



# 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):	211303
Application:	ANDA
DUNS:	11-698-2244
Proprietary Name (if Applicable) and Established Name:	Permethrin Cream 5% w/w
Selling Unit NDC:	21922-021-07
Individual Unit NDC:	
UPC:	321922021073
UDI	
CVX Code:	
MXV Code:	
Description:	Permethrin Cream 5% w/w
Active Ingredient(s):	Permethrin
URL for Additional Product Information:	
Address:	200 Meredith Avenue, Suite 101A
City:	Durham
State:	NC
Zip:	27713
Key Contact:	Kamesh Venugopal
Phone Number:	1-919-767-3292
Product Therapeutic Classification:	For the treatment of infestation with Sarcoptes scabiei (Scabies)

SPECIAL HANDLING AND STORAGE REQUIREMENTS*	
<b>a. Temperature – Indicate the USP temperature range for this product.</b>	
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>b. Contact for temperature excursion questions:</b>	
Name:	Dipti Kamani
Number:	919-767-3292
Group E-mail:	usreg@encubeethicals.com
<b>c. Special regulations for product in any states?</b>	
Special returns requirements for this product?	No
<b>d. Store product (unit of sale) upright?</b>	
Protect product (unit of sale) from light?	No
<b>e. Shelf life:</b>	
Initial shelf life at launch (if different):	24 Months

ADDITIONAL PRODUCT INFORMATION	
Is the Product... a legend device? reverse numbered? co-licensed?	No
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:	
Country of Origin	India
Is this product covered under the Trade Agreements Act (TAA)?	No

PRODUCT DESCRIPTION INFORMATION	
Size:	60 gram
Strength:	5%
Dosage Form:	Topical cream
Product Shape:	
Product Color:	White to off white cream
Product Imprint:	

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

FOR GENERIC DRUG PRODUCTS	
I. Orange Book Rating:	AB
II. Generic Equivalent to What Brand?:	ELIMITE™
<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:	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		
Box/ Carton/ Bundle/ Inner Pack:	0.1546	6.22	1.574	1.378	13.4910058	1
Case:	0.964	4.448	6.535	3.464	100.690444	6
Pallet:	13.364	13.582	9.567	10.82	1405.93992	72
UPC:	632.12	45.039	46.456	39.409	82456.7033	3168
Case:						
Carton:						

GTIN PRODUCT INFORMATION						
Serialized?	If not, when?	Items aggregated?	Level		Quantity	GTIN-14
			Item	Saleable Unit		
<input checked="" type="checkbox"/>		<input checked="" type="checkbox"/>	Box/ Carton/ Bundle/ Inner Pack	<input checked="" type="checkbox"/>	1	00321922021073
<input checked="" type="checkbox"/>		<input checked="" type="checkbox"/>	Case	<input checked="" type="checkbox"/>	6	10321922021070
<input checked="" type="checkbox"/>		<input checked="" type="checkbox"/>	Pallet	<input checked="" type="checkbox"/>	72	30321922021074
					3168	50321922021078

COST INFORMATION		WHOLESALE USE ONLY:	
Regular Cost		Vendor #:	
Invoice Cost (WAC) (\$)	\$30.00	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?

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? 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#

### 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)

If yes, indicate which:

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:

### 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 #:

PCPDP #:

NPI #:

Comments:

**Registry:** No

Registry Program Contact Name:  Phone:

Comments:

### RETURN INSTRUCTIONS

Contact tel. # if product received damaged:

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:

21 January 2020

**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> <table style="width: 100%; border-collapse: collapse;"> <tr> <td style="width: 20%;">a. EDI</td> <td style="width: 10%; text-align: center;"><input type="checkbox"/></td> <td style="width: 10%; text-align: center;">Yes</td> <td style="width: 10%;"></td> <td style="width: 10%;"></td> <td style="width: 10%;"></td> <td style="width: 10%;"></td> <td style="width: 10%;"></td> </tr> <tr> <td>b. Autofax</td> <td style="text-align: center;"><input type="checkbox"/></td> <td></td> <td>Fax Number:</td> <td colspan="4" style="border: 1px solid black;"></td> </tr> <tr> <td>c. Fax</td> <td style="text-align: center;"><input type="checkbox"/></td> <td style="text-align: center;">Yes</td> <td>Fax Number:</td> <td colspan="4" style="border: 1px solid black;">984-439-2761</td> </tr> <tr> <td>d. Phone only</td> <td style="text-align: center;"><input type="checkbox"/></td> <td></td> <td>Phone No.:</td> <td colspan="4" style="border: 1px solid black;"></td> </tr> <tr> <td>e. Supplier Web Site only</td> <td style="text-align: center;"><input type="checkbox"/></td> <td></td> <td>Site Address:</td> <td colspan="4" style="border: 1px solid black;"></td> </tr> </table> <p>Minimum Order Quantity: <input style="width: 100%;" type="text"/></p> <p>Supplier's Customer Service Number: <input style="width: 100%;" type="text"/></p> <p>Contracted 3PL company / contact #:</p> <table style="width: 100%; border-collapse: collapse;"> <tr> <td style="width: 20%;">Name:</td> <td style="border: 1px solid black;"></td> </tr> <tr> <td>Phone:</td> <td style="border: 1px solid black;"></td> </tr> </table>	a. EDI	<input type="checkbox"/>	Yes						b. Autofax	<input type="checkbox"/>		Fax Number:					c. Fax	<input type="checkbox"/>	Yes	Fax Number:	984-439-2761				d. Phone only	<input type="checkbox"/>		Phone No.:					e. Supplier Web Site only	<input type="checkbox"/>		Site Address:					Name:		Phone:		<p><b>Purchase order daily receipt cut off time by supplier</b></p> <p>Cut off time: <input style="width: 150px;" type="text" value="2:00 AM"/></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 style="width: 50px;" type="text"/></p> <p>Ships for second day receipt: <input style="width: 50px;" type="text"/></p> <p>Ships regular ground for 3-10 days receipt: <input style="width: 50px;" type="text"/></p>
a. EDI	<input type="checkbox"/>	Yes																																											
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c. Fax	<input type="checkbox"/>	Yes	Fax Number:	984-439-2761																																									
d. Phone only	<input type="checkbox"/>		Phone No.:																																										
e. Supplier Web Site only	<input type="checkbox"/>		Site Address:																																										
Name:																																													
Phone:																																													
Expedited Freight Charges or Other Designated Drop Ship Fees:	Overnight and Priority Overnight PO Processing																																												
<p>Expedited freight fees billed with each order: <input style="width: 100px;" type="text" value="Yes"/></p> <p>Drop Ship service fee billed with each order: <input style="width: 100px;" type="text" value="Yes"/></p> <p>Drop Ship miscellaneous fees billed: <input style="width: 100px;" type="text" value="Yes"/></p> <p>Comments: <div style="border: 1px solid black; height: 60px; width: 100%;"></div></p>	<p><b>Overnight receipt available:</b> <input style="width: 50px;" type="text"/></p> <p>PO Receipt cut off time: <input style="width: 150px;" type="text"/></p> <p>Days of week overnight is available:</p> <table style="width: 100%; border-collapse: collapse;"> <tr><td><input type="checkbox"/></td><td>Monday</td></tr> <tr><td><input type="checkbox"/></td><td>Tuesday</td></tr> <tr><td><input type="checkbox"/></td><td>Wednesday</td></tr> <tr><td><input type="checkbox"/></td><td>Thursday</td></tr> <tr><td><input type="checkbox"/></td><td>Friday</td></tr> </table> <p><b>Priority Overnight receipt available:</b> <input style="width: 50px;" type="text"/></p> <p>PO Receipt Cut off time: <input style="width: 150px;" type="text"/></p> <p><b>Saturday Overnight receipt available:</b> <input style="width: 50px;" type="text"/></p> <p>PO Receipt Cut off time: <input style="width: 150px;" type="text"/></p> <p>Order receipt method:</p> <table style="width: 100%; border-collapse: collapse;"> <tr> <td style="width: 20%;">Phone:</td> <td style="width: 20%; border: 1px solid black;"></td> <td style="width: 20%;">Phone #:</td> <td style="width: 20%; border: 1px solid black;"></td> </tr> <tr> <td>Fax:</td> <td style="border: 1px solid black;"></td> <td>Fax #:</td> <td style="border: 1px solid black;"></td> </tr> <tr> <td>EDI:</td> <td style="border: 1px solid black;"></td> <td></td> <td></td> </tr> </table> <p>Overnight Fees apply: <input style="width: 50px;" type="text"/></p> <p>Other fees apply: <input style="width: 50px;" type="text"/></p>	<input type="checkbox"/>	Monday	<input type="checkbox"/>	Tuesday	<input type="checkbox"/>	Wednesday	<input type="checkbox"/>	Thursday	<input type="checkbox"/>	Friday	Phone:		Phone #:		Fax:		Fax #:		EDI:																									
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EDI:																																													
Class of Trade Restriction:	Return Instructions																																												
<p>No restriction: Select YES if sold to retail pharmacy, hospitals, clinics and physician offices <input style="width: 50px;" type="text"/></p> <p>Restricted to retail pharmacy only: <input style="width: 50px;" type="text"/></p> <p>Restricted to hospital, clinics, and physician offices only: <input style="width: 50px;" type="text"/></p> <p>Restricted from US territories? (explain in comments) <input style="width: 50px;" type="text"/></p> <p>Comments: <div style="border: 1px solid black; height: 40px; width: 100%;"></div></p>	<p>Contact # if product is received damaged: <input style="width: 150px;" type="text"/></p> <p>Is product returnable for credit: <input style="width: 50px;" type="text"/></p> <p>URL/Link to returns policy: <input style="width: 150px;" type="text"/></p> <p>Special regulations or returns requirements for this product in certain states? <input style="width: 50px;" type="text"/></p> <p>If so, which states? Other requirements? Comments?  <div style="border: 1px solid black; height: 40px; width: 100%;"></div> </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: 150px;" type="text"/></p> <p>Physician State License #: <input style="width: 150px;" type="text"/></p> <p>Physician/Clinic DEA #: <input style="width: 150px;" type="text"/></p> <p>Physician/Clinic Specialty: <input style="width: 150px;" type="text"/></p>	<p>Is product order for scheduled patient procedure? <input style="width: 50px;" type="text"/></p> <p>Is product order for restocking purposes? <input style="width: 50px;" type="text"/></p>																																												
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