



Standard Pharmaceutical Product Information (Rx Product Only)

Introduction Type: New Item Final VersionDate:

PRODUCT INFORMATION	
Company Name:	Encube Ethicals Inc.
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:	21922-029-05
UDI	
Individual Unit NDC:	
UPC:	321922029055
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
City:	Durham
Key Contact:	Kamesh Venugopal
Phone Number:	+1-269-806-2796
State:	NC
Address 2:	
Zip:	27713
Email:	kamesh.v@encubeethicals.com
Fax:	984-439-2761
Application:	ANDA
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?	Yes
Protect product (unit of sale) from light?	No
e. Shelf life:	18 Months
Initial shelf life at launch (if different):	

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:	30g
Strength:	2%
Dosage Form:	Cream
Product Shape:	
Product Color:	White Cream
Product Imprint:	

ORDER INFORMATION	
Unit of Sale	What is the NDC selling unit?
<input checked="" type="checkbox"/> Bottle	21922-029-05
<input type="checkbox"/> Box/Carton	(Write-in, e.g. 1 Box of 10 Vials)
<input type="checkbox"/> Ampule	
<input type="checkbox"/> Glass	Minimum order quantity? Yes
<input type="checkbox"/> Tube	
<input type="checkbox"/> Vial Liquid Sgl	
<input type="checkbox"/> Vial Liquid Multi	If Yes, how many of which package type?
<input type="checkbox"/> Vial Powder Sgl	Each
<input type="checkbox"/> Vial Power Multi	Inner/ Carton/Pack
<input type="checkbox"/> Other: Write In	1 Case

FOR GENERIC DRUG PRODUCTS	
I. Orange Book Rating:	AB
II. Generic Equivalent to What Brand?:	BACTROBAN (RLD, GLAXOSMITHKLINE)
<input type="checkbox"/> Authorized Generic	*If Authorized Generic, other section fields are not applicable

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
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
GLN:	890600527
If Yes, was original product purchased direct from mfr?	
If yes, attach documentation from FDA.	

ITEM AND PACKING INFORMATION						
Item:	Weight Lbs.	Dimensions (US msmts.)			Volume (Cube)	# Pieces:
		Depth	Height	Width		
Item:	0.08	5.39	1.42	1.22	9.337636	1
Box/Carton/Bundle/Inner Pack:	2.46	7.56	5.9	4.96	221.23584	24
Case:	17.76	17.156	6.3	15.39	1663.39429	144
Pallet:	622.98	47.244	47.244	35.433	79086.2978	5184
UPC:	Case:	NA				
	Carton:	321922029055				

GTIN PRODUCT INFORMATION						
Serialized? If not, when? Items aggregated?	Level	Selling Unit		Quantity	GTIN-14	
		Item	Unit			
Yes		<input checked="" type="checkbox"/>		1	00321922029055	
	Box/Carton/Bundle/Inner Pack	<input checked="" type="checkbox"/>		24	10321922029052	
	Case	<input checked="" type="checkbox"/>		144	30321922029056	
Yes	Pallet	<input checked="" type="checkbox"/>		5184	50321922029050	

COST INFORMATION		WHOLESALE USE ONLY:	
Regular Cost		Vendor #:	
Invoice Cost (WAC) (\$)		Whsl. Code #:	
Federal Excise Tax Per Unit of Sale		Fineline Code:	
As of date:			

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

Organic Corrosive

Inorganic Oxidizer

Steroid/Androgen 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 type="checkbox"/> Yes</p> <p>b. Autofax <input type="checkbox"/> Fax Number: <input style="width: 150px;" type="text"/></p> <p>c. Fax <input type="checkbox"/> Yes Fax Number: <input style="width: 150px; border-bottom: 1px solid black;" type="text" value="984-439-2761"/></p> <p>d. Phone only <input type="checkbox"/> Phone No.: <input style="width: 150px;" type="text"/></p> <p>e. Supplier Web Site only <input type="checkbox"/> Site Address: <input style="width: 150px;" type="text"/></p> <p>Minimum Order Quantity: <input style="width: 50px; border-bottom: 1px solid black;" type="text" value="144"/> Units</p> <p>Supplier's Customer Service Number: <input style="width: 150px;" type="text"/></p> <p>Contracted 3PL company / contact #: Name: <input style="width: 150px;" type="text"/> Phone: <input style="width: 150px;" type="text"/></p>	<p>Purchase order daily receipt cut off time by supplier</p> <p>Cut off time: <input style="width: 100px; border-bottom: 1px solid black;" type="text" value="12pm"/> Eastern</p> <p>Shipping lead time of PO: <input style="width: 50px;" type="text"/> Hours <input style="width: 50px;" 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 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: 80px;" type="text"/></p>	<p>Overnight receipt available: <input type="checkbox"/></p> <p>PO Receipt cut off time: <input style="width: 150px;" 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 style="width: 150px;" type="text"/></p> <p>Saturday Overnight receipt available: <input type="checkbox"/></p> <p>PO Receipt Cut off time: <input style="width: 150px;" type="text"/></p> <p>Order receipt method: Phone: <input style="width: 50px;" type="text"/> Phone #: <input style="width: 100px;" type="text"/> Fax: <input style="width: 50px;" type="text"/> Fax #: <input style="width: 100px;" type="text"/> EDI: <input style="width: 50px;" 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 style="width: 150px; border-bottom: 1px solid black;" 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 style="width: 150px; border-bottom: 1px solid black;" 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 style="width: 100px;" type="text"/></p> <p>Physician Name: <input style="width: 250px;" type="text"/></p> <p>Physician/Clinic Phone #: <input style="width: 250px;" type="text"/></p> <p>Physician State License #: <input style="width: 250px;" type="text"/></p> <p>Physician/Clinic DEA #: <input style="width: 250px;" type="text"/></p> <p>Physician/Clinic Specialty: <input style="width: 250px;" 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: 100%;" type="text"/>	