

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

Version 2021

Introduction Type:  New Item

Final Version

Date: 1/19/2023

**PRODUCT INFORMATION** **SPECIAL HANDLING AND STORAGE REQUIREMENTS\***

Company Name: SOLA Pharmaceuticals  
 Application Number for NDA/ANDA/BLA (drug); PMA/510(k)(med device): 203152  
 Application: ANDA  
 Medical Device Class, if applicable:  
 DUNS: 080121345  
 Proprietary Name (if Applicable) and Established Name: Olopatadine HCL 0.1% Ophthalmic Solution  
 Selling Unit NDC: 70512-520-05  
 Unit of Use NDC:  
 CVX Code:  
 UPC: 705120520055  
 MVX Code:  
 Description: Olopatadine HCL 0.1% Ophthalmic Solution, 5mL  
 Active Ingredient(s): Olopatadine 0.1%  
 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:

a. Temperature – Indicate the USP temperature range for this product.  
 Temperature Range  
 Other Temperature Range Requirement (write in): Store at 39°-77°F (4°-25°C)  
 Notes  
 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: 866-747-7365  
 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?  
 Protect product (unit of sale) from light?  Yes  
 e. Shelf life:  
 Initial shelf life at launch (if different): 24 Months

ADDITIONAL PRODUCT INFORMATION	PRODUCT DESCRIPTION INFORMATION
The product is? a legend device? <input type="checkbox"/> No if yes, enter class # a product kit? <input type="checkbox"/> No if yes, list NDCs of component parts reverse numbered? co-licensed? <input type="checkbox"/> No latex-free? <input type="checkbox"/> No preservative-free? <input type="checkbox"/> No correctional institution block? <input type="checkbox"/> No opioid? <input type="checkbox"/> No Cannabinoid? <input type="checkbox"/> No If Unit Dose, is item bar coded to unit dose for hospital scanning? <input type="checkbox"/> No If Unit Dose, indicate NDC here:	Is the Product... Direct-Ship Only <input type="checkbox"/> Is the Product... Orphan Drug Status <input type="checkbox"/> FDA Approval Status Allergens Present Country of Origin: India Is this product covered under the Trade Agreements Act (TAA)? <input type="checkbox"/> No
	Size: 5mL Strength: 0.1% Dosage Form: Ophthalmic solution Product Shape: Product Color: Colorless, clear solution Product Imprint:

**ORDER INFORMATION**

Unit of Sale <input checked="" type="checkbox"/> Bottle <input 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 24 bottles (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
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**FOR GENERIC DRUG PRODUCTS**

I. Orange Book Rating:  Authorized Generic \*If Authorized Generic, other section fields are not applicable  
 II. Generic Equivalent to What Brand?: Pataday®

**PHARMACY ORDER / BILL UNIT**

Rec. sell unit to customer? 1 bottle (Write-in, e.g. 1 Vial)	Rx billing unit to pharmacy: <input checked="" type="checkbox"/> Each <input type="checkbox"/> Gram <input type="checkbox"/> Milliliter
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**DRUG SUPPLY CHAIN SECURITY ACT (DSCSA) INFORMATION**

Does supplier meet DSCSA definition of manufacturer?  Yes  
 Is product exempt from DSCSA?  Yes  
 If yes, select exemption:  
 Other exemption - Write in: OTC exemption  
 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: 0370512000004  
 GCP: 0370512

If yes, was original product purchased direct from mfr?  
 Provide source manufacturer for repackaged product

**ITEM AND PACKING INFORMATION**

	Weight Lbs.	Dimensions (US msmts.) Depth	Width	Height	Volume (Cube)	Saleable # Pieces
Item/Each:	0.0567	1.5	3	1.5	6	1
Box/Carton/Bundle/ Inner Pack:	0.95	5	7.5	3	112.5	24
Case:	9.6	16	8	12	1536	192
Pallet:	489.88	47.24	39.37	46.45	86389.512	8640

**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		00370512520052	
<input checked="" type="checkbox"/> Box/Carton/Bundle/Inner Pack	24		30370512520053	
<input checked="" type="checkbox"/> Case	192		50370512520057	
<input checked="" type="checkbox"/> Pallet	8640		70370512520051	

**COST INFORMATION** **WHOLESALE USE ONLY:**

Regular Cost Invoice Cost (WAC) (\$) \$7.60 As of date: 7/5/22	Vendor #: Whst. Code #: FineLine Code:
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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: \_\_\_\_\_



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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.)  Yes

e. Does the product contain DEHP?  No

Is this product regulated for shipment by DOT?  
 (if yes, answer a-e below and provide SDS)  No

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)  No

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#

### SDS Hazard Classification

<input type="checkbox"/> Organic	<input type="checkbox"/> Corrosive
<input type="checkbox"/> Inorganic	<input type="checkbox"/> Oxidizer
<input type="checkbox"/> Steroid/Androgen	<input checked="" type="checkbox"/> 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?  No  
 If yes, indicate which:

### 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:

Supplier Manages REMS registry exclusively:

Wholesale distributor support:

Provider Name:

Site Enrollment Number assigned by Supplier:

Phone:

DEA #:

NCPDP#:

NPI #:

Comments

**Registry:**  No

Registry Program Contact Name:

Phone:

Comments

### ADD'L STORAGE INFORMATION

Is the Product...  
 Controlled Substance?  No  
 Controlled by State(s)?  No  
 ARCOS Reportable?  No  
 Schedule No.

Controlled Substance Code

Listed Chemical (List I or II)  No

If yes, indicate which:

Is it a scheduled listed chemical product?:  No

### 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:

### RETURN INSTRUCTIONS

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

Is product returnable for credit:  Yes

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:



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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>ADDITIONAL INFORMATION</b> Is product order for scheduled patient procedure? <input type="checkbox"/> Is product order for restocking purposes? <input type="checkbox"/>
<b>Miscellaneous Notes:</b> <input type="text"/>	