



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

Version 2021 Introduction Type:  New Item  Final Version Date: 9/9/2022

**PRODUCT INFORMATION** **SPECIAL HANDLING AND STORAGE REQUIREMENTS\***

Company Name: TAGI Pharma, Inc. Application: ANDA  
 Application Number for NDA/ANDA/BLA (drug); PMA/510(k)(med device): 212875  
 Medical Device Class, if applicable:  
 DUNS: 963322560  
 Proprietary Name (If Applicable) and Established Name: Chlorthalidone Tablets, USP  
 Selling Unit NDC: 51224-118-50 Unit of Use NDC: UPC: CVX Code: MVX Code:  
 Description: Chlorthalidone Tablets USP, 50mg 100ct  
 Active Ingredient(s): Chlorthalidone  
 URL for Additional Product Information: [www.tagipharma.com](http://www.tagipharma.com)  
 Address: 722 Progressive Ln Room 205 Address 2: State: IL Zip: 61080  
 City: South Beloit Email: dsundstrom@tagipharma.com  
 Key Contact: Drake Sundstrom Fax: 815-624-4628  
 Phone Number: 815-624-7685  
 Product Therapeutic Classification:

**a. Temperature – Indicate the USP temperature range for this product.**  
 Temperature Range:   
 Other Temperature Range Requirement (write in):  
 Notes:  
 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:  
 Number: 815-624-7685  
 Group E-mail: [druginfo@tagipharma.com](mailto:druginfo@tagipharma.com)

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

**d. Store product (unit of sale) upright?**  Yes  
 Protect product (unit of sale) from light?  Yes

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

ADDITIONAL PRODUCT INFORMATION		PRODUCT DESCRIPTION INFORMATION	
The product is a legend device? <input type="checkbox"/> No	Is the Product... Direct And Drop-Ship <input type="checkbox"/> Neither	Size:	100
if yes, enter class # a product kit? <input type="checkbox"/>	Is the Product... Orphan Drug Status <input type="checkbox"/>	Strength:	50mg
if yes, list NDCs of component parts reverse numbered? <input type="checkbox"/>	FDA Approval Status <input type="checkbox"/>	Dosage Form:	Tablet
co-licensed? <input type="checkbox"/> No	Allergens Present <input type="checkbox"/>	Product Shape:	Round
latex-free? <input type="checkbox"/> Yes	Country of Origin <input type="text" value="Portugal"/>	Product Color:	Pale Green
preservative-free? <input type="checkbox"/> Yes	Is this product covered under the Trade Agreements Act (TAA)? <input type="checkbox"/> Yes	Product Imprint:	Scored tablet debossed with "TP" in top score and "50" in bottom score and plain on the other side
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"/> No			
If Unit Dose, indicate NDC here: <input type="text"/>			

**ORDER INFORMATION**

Unit of Sale	What is the NDC selling unit?
<input checked="" type="checkbox"/> Bottle	1 bottle of 100 tablets
<input 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	Minimum order quantity? <input type="checkbox"/> Yes
<input type="checkbox"/> Vial Liquid Sgl	
<input type="checkbox"/> Vial Liquid Multi	
<input type="checkbox"/> Vial Powder Sgl	If Yes, how many of which package type?
<input type="checkbox"/> Vial Power Multi	<input type="text" value="6"/> Each
<input type="checkbox"/> Other: Write In	<input type="text"/> Inner/ Carton/ Pack
	<input type="text"/> Case

**FOR GENERIC DRUG PRODUCTS**

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

**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  
 If yes, attach documentation from FDA.  
 GLN: 035122400001  
 GCP:   
 If yes, was original product purchased direct from mfr?   
 Provide source manufacturer for repackaged product

**ITEM AND PACKING INFORMATION**

Item/Each:	Weight Lbs.	Dimensions (US msmts.)			Volume (Cube)	Saleable # Pieces
		Depth	Width	Height		
Box/Carton/Bundle/Inner Pack:	0.02	1.5	1.5	3.16	7.11	1
Case:	2.16	9.65	6.42	3.54	219.31362	24
Pallet:						

**GTIN AND HIBCC PRODUCT INFORMATION**

Saleable Unit of Measure	Saleable Quantity	HIBCC	GTIN-14	Unit of Use GTIN-14
<input checked="" type="checkbox"/> Item/Each	1		00351224118508	
<input type="checkbox"/> Box/Carton/Bundle/Inner Pack				
<input type="checkbox"/> Case	24		50351224118503	
<input type="checkbox"/> Pallet				

**COST INFORMATION** **WHOLESALE USE ONLY:**

Regular Cost   
 Invoice Cost (WAC) (\$)   
 As of date: 9/9/2022  
 Vendor #:   
 Whsl. Code #:   
 Finline Code:



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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?  Yes
- 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)

- 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)

- 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  No
- Cargo  No
- Passenger & Cargo  No

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#

Chlorthalidone

### ADD'L STORAGE INFORMATION

Is the Product...

- Controlled Substance?  No  Yes
- Controlled Substance Code
- Controlled by State(s)?  No  Yes
- Listed Chemical (List I or II)  No  Yes
- ARCOS Reportable?  No  Yes
- If yes, indicate which:
- Schedule No.
- Is it a scheduled listed chemical product?:  No  Yes

### CLASS OF TRADE RESTRICTION:

- No restriction: Select YES if sold to retail pharmacy, hospitals, clinics and physician offices  Yes  No
- Restricted to retail pharmacy only:  No  Yes
- Restricted to hospital, clinics, and physician offices only:  No  Yes
- Restricted from US territories? (explain in comments)  No  Yes

Comments:

### SDS Hazard Classification

- Organic  Corrosive
- Inorganic  Oxidizer
- Steroid/Androgen  Contact Hazard

Does the product have an Aerosol class? If yes, identify NFPA Storage Level:  No

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  No

Limited Distribution Requirement  No

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

#### REMS:

REMS Program Manager Name:  Phone:

Supplier Manages REMS registry exclusively:  Yes  No

Wholesale distributor support:  Yes  No

Provider Name:  DEA #:

Site Enrollment Number assigned by Supplier:  NCPDP#:

NPI #:

Comments

#### Registry:

Registry Program Contact Name:  Phone:

Comments

### RETURN INSTRUCTIONS

Contact tel. # if product received damaged: 800-397-9228

Is product returnable for credit:  Yes  No

URL/Link to returns policy:

Special regulations or returns requirements for this product in certain states?  Yes  No

If so, which states? Other requirements? Comments: Georgia, Mississippi, and North Carolina. Requests can be made via fax: (815) 624-0608 or email customercare@tagipharma.com

### MISCELLANEOUS NOTES and/or Image of Product Barcode:

