDP#:

NPI #:

Comments

**Registry:**  No  Yes

Registry Program Contact Name:       Phone:

Comments

### RETURN INSTRUCTIONS

Contact tel. # if product received damaged:

Is product returnable for credit:  No  Yes

URL/Link to returns policy:

Special regulations or returns requirements for this product in certain states?  No  Yes

If so, which states? Other requirements? Comments?

### MISCELLANEOUS NOTES and/or Image of Product Barcode:



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FOR DESIGNATED DROP SHIP PRODUCT ONLY - if not a designated drop ship, do not complete.

Order Method for Designated Drop Ship Product	Standard Order Receipt and Processing
Purchase orders may be accepted by: a. EDI <input type="checkbox"/> b. Autofax <input type="checkbox"/> c. Fax <input type="checkbox"/> d. Phone only <input type="checkbox"/> e. Supplier Web Site only <input type="checkbox"/> Minimum Order Quantity: <input type="text"/> Supplier's Customer Service Number: <input type="text"/> Contracted 3PL company / contact #: <input type="text"/> Name: <input type="text"/> Phone: <input type="text"/> Fax Number: <input type="text"/> Fax Number: <input type="text"/> Phone No.: <input type="text"/> Site Address: <input type="text"/>	<b>Purchase order daily receipt cut off time by supplier</b> Cut off time: <input type="text"/> Shipping lead time of PO: <input type="text"/> Hours <input type="text"/> Days Ships same day for next day receipt: <input type="checkbox"/> Ships for second day receipt: <input type="checkbox"/> Ships regular ground for 3-10 days receipt: <input type="checkbox"/>
<b>Expedited Freight Charges or Other Designated Drop Ship Fees:</b> Expedited freight fees billed with each order: <input type="text"/> Drop Ship service fee billed with each order: <input type="text"/> Drop Ship miscellaneous fees billed: <input type="text"/> Comments: <input type="text"/>	<b>Overnight and Priority Overnight PO Processing</b> <b>Overnight receipt available:</b> <input type="checkbox"/> PO Receipt cut off time: <input type="text"/> Days of week overnight is available: <input type="checkbox"/> Monday <input type="checkbox"/> Tuesday <input type="checkbox"/> Wednesday <input type="checkbox"/> Thursday <input type="checkbox"/> Friday <b>Priority Overnight receipt available:</b> <input type="checkbox"/> PO Receipt Cut off time: <input type="text"/> <b>Saturday Overnight receipt available:</b> <input type="checkbox"/> PO Receipt Cut off time: <input type="text"/> Order receipt method: Phone: <input type="text"/> Phone #: <input type="text"/> Fax: <input type="text"/> Fax #: <input type="text"/> EDI: <input type="text"/> Overnight Fees apply: <input type="checkbox"/> Other fees apply: <input type="checkbox"/>
<b>Class of Trade Restriction:</b> No restriction: Select YES if sold to retail pharmacy, hospitals, clinics and physician offices <input type="checkbox"/> Restricted to retail pharmacy only: <input type="checkbox"/> Restricted to hospital, clinics, and physician offices only: <input type="checkbox"/> Restricted from US territories? (explain in comments) <input type="checkbox"/> Comments: <input type="text"/>	<b>Return Instructions</b> Contact # if product is received damaged: <input type="text"/> Is product returnable for credit: <input type="checkbox"/> URL/Link to returns policy: <input type="text"/> Special regulations or returns requirements for this product in certain states? <input type="checkbox"/> If so, which states? Other requirements? Comments? <input type="text"/>
<b>Other Data Information Required to Process PO:</b> Patient Procedure Date: <input type="text"/> Physician Name: <input type="text"/> Physician/Clinic Phone #: <input type="text"/> Physician State License #: <input type="text"/> Physician/Clinic DEA #: <input type="text"/> Physician/Clinic Specialty: <input type="text"/> <b>Miscellaneous Notes:</b> <input type="text"/>	<b>ADDITIONAL INFORMATION</b> Is product order for scheduled patient procedure? <input type="checkbox"/> Is product order for restocking purposes? <input type="checkbox"/>