



# 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):	211295
DUNS:	11-698-2244
Proprietary Name (If Applicable) and Established Name:	Clobetasol Propionate Ointment USP, 0.05%
Selling Unit NDC:	21922-017-07
UDI	CVX Code: MVX Code:
UPC:	321922017076
Description:	Clobetasol propionate ointment USP, 0.05% is white smooth, homogeneous ointment free from foreign particles and without any phase separation and leakage. Packed in aluminium collapsible tube.
Active Ingredient(s):	Clobetasol Propionate USP
URL for Additional Product Information:	
Address:	200 Meredith Avenue, Suite 101A
City:	Durham
Key Contact:	Kamesh Venugopal
Phone Number:	1-919-767-3292
Product Therapeutic Classification:	Super-high potency corticosteroid formulations indicated for the

SPECIAL HANDLING AND STORAGE REQUIREMENTS*	
a. Temperature – Indicate the USP temperature range for this product.	
Temperature Range	
Other Temperature Range Requirement (write in)	Store at controlled room temperature
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:	919-767-3292
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?	No
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?	
co-licensed?	
Is the Product... Direct-Ship Only	
Is the Product... Unit of Use	
If Unit Dose, is item bar coded to unit dose for hospital scanning?	
If Unit Dose NDC, indicate NDC here:	21922-017-07
Country of Origin	India
Is this product covered under the Trade Agreements Act (TAA)?	

PRODUCT DESCRIPTION INFORMATION	
Size:	60 g tube
Strength:	0.05%
Dosage Form:	Topical Ointment
Product Shape:	
Product Color:	a white smooth, homogeneous ointment
Product Imprint:	

ORDER INFORMATION	
Unit of Sale	What is the NDC selling unit?
<input type="checkbox"/> Bottle	21922-017-07
<input checked="" type="checkbox"/> Box/Carton	(Write-in, e.g. 1 Box of 10 Vials)
<input type="checkbox"/> Ampule	
<input type="checkbox"/> Glass	Minimum order quantity?
<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	<input type="checkbox"/> Each
<input type="checkbox"/> Vial Power Multi	<input type="checkbox"/> Inner/ Carton/Pack
<input type="checkbox"/> Other: Write In	<input type="checkbox"/> Case

FOR GENERIC DRUG PRODUCTS	
I. Orange Book Rating:	AB
II. Generic Equivalent to What Brand?:	Temovate® (clobetasol propionate ointment, 0.05%)
<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)	<input 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?	No
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:	8906005273444
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:	0.1546	1.574804	1.3385834	6.299216	13.2787882	1
Box/Carton/Bundle/Inner Pack:	0.964	4.1732306	3.3070884	6.4960665	89.6537891	6
Case:	15.1	13.464574	10.393706	8.9370127	1250.70661	72
Pallet:	642.12	43.30711	38.740178	43.937032	73714.2637	3168
UPC:	Case:	30321922017077				
	Carton:	00321922017076				

GTIN PRODUCT INFORMATION						
Serialized? If not, when? Items aggregated?	Level	Item	Saleable Unit	Quantity	GTIN-14	
					GTIN-14	GTIN-14
<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	Box/Carton/Bundle/Inner Pack	<input checked="" type="checkbox"/>	1	00321922017076	
<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	Case	<input checked="" type="checkbox"/>	6	10321922017073	
<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	Pallet	<input checked="" type="checkbox"/>	72	30321922017077	
				3168	50321922017071	

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? Yes

Is this product regulated for shipment by DOT or IATA? No

(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#

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
<input type="checkbox"/> Aerosol Class; Identify NFPA Storage Level: <input style="width: 100px;" type="text"/>	
Is the product a NIOSH hazardous drug? <input style="width: 100px;" type="text"/>	
If yes, indicate which: <input style="width: 100%; height: 20px;" type="text"/>	

Hazardous Waste Identification
EPA Hazardous Waste Code: <input style="width: 100%; height: 20px;" type="text"/>

REMS or REGISTRY RESTRICTIONS
Is there a REMS on this product? <span style="float: right;">No</span>
If Yes, is it managed with a pharmacy registry? <input style="width: 100px;" type="text"/> Website URL: <input style="width: 100%; height: 20px;" type="text"/>
Comments / Details: (For example, iPledge program?) <input style="width: 100%; height: 20px;" type="text"/>
<b>REMS:</b> <input style="width: 100px;" type="text"/> REMS Program Manager Name: <input style="width: 100%; height: 20px;" type="text"/> Phone: <input style="width: 100px;" type="text"/> Supplier Manages REMS registry exclusively: <input style="width: 100px;" type="text"/> Wholesale distributor support: Provider Name: <input style="width: 100%; height: 20px;" type="text"/> Site Enrollment Number assigned by Supplier: <input style="width: 100%; height: 20px;" type="text"/>
DEA #: <input style="width: 100px;" type="text"/> PCPDP #: <input style="width: 100px;" type="text"/> NPI #: <input style="width: 100px;" type="text"/>

Comments

**Registry:**   
 Registry Program Contact Name:  Phone:

Comments

ADD'L STORAGE INFORMATION
Is the Product...
Controlled Substance? <span style="float: right;">No</span>
Controlled by State(s)? <span style="float: right;">No</span>
ARCOS Reportable? <span style="float: right;">No</span>
Schedule No. (inc. N for non-narcotic) <input style="width: 100px;" type="text"/>
Controlled Substance Code <input style="width: 100px;" type="text"/>
Listed Chemical (List I or II) <span style="float: right;">No</span>
If yes, indicate which: <input style="width: 100%; height: 20px;" type="text"/>
Is it a scheduled listed chemical product?: <input style="width: 100px;" type="text"/>

RETURN INSTRUCTIONS
Contact tel. # if product received damaged: <input style="width: 100%; height: 20px; text-align: center; value: 1-919-767-3292;" type="text"/>
Is product returnable for credit: <span style="float: right;">Yes</span>
URL/Link to returns policy: <input style="width: 100%; height: 20px;" type="text"/>
Special regulations or returns requirements for this product in certain states? <span style="float: right;">No</span>
If so, which states? Other requirements? Comments? <input style="width: 100%; height: 40px;" type="text"/>

CLASS OF TRADE RESTRICTION:
No restriction: Select YES if sold to retail pharmacy, hospitals, clinics and physician offices <span style="float: right;">Yes</span>
Restricted to retail pharmacy only: <span style="float: right;">No</span>
Restricted to hospital, clinics, and physician offices only: <span style="float: right;">No</span>
Restricted from US territories? (explain in comments) <span style="float: right;">No</span>
Comments: <input style="width: 100%; height: 40px;" type="text"/>

MISCELLANEOUS NOTES and/or Image of Product Barcode:
<input style="width: 100%; height: 40px;" type="text"/>

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"/></p> <p>b. Autofax <input type="checkbox"/></p> <p>c. Fax <input type="checkbox"/></p> <p>d. Phone only <input type="checkbox"/></p> <p>e. Supplier Web Site only <input type="checkbox"/></p> <p>Minimum Order Quantity: <input type="text"/></p> <p>Supplier's Customer Service Number: <input type="text"/></p> <p>Contracted 3PL company / contact #: <input type="text"/></p> <p style="margin-left: 20px;">Name: <input type="text"/></p> <p style="margin-left: 20px;">Phone: <input type="text"/></p> <p style="margin-left: 20px;">Fax Number: <input type="text"/></p> <p style="margin-left: 20px;">Fax Number: <input type="text"/></p> <p style="margin-left: 20px;">Phone No.: <input type="text"/></p> <p style="margin-left: 20px;">Site Address: <input type="text"/></p>	<p><b>Purchase order daily receipt cut off time by supplier</b></p> <p>Cut off time: <input type="text"/></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 type="checkbox"/></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="text"/></p> <p>Drop Ship service fee billed with each order: <input type="text"/></p> <p>Drop Ship miscellaneous fees billed: <input type="text"/></p> <p>Comments: <input style="width: 100%; height: 80px;" type="text"/></p>	<p><b>Overnight receipt available:</b> <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><b>Priority Overnight receipt available:</b> <input type="checkbox"/></p> <p>PO Receipt Cut off time: <input type="text"/></p> <p><b>Saturday Overnight receipt available:</b> <input type="checkbox"/></p> <p>PO Receipt Cut off time: <input type="text"/></p> <p>Order receipt method: <input type="text"/></p> <p>Phone: <input type="text"/> Phone #: <input type="text"/></p> <p>Fax: <input type="text"/> Fax #: <input type="text"/></p> <p>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"/></p> <p>Restricted to retail pharmacy only: <input type="checkbox"/></p> <p>Restricted to hospital, clinics, and physician offices only: <input type="checkbox"/></p> <p>Restricted from US territories? (explain in comments) <input type="checkbox"/></p> <p>Comments: <input style="width: 100%; height: 80px;" type="text"/></p>	<p>Contact # if product is received damaged: <input type="text"/></p> <p>Is product returnable for credit: <input type="checkbox"/></p> <p>URL/Link to returns policy: <input type="text"/></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: 80px;" 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: 100px;" type="text"/>	