



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

Version 2021 Introduction Type: New Item Final Version Date:

PRODUCT INFORMATION

Company Name: SOLA Pharmaceuticals Application:

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: Lidocaine 4% Patch

Selling Unit NDC: 70512-812-30 Unit of Use NDC: UPC: 370512812300

UDI: CVX Code: MVX Code:

Description: Lidocaine 4% Patch, 30ct

Active Ingredient(s): Lidocaine 4%

URL for Additional Product Information:

Address: 655 Highlandia Dr. Address 2:

City: Baton Rouge State: LA Zip: 70810

Key Contact: Email: info@solameds.us

Phone Number: 866-747-7365 Fax: 800-754-9550

Product Therapeutic Classification: Topical Anesthetic

SPECIAL HANDLING AND STORAGE REQUIREMENTS*

a. Temperature – Indicate the USP temperature range for this product.
Temperature Range:

Other Temperature Range Requirement (write in):

Notes: Avoid storing product in direct sunlight; protect product from excessive moisture

Is this product to be shipped to customers on ice? No

Is this product to be shipped to customers on dry ice? No

b. Contact for temperature excursion questions:
Name:

Number:

Group E-mail: info@solameds.us

c. Special regulations for product in any states?
Special returns requirements for this product? No

d. Store product (unit of sale) upright? No

Protect product (unit of sale) from light? No

e. Shelf life:
Initial shelf life at launch (if different): Months

ADDITIONAL PRODUCT INFORMATION

The product is a legend device? No

if yes, enter class #

a product kit? No

if yes, list NDCs of component parts reverse numbered?

co-licensed? No

latex-free? Yes

preservative-free? Yes

correctional institution block? No

opioid? No

Cannabinoid? No

If Unit Dose, is item bar coded to unit dose for hospital scanning? No

If Unit Dose, indicate NDC here:

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)? No

PRODUCT DESCRIPTION INFORMATION

Size: 30 patches

Strength: 4%

Dosage Form: Topical patch

Product Shape: Rectangle

Product Color: White

Product Imprint:

ORDER INFORMATION

Unit of Sale: Bottle Box/Carton Ampule Glass Tube Vial Liquid Sgl Vial Liquid Multi Vial Powder Sgl Vial Power Multi Other: Write In

What is the NDC selling unit?
(Write-in, e.g. 1 Box of 10 Vials)

Minimum order quantity? Yes

If Yes, how many of which package type?
 Each Inner/ Carton/ Pack Case

FOR GENERIC DRUG PRODUCTS

Authorized Generic *If Authorized Generic, other section fields are not applicable

I. Orange Book Rating:

II. Generic Equivalent to What Brand?:

PHARMACY ORDER / BILL UNIT

Rec. sell unit to customer?
(Write-in, e.g. 1 Vial)

Rx billing unit to pharmacy:
 Each Gram Milliliter

DRUG SUPPLY CHAIN SECURITY ACT (DSCSA) INFORMATION

Does supplier meet DSCSA definition of manufacturer? Yes No

Is product exempt from DSCSA? Yes No

If yes, select exemption:

Other exemption - Write in:

Is product repackaged? No

Is product sold by manufacturer's exclusive distributor? No

Has FDA granted waiver/exception/exemption for product? No

If yes, attach documentation from FDA.

GLN:

GCP:

If yes, was original product purchased direct from mfr?

Provide source manufacturer for repackaged product

ITEM AND PACKING INFORMATION

Item/Each:	Weight Lbs.	Dimensions (US msmts.)			Volume (Cube)	Saleable # Pieces
		Depth	Width	Height		
Box/Carton/Bundle/Inner Pack:	1.25	2.5	7	5.75	100.625	1
Case:	31.05	16.5	15	12	2970	24
Pallet:	775.2	40.5	37.5	52.5	79734.375	576

GTIN AND HIBCC PRODUCT INFORMATION

Saleable Unit of Measure	Saleable Quantity	HIBCC	GTIN-14	Unit of Use GTIN-14
<input checked="" type="checkbox"/> Item/Each	1			
<input checked="" type="checkbox"/> Box/Carton/Bundle/Inner Pack	24		00370512812300	
<input type="checkbox"/> Case			50370512812305	
<input type="checkbox"/> Pallet				

COST INFORMATION

Regular Cost:

Invoice Cost (WAC) (\$):

As of date:

WHOLESALE USE ONLY:
Vendor #:

Whsl. Code #:

Fineline Code:



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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)

- 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)

- 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:

- 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 by State(s)? No Yes
- ARCOS Reportable? No Yes
- Schedule No.
- Controlled Substance Code
- Listed Chemical (List I or II) No Yes
- If yes, indicate which:
- 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
- Inorganic
- Steroid/Androgen
- Corrosive
- Oxidizer
- Contact Hazard

Does the product have an Aerosol class? If yes, identify NFPA Storage Level: No
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
If Yes, is it managed with a pharmacy registry? No
Website URL:

Med Guide Required No
Limited Distribution Requirement No
Comments / Details: (For example, iPledge program?)

REMS: No
REMS Program Manager Name: Phone:
Supplier Manages REMS registry exclusively: Yes No
Wholesale distributor support: Yes No
Provider Name: DEA #:
Site Enrollment Number assigned by Supplier: NCPDP#:
NPI #:

Comments

Registry: No
Registry Program Contact Name: Phone:
Comments

RETURN INSTRUCTIONS

Contact tel. # if product received damaged: 866-747-7365

Is product returnable for credit: No

URL/Link to returns policy:

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

If so, which states? Other requirements? Comments:

MISCELLANEOUS NOTES and/or Image of Product Barcode:

