



Standard Pharmaceutical Product Information (Rx Product Only)

© August 2014

Introduction Type: New Item

Final Version

Date: 9/25/2017

PRODUCT INFORMATION

Company Name: TWi Pharmaceuticals USA, Inc. Application: ANDA
 Application Number for NDA/ANDA/BLA (drug); PMA/510(k)(med device): A065336
 DUNS: 080216652
 Proprietary Name (if Applicable) and Established Name: Cephalixin for Oral Suspension 250mg per 5mL - 100mL (When Mixed)
 Selling Unit NDC: 24979-155-14 Individual Unit NDC: 24979-155-14 UPC: N3 24979 15514 2
 UDI: CVX Code: MVX Code:
 Description: Cephalixin for Oral Suspension 250mg per 5mL - 100mL
 Active Ingredient(s): Cephalixin
 URL for Additional Product Information: www.twipharma.com
 Address: 115 West Century Road - Suite 180 Address 2:
 City: Paramus State: NJ Zip: 07652
 Key Contact: Linda Nesbitt Email: linda.nesbitt@twipharmausa.com
 Phone Number: 201-762-1405 Fax: 201-225-0051
 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: Linda Nesbitt
 Number: 201-762-1405
 Group E-mail: linda.nesbitt@twipharmausa.com

c. Special regulations for product in any states?
 Special returns requirements for this product? No

d. Store product (unit of sale) upright?
 Protect product (unit of sale) from light? No

e. Shelf life:
 Initial shelf life at launch (if different): 24 Months

ADDITIONAL PRODUCT INFORMATION

Is the Product...
 a legend device? No
 reverse numbered? No
 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: Taiwan
 Is this product covered under the Trade Agreements Act (TAA)? No

PRODUCT DESCRIPTION INFORMATION

Size: 100 mL
 Strength: 250mg per 5mL
 Dosage Form: Oral Suspension
 Product Shape: N/A
 Product Color: White to Off-White Powder
 Product Imprint: N/A

ORDER INFORMATION

Unit of Sale:
 Bottle
 Box/ Carton
 Ampule
 Glass
 Tube
 Vial Liquid Sgl
 Vial Liquid Multi
 Vial Powder Sgl
 Vial Powder Multi
 Other: Write In

What is the NDC selling unit?
 1 bottle
 (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
 Case

FOR GENERIC DRUG PRODUCTS

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

PHARMACY ORDER / BILL UNIT

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

GLN: *0324979000008

ITEM AND PACKING INFORMATION

Item:	Weight Lbs.	Dimensions (US msmts.)			Volume (Cube)	# Pieces:
		Depth	Height	Width		
Box/ Carton/ Bundle/ Inner Pack:	N/A	N/A	N/A	N/A	N/A	N/A
Case:	8.04	13.22	4.09	8.89		24
Pallet:	1005	43.3	67.71	43.3		3,000
UPC:	Case:					
	Carton:					

GTIN PRODUCT INFORMATION

Serialized? If not, when? Items aggregated?	Level	Saleable Unit		Quantity	GTIN-14
		Item	Unit		
<input checked="" type="checkbox"/>	Box/ Carton/ Bundle/ Inner Pack	<input checked="" type="checkbox"/>	2D	1	00324979155142
<input checked="" type="checkbox"/>	Case	<input checked="" type="checkbox"/>	2D	24	60324979155144
<input checked="" type="checkbox"/>	Pallet	<input checked="" type="checkbox"/>	2D		
			2D		
			2D		
			2D		
			2D		
			2D		
			2D		

November, 2018
 Yes

COST INFORMATION

Regular Cost
 Invoice Cost (WAC) (\$)
 Federal Excise Tax Per Unit of Sale
 As of date:

WHOLESALE USE ONLY:

Vendor #:
 Whsl. Code #:
 Fine Line Code:

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? _____

Does the product label bear a CA Prop 65 warning? _____

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) 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? _____
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: _____

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: _____

Registry Program Contact Name: _____ Phone: _____

Comments _____

RETURN INSTRUCTIONS

Contact tel. # if product received damaged: 201-762-1405

Is product returnable for credit: _____

URL/Link to returns policy: _____

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> <table style="width: 100%; border-collapse: collapse;"> <tr> <td style="width: 25%;">a. EDI</td> <td style="width: 25%;"><input type="text"/></td> <td style="width: 25%;">Fax Number:</td> <td style="width: 25%;"><input type="text"/></td> </tr> <tr> <td>b. Autofax</td> <td><input type="text"/></td> <td>Fax Number:</td> <td><input type="text"/></td> </tr> <tr> <td>c. Fax</td> <td><input type="text"/></td> <td>Phone No.:</td> <td><input type="text"/></td> </tr> <tr> <td>d. Phone only</td> <td><input type="text"/></td> <td>Site Address:</td> <td><input type="text"/></td> </tr> <tr> <td>e. Supplier Web Site only</td> <td><input type="text"/></td> <td></td> <td></td> </tr> </table> <p>Minimum Order Quantity: <input type="text"/></p> <p>Supplier's Customer Service Number: <input type="text"/></p> <p>Contracted 3PL company / contact #:</p> <table style="width: 100%; border-collapse: collapse;"> <tr> <td style="width: 20%;">Name:</td> <td><input type="text"/></td> </tr> <tr> <td>Phone:</td> <td><input type="text"/></td> </tr> </table>	a. EDI	<input type="text"/>	Fax Number:	<input type="text"/>	b. Autofax	<input type="text"/>	Fax Number:	<input type="text"/>	c. Fax	<input type="text"/>	Phone No.:	<input type="text"/>	d. Phone only	<input type="text"/>	Site Address:	<input type="text"/>	e. Supplier Web Site only	<input type="text"/>			Name:	<input type="text"/>	Phone:	<input type="text"/>	<p>Purchase order daily receipt cut off time by supplier</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="text"/></p> <p>Ships for second day receipt: <input type="text"/></p> <p>Ships regular ground for 3-10 days receipt: <input type="text"/></p>
a. EDI	<input type="text"/>	Fax Number:	<input type="text"/>																						
b. Autofax	<input type="text"/>	Fax Number:	<input type="text"/>																						
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d. Phone only	<input type="text"/>	Site Address:	<input type="text"/>																						
e. Supplier Web Site only	<input type="text"/>																								
Name:	<input type="text"/>																								
Phone:	<input type="text"/>																								
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: 50px;" type="text"/></p>	<p>Overnight receipt available: <input type="text"/></p> <p>PO Receipt cut off time: <input 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>Priority Overnight receipt available: <input type="text"/></p> <p>PO Receipt Cut off time: <input type="text"/></p> <p>Saturday Overnight receipt available: <input type="text"/></p> <p>PO Receipt Cut off time: <input 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: 30%;"><input type="text"/></td> <td style="width: 20%;">Phone #:</td> <td style="width: 30%;"><input type="text"/></td> </tr> <tr> <td>Fax:</td> <td><input type="text"/></td> <td>Fax #:</td> <td><input type="text"/></td> </tr> <tr> <td>EDI:</td> <td><input type="text"/></td> <td></td> <td></td> </tr> </table> <p>Overnight Fees apply: <input type="text"/></p> <p>Other fees apply: <input type="text"/></p>	<input type="checkbox"/>	Monday	<input type="checkbox"/>	Tuesday	<input type="checkbox"/>	Wednesday	<input type="checkbox"/>	Thursday	<input type="checkbox"/>	Friday	Phone:	<input type="text"/>	Phone #:	<input type="text"/>	Fax:	<input type="text"/>	Fax #:	<input type="text"/>	EDI:	<input type="text"/>				
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Fax:	<input type="text"/>	Fax #:	<input type="text"/>																						
EDI:	<input type="text"/>																								
Class of Trade Restriction:	Return Instructions																								
<p>No restriction: Select YES if sold to retail pharmacy, hospitals, clinics and physician offices <input type="text"/></p> <p>Restricted to retail pharmacy only: <input type="text"/></p> <p>Restricted to hospital, clinics, and physician offices only: <input type="text"/></p> <p>Restricted from US territories? (explain in comments) <input type="text"/></p> <p>Comments: <input style="width: 100%; height: 50px;" type="text"/></p>	<p>Contact # if product is received damaged: <input type="text"/></p> <p>Is product returnable for credit: <input type="text"/></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="text"/></p> <p>If so, which states? Other requirements? Comments? <input style="width: 100%; height: 50px;" 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="text"/></p> <p>Is product order for restocking purposes? <input type="text"/></p>																								
Miscellaneous Notes:																									
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