



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

Version 2021

Introduction Type:  New Item

Final Version

Date: 03/21/2023

PRODUCT INFORMATION				SPECIAL HANDLING AND STORAGE REQUIREMENTS*			
Company Name: Encube Ethicals, Inc.		Application: ANDA		<b>a. Temperature – Indicate the USP temperature range for this product.</b>			
Application Number for NDA/ANDA/BLA (drug); PMA/510(k)(med device): A200298				Temperature Range: <input type="text"/> Controlled Room – between 20 and 25 C (68° – 77° F)			
Medical Device Class, if applicable:				Other Temperature Range Requirement (write in): <input type="text"/>			
DUNS: 11-698-2244				Notes: <input type="text"/>			
Proprietary Name (If Applicable) and Established Name: Adapalene Gel 0.3%				Is this product to be shipped to customers on ice? <input type="checkbox"/> No			
Selling Unit NDC: 21922-051-06		Unit of Use NDC: EA		Is this product to be shipped to customers on dry ice? <input type="checkbox"/> No			
UDI:		CVX Code:					
Description: Adapalene Gel 0.3%		UPC: 321922051063					
Active Ingredient(s): Adapalene		MVX Code:					
URL for Additional Product Information:		Address 2:		<b>b. Contact for temperature excursion questions:</b>			
Address: 200 Meredith Avenue, Suite 202				Name: Dipti Kamani			
City: Durham		State: NC		Number: 919-767-3292			
Key Contact: Kamesh Venugopal		Zip: 27713		Group E-mail: usreg@encubeethicals.com			
Phone Number: 1-919-767-3292		Email: Kamesh.V@encubeethicals.com					
Product Therapeutic Classification: Treatment of acne vulgaris in patients 12 years of age and older.		Fax: 984-439-2761		<b>c. Special regulations for product in any states?</b>			
				Special returns requirements for this product? <input type="checkbox"/> No			
				<b>d. Store product (unit of sale) upright?</b>			
				Protect product (unit of sale) from light? <input type="checkbox"/> No			
				<b>e. Shelf life:</b>			
				Initial shelf life at launch (if different): <input type="text"/> 24 Months			
ADDITIONAL PRODUCT INFORMATION				ORDER INFORMATION			
The product is?		Is the Product... Direct-Ship Only		Size:		45 gram	
a legend device? <input type="checkbox"/> No		Is the Product... Unit of Use		Strength:		0.30%	
if yes, enter class #		Orphan Drug Status		Dosage Form:		Gel	
a product kit? <input type="checkbox"/> No		FDA Approval Status		Product Shape:			
if yes, list NDCs of component parts		Allergens Present		Product Color:		Off-white aqueous Gel	
reverse numbered? <input type="checkbox"/> No		Country of Origin		Product Imprint:			
co-licensed? <input type="checkbox"/> No		India					
latex-free? <input type="checkbox"/> Yes		Is this product covered under the Trade Agreements Act (TAA)? <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"/>							
If Unit Dose, indicate NDC here: <input type="text"/>							
FOR GENERIC DRUG PRODUCTS				PHARMACY ORDER / BILL UNIT			
I. Orange Book Rating: AB		<input type="checkbox"/> Authorized Generic *If Authorized Generic, other section fields are not applicable		Rec. sell unit to customer? <input type="text"/>		Rx billing unit to pharmacy:	
II. Generic Equivalent to What Brand?: DIFFERIN				(Write-in, e.g. 1 Vial)		<input checked="" type="checkbox"/> Each	
						<input type="checkbox"/> Gram	
						<input type="checkbox"/> Milliliter	
DRUG SUPPLY CHAIN SECURITY ACT (DSCSA) INFORMATION				ITEM AND PACKING INFORMATION			
Does supplier meet DSCSA definition of manufacturer? <input type="checkbox"/> Yes		GLN: 0860002158402		Weight Lbs.		Dimensions (US msmts.)	
Is product exempt from DSCSA? <input type="checkbox"/> No		GCP: <input type="text"/>		Depth		Width	
If yes, select exemption:				Height		Volume (Cube)	
Other exemption - Write in: <input type="text"/>				Item/Each:		11.4	
Is product repackaged? <input type="checkbox"/> No		If yes, was original product purchased direct from mfr? <input type="checkbox"/>		Box/ Carton/ Bundle/ Inner Pack:		1	
Is product sold by manufacturer's exclusive distributor? <input type="checkbox"/> No		Provide source manufacturer for repackaged product: <input type="text"/>		Case:		48	
Has FDA granted waiver/exception/exemption for product? <input type="checkbox"/> No				Pallet:		4800	
If yes, attach documentation from FDA: <input type="text"/>							
GTIN AND HIBCC PRODUCT INFORMATION				COST INFORMATION			
Saleable Unit of Measure		Saleable Quantity		HIBCC		GTIN-14	
<input checked="" type="checkbox"/> Item/Each		1				Unit of Use GTIN-14	
<input type="checkbox"/> Box/ Carton/ Bundle/ Inner Pack						EA	
<input checked="" type="checkbox"/> Case		48				Regular Cost	
<input checked="" type="checkbox"/> Pallet		4800				Invoice Cost (WAC) (\$)	
						\$66.52	
						Vendor #:	
						Whsl. Code #:	
						Fineline Code:	
						As of date: <input type="text"/>	

\*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:

Kamesh Venugopal



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

Version 2021

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.)  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)  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:  
 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

Organic  Corrosive  
 Inorganic  Oxidizer  
 Steroid/Androgen  Contact Hazard

Does the product have an Aerosol class? If yes, identify  No

NFPA Storage Level:

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?  
 Website URL:

Med Guide Required

Limited Distribution Requirement

Comments / Details: (For example, iPledge program?)

**REMS:**  No

REMS Program Manager Name:  Phone:

Supplier Manages REMS registry exclusively:

Wholesale distributor support:

Provider Name:  DEA #:

Site Enrollment Number assigned by Supplier:  NCPDP#:

NPI #:

Comments

**Registry:**

Registry Program Contact Name:  Phone:

Comments

### ADD'L STORAGE INFORMATION

Is the Product...  
 Controlled Substance?  No Controlled Substance Code

Controlled by State(s)?  No Listed Chemical (List I or II)

ARCOS Reportable?  No If yes, indicate which:

Schedule No.  Is it a scheduled listed chemical product?:

### 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:  1-919-767-3292

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:



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

Version 2021

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"/></p> <p>c. Fax <input type="checkbox"/> Yes Fax Number: 984-439-2761</p> <p>d. Phone only <input type="checkbox"/> Phone No.:</p> <p>e. Supplier Web Site only <input type="checkbox"/> Site Address:</p> <p>Minimum Order Quantity: 48 Units</p> <p>Supplier's Customer Service Number:</p> <p>Contracted 3PL company / contact #: Name: Phone:</p>	<p><b>Purchase order daily receipt cut off time by supplier</b></p> <p>Cut off time: 12:00 PM Eastern</p> <p>Shipping lead time of PO: Hours 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="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:</p>	<p><b>Overnight receipt available:</b> <input type="checkbox"/></p> <p>PO Receipt cut off time:</p> <p>Days of week overnight is available:</p> <p><input type="checkbox"/> Monday  <input type="checkbox"/> Tuesday  <input type="checkbox"/> Wednesday  <input type="checkbox"/> Thursday  <input type="checkbox"/> Friday</p> <p><b>Priority Overnight receipt available:</b> <input type="checkbox"/></p> <p>PO Receipt Cut off time:</p> <p><b>Saturday Overnight receipt available:</b> <input type="checkbox"/></p> <p>PO Receipt Cut off time:</p> <p>Order receipt method: Phone: Phone #: Fax: Fax #: EDI:</p> <p>Overnight Fees apply: Other fees apply:</p>
Class of Trade Restriction:	
<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:</p>	<p><b>Return Instructions</b></p> <p>Contact # if product is received damaged:</p> <p>Is product returnable for credit: <input type="checkbox"/></p> <p>URL/Link to returns policy:</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:</p>
Other Data Information Required to Process PO:	ADDITIONAL INFORMATION
<p>Patient Procedure Date:</p> <p>Physician Name:</p> <p>Physician/Clinic Phone #:</p> <p>Physician State License #:</p> <p>Physician/Clinic DEA #:</p> <p>Physician/Clinic Specialty:</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:	