



Standard Pharmaceutical Product Information (Rx Product Only)

Introduction Type: New Item Final Version

Date: 01-09-2021

PRODUCT INFORMATION

Company Name: Encube Ethicals Inc. Application: ANDA
 Application Number for NDA/ANDA/BLA (drug); PMA/510(k)(med device): 213076
 DUNS: 11-698-2244
 Proprietary Name (If Applicable) and Established Name: Mupirocin Cream 2%
 Selling Unit NDC: 21922-029-04 Individual Unit NDC: _____ UPC: 321922029048
 UDI: _____ CVX Code: _____ MXV Code: _____
 Description: Mupirocin Cream USP, 2% is a white cream that contains 20 mg (2% w/w) of mupirocin per gram in an oil- and water-based emulsion supplied in 15-gram and 30-gram tubes.
 Active Ingredient(s): Mupirocin
 URL for Additional Product Information: _____
 Address: 200 Meredith Avenue, Suite 101A Address 2: _____
 City: Durham State: NC Zip: 27713
 Key Contact: Kamesh Venugopal Email: kamesh.v@encubeethicals.com
 Phone Number: +1-269-806-2796 Fax: 984-439-2761
 Product Therapeutic Classification: _____

SPECIAL HANDLING AND STORAGE REQUIREMENTS*

a. Temperature – Indicate the USP temperature range for this product.
 Temperature Range: Controlled Room – between 20 and 25 C (68° – 77° F)
 Other Temperature Range Requirement (write in): _____
 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: Dipti Kamani
 Number: +1-781-789-0567
 Group E-mail: usreg@encubeethicals.com
 c. Special regulations for product in any states?
 Special returns requirements for this product? _____
 d. Store product (unit of sale) upright?
 Protect product (unit of sale) from light? Yes No
 e. Shelf life:
 Initial shelf life at launch (if different): 18 Months

ADDITIONAL PRODUCT INFORMATION

Is the Product...
 a legend device? No
 reverse numbered? No
 co-licensed? No
 Is the Product...
 Is the Product...
 If Unit Dose, is item bar coded to unit dose for hospital scanning?
 If Unit Dose NDC, indicate NDC here: _____
 Country of Origin: India
 Is this product covered under the Trade Agreements Act (TAA)?

PRODUCT DESCRIPTION INFORMATION

Size: 15g
 Strength: 2%
 Dosage Form: Cream
 Product Shape: _____
 Product Color: White Cream
 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? 21922-029-04 (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
 1 Case

FOR GENERIC DRUG PRODUCTS

I. Orange Book Rating: AB Authorized Generic *If Authorized Generic, other section fields are not applicable
 II. Generic Equivalent to What Brand?: BACTROBAN (RLD, GLAXOSMITHKLINE)

PHARMACY ORDER / BILL UNIT

Rec. sell unit to customer? _____ Rx billing unit to pharmacy: _____
 (Write-in, e.g. 1 Vial) _____ Each
 _____ Gram
 _____ Milliliter

DRUG SUPPLY CHAIN SECURITY ACT (DSCSA) INFORMATION

Does supplier meet DSCSA definition of manufacturer? Yes
 Is product exempt from DSCSA? No GLN: 890600527
 If yes, select exemption: _____
 Other exemption - Write in: _____
 Is product repackaged? No If Yes, was original product purchased direct from mfr? _____
 Is product sold by manufacturer's exclusive distributor? No
 Has FDA granted waiver/exception/exemption for product? No If yes, attach documentation from FDA.

ITEM AND PACKING INFORMATION

Item:	Weight Lbs.	Dimensions (US msmts.)			Volume (Cube)	# Pieces:
		Depth	Height	Width		
Item:	0.06	4.53	1.18	0.98	5.238492	1
Box/Carton/Bundle/Inner Pack:	1.49	6.14	4.72	4.96	143.744768	24
Case:	10.75	14.76	5.59	12.68	1046.20651	144
Pallet:	579.49	45.7	42.992	39.37	77351.5933	7776
UPC:	Case: NA					
	Carton: 321922029048					

GTIN PRODUCT INFORMATION

Serialized? If not, when? Items aggregated?	Level	Item	Selling Unit	Quantity	GTIN-14	
					Serialized	GTIN-14
<input checked="" type="checkbox"/>	Item	Box/Carton/Bundle/Inner Pack	1	1	<input checked="" type="checkbox"/>	00321922029048
<input checked="" type="checkbox"/>	Case		24	24	<input checked="" type="checkbox"/>	10321922029045
<input checked="" type="checkbox"/>	Pallet		144	144	<input checked="" type="checkbox"/>	30321922029049
<input checked="" type="checkbox"/>			7776	7776	<input checked="" type="checkbox"/>	50321922029043

COST INFORMATION**WHOLESALE USE ONLY:**

Regular Cost _____ Vendor #: _____
 Invoice Cost (WAC) (\$) _____ Whsl. Code #: _____
 Federal Excise Tax Per Unit of Sale _____ Finesline Code: _____
 As of date: _____

*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: _____

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? No

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? No

(If yes, attach SDS with special instructions.)

e. Does the product contain DEHP? No

Is this product regulated for shipment by DOT or IATA? Yes

(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

Controlled by State(s)? No

ARCOS Reportable? No

Schedule No. (inc. N for non-narcotic) []

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 No

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	
<input type="checkbox"/> Organic	<input type="checkbox"/> Corrosive
<input type="checkbox"/> Inorganic	<input type="checkbox"/> Oxidizer
<input type="checkbox"/> Steroid/Androgen	<input type="checkbox"/> Contact Hazard
Aerosol Class; Identify NFPA Storage Level: []	
Is the product a NIOSH hazardous drug? No	
If yes, indicate which: []	

Hazardous Waste Identification
EPA Hazardous Waste Code: []

REMS or REGISTRY RESTRICTIONS	
Is there a REMS on this product? No	
If Yes, is it managed with a pharmacy registry? []	
Website URL: []	
Comments / Details: (For example, iPledge program?) []	
REMS: No	
REMS Program Manager Name: []	Phone: []
Supplier Manages REMS registry exclusively: []	
Wholesale distributor support: []	
Provider Name: []	
Site Enrollment Number assigned by Supplier: []	DEA #: No
	PCDP #: No
	NPI #: No

Comments []	
Registry: No	
Registry Program Contact Name: []	Phone: []
Comments []	

RETURN INSTRUCTIONS	
Contact tel. # if product received damaged: 919-767-3292	
Is product returnable for credit: Yes	
URL/Link to returns policy: Contact Manufacturer	
Special regulations or returns requirements for this product in certain states? []	
If so, which states? Other requirements? Comments? []	

MISCELLANEOUS NOTES and/or Image of Product Barcode:

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
<p>Purchase orders may be accepted by:</p> <p>a. EDI <input checked="" type="checkbox"/> Yes</p> <p>b. Autofax <input type="checkbox"/> Fax Number: <input type="text"/></p> <p>c. Fax <input checked="" type="checkbox"/> Yes Fax Number: 984-439-2761</p> <p>d. Phone only <input type="checkbox"/> Phone No.: <input type="text"/></p> <p>e. Supplier Web Site only <input type="checkbox"/> Site Address: <input type="text"/></p> <p>Minimum Order Quantity: <input type="text" value="144"/> Units</p> <p>Supplier's Customer Service Number: <input type="text"/></p> <p>Contracted 3PL company / contact #: Name: <input type="text"/> Phone: <input type="text"/></p>	<p>Purchase order daily receipt cut off time by supplier</p> <p>Cut off time: <input type="text" value="12pm"/> Eastern</p> <p>Shipping lead time of PO: <input type="text"/> Hours <input type="text"/> Days</p> <p>Ships same day for next day receipt: <input type="checkbox"/></p> <p>Ships for second day receipt: <input type="checkbox"/></p> <p>Ships regular ground for 3-10 days receipt: <input checked="" type="checkbox"/> Yes</p>
Expedited Freight Charges or Other Designated Drop Ship Fees:	Overnight and Priority Overnight PO Processing
<p>Expedited freight fees billed with each order: <input type="checkbox"/> Yes</p> <p>Drop Ship service fee billed with each order: <input type="checkbox"/> Yes</p> <p>Drop Ship miscellaneous fees billed: <input type="checkbox"/> Yes</p> <p>Comments: <input style="width: 100%; height: 40px;" type="text"/></p>	<p>Overnight receipt available: <input type="checkbox"/></p> <p>PO Receipt cut off time: <input type="text"/></p> <p>Days of week overnight is available:</p> <p><input type="checkbox"/> Monday</p> <p><input type="checkbox"/> Tuesday</p> <p><input type="checkbox"/> Wednesday</p> <p><input type="checkbox"/> Thursday</p> <p><input type="checkbox"/> Friday</p> <p>Priority Overnight receipt available: <input type="checkbox"/></p> <p>PO Receipt Cut off time: <input type="text"/></p> <p>Saturday Overnight receipt available: <input type="checkbox"/></p> <p>PO Receipt Cut off time: <input type="text"/></p> <p>Order receipt method: Phone: <input type="text"/> Phone #: <input type="text"/> Fax: <input type="text"/> Fax #: <input type="text"/> EDI: <input type="text"/></p> <p>Overnight Fees apply: <input type="checkbox"/></p> <p>Other fees apply: <input type="checkbox"/></p>
Class of Trade Restriction:	Return Instructions
<p>No restriction: Select YES if sold to retail pharmacy, hospitals, clinics and physician offices <input type="checkbox"/> Yes</p> <p>Restricted to retail pharmacy only: <input type="checkbox"/> No</p> <p>Restricted to hospital, clinics, and physician offices only: <input type="checkbox"/> No</p> <p>Restricted from US territories? (explain in comments) <input type="checkbox"/> No</p> <p>Comments: <input style="width: 100%; height: 40px;" type="text"/></p>	<p>Contact # if product is received damaged: <input type="text" value="919-767-3292"/></p> <p>Is product returnable for credit: <input type="checkbox"/> Yes</p> <p>URL/Link to returns policy: <input type="text" value="Please contact manufacturer"/></p> <p>Special regulations or returns requirements for this product in certain states? <input type="checkbox"/></p> <p>If so, which states? Other requirements? Comments? <input style="width: 100%; height: 40px;" type="text"/></p>
Other Data Information Required to Process PO:	ADDITIONAL INFORMATION
<p>Patient Procedure Date: <input type="text"/></p> <p>Physician Name: <input type="text"/></p> <p>Physician/Clinic Phone #: <input type="text"/></p> <p>Physician State License #: <input type="text"/></p> <p>Physician/Clinic DEA #: <input type="text"/></p> <p>Physician/Clinic Specialty: <input type="text"/></p>	<p>Is product order for scheduled patient procedure? <input type="checkbox"/></p> <p>Is product order for restocking purposes? <input type="checkbox"/></p>
Miscellaneous Notes:	
<input style="width: 100%; height: 80px;" type="text"/>	