



# Standard Pharmaceutical Product Information (Rx Product Only)

<b>Company Name:</b> TAGE Pharma, Inc.	<b>Application:</b> ANDA	<b>Introduction Type:</b> New Item	<b>Date:</b> 3/15/2019
<b>Application Number for NDA/ANDA/BLA (drug):</b> PMA1510 (need device):	<b>Application:</b> A202765	<b>SPECIAL HANDLING AND STORAGE REQUIREMENTS*</b>	
<b>DUNS:</b>	<b>Proprietary Name (if Applicable) and Established Name:</b> Benzonatate Capsules, USP	<b>a. Temperature</b> - Indicate the USP temperature range for this product. Temperature Range: _____ Controlled Room - between 20 and 25 C (68° - 77° F) Other Temperature Range Requirement: _____	
<b>Selling Unit NDC:</b>	<b>Individual Unit NDC:</b>	<b>b. Contact for temperature excursion questions:</b> Name: Mat Mehris Number: 815-824-7885 Group E-mail: druginfo@lagipharma.com	
<b>UDI</b>	<b>CVX Code:</b>	<b>c. Special regulations for product in any states?</b> Special returns requirements for this product? No Special returns requirements for this product? No	
<b>Description:</b>	<b>Benzonatate Capsules, USP 100mg</b>	<b>d. Store product (unit of sale) upright?</b> Yes <b>Protect product (unit of sale) from light?</b> Yes <b>e. Shelf life:</b> Initial shelf life at launch (if different): 24 Months	
<b>Active Ingredient(s):</b>	Benzonatate	<b>ORDER INFORMATION</b>	
<b>URL for Additional Product Information:</b>	www.lagipharma.com	<b>Unit of Sale:</b> X Bottle Box/Carton Ampule Glass Tube Vial/Liquid Sgl Vial/Liquid Multi Vial Powder Sgl Vial Powder Multi Other: Write In	
<b>Address:</b>	722 Progressive Lane South Bend Melissa Bradley 815-824-7885	<b>What is the NDC selling unit?</b> 1 Bottle of 100 capsules (Write-in, e.g. 1 Box of 10 Vials) <b>Minimum order quantity?</b> Yes	
<b>City:</b>	South Bend	<b>If Yes, how many of which package type?</b> Each 12 Inner/Carton/Pack Case	
<b>Key Contact:</b>	Melissa Bradley	<b>PHARMACY ORDER / BILL UNIT</b>	
<b>Phone Number:</b>	815-824-7885	Rx billing unit to pharmacy: Each Gram Milliliter	
<b>Product Therapeutic Classification:</b>		<b>ITEM AND PACKING INFORMATION</b>	
<b>Is the Product...</b>	<b>Additional Product Information</b>	<b>Weight Lbs.</b> 0.0004 <b>Dimensions (US mms.)</b> Depth 1.57 Height 2.78 Width 1.57 <b>Volume (Cubes)</b> 1 <b># Pieces:</b> 12 288	
<b>a legend device?</b> No	<b>Size:</b> 100 Capsules	<b>Regular Cost</b>	
<b>reverse numbered?</b> No	<b>Strength:</b> 100mg	<b>Invoice Cost (WAC) (\$)</b> \$28.70 <b>Vendor #:</b>	
<b>co-licensed?</b> No	<b>Dosage Form:</b> Capsules	<b>Federal Excise Tax Per Unit of Sale</b>	
<b>Is the Product...</b>	<b>Product Shape:</b> Oval-shaped capsule	<b>As of date:</b> 3/15/2019	
<b>Is the Product...</b>	<b>Product Color:</b> yellow	<b>WHOLESALE USE ONLY:</b>	
<b>Neither</b>	<b>Product Imprint:</b> 1	<b>Regular Cost</b>	
<b>If Unit Dose, is item bar coded to unit dose for hospital scanning?</b>		<b>Invoice Cost (WAC) (\$)</b>	
<b>If Unit Dose NDC, indicate NDC here:</b>		<b>Vendor #:</b>	
<b>Country of Origin:</b> China		<b>Federal Excise Tax Per Unit of Sale</b>	
<b>Is this product covered under the Trade Agreements Act (TAA)?</b> No		<b>As of date:</b>	
		<b>Signature:</b>	
		<b>Attach copy of SAFETY DATA SHEET (SDS) or non hazard letter, PACKAGE INSERT, LABEL AND PHOTO OF PRODUCT PACKAGING and BARCODE.</b>	
		<b>*Please provide any additional information on page 2.</b>	



# Standard Pharmaceutical Product Information (Page 2)

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? (if yes, attach SDS with special instructions.)  No
- 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? (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?  No

## 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

- Organic
- Inorganic
- Steroid/Androgen
- Corrosive
- Oxidizer
- 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?  No

Website URL:

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

## REMS:

- No
- REMS Program Manager Name:
- Supplier Manages REMS registry exclusively:
- Wholesale distributor support:
- Provider Name:
- Site Enrollment Number assigned by Supplier:

Phone:

DEA #:

PCPDP #:

NPI #:

Comments

Registry:

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?  Yes

If so, which states? Other requirements? Comments?

(Georgia, Mississippi and North Carolina. Requests can be made via fax: 815-624-7687 or email: customercare@lagipharma.com)

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

Release DATE:



# Standard Pharmaceutical Product Information (Page 3)

FOR DESIGNATED DROP SHIP PRODUCT ONLY - if not a designated drop ship, do not complete.

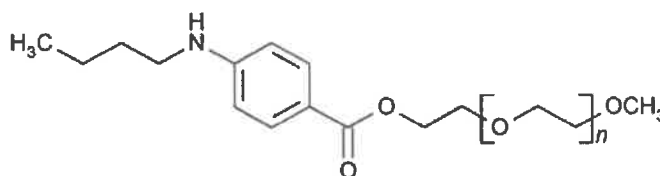
Order Method for Designated Drop Ship Product	Standard Order Receipt and Processing										
<p>Purchase orders may be accepted by:</p> <p>a. EDI <input type="checkbox"/> Yes <input type="checkbox"/> No</p> <p>b. Autofax <input type="checkbox"/> Yes <input type="checkbox"/> No</p> <p>c. Fax <input type="checkbox"/> Yes <input type="checkbox"/> No</p> <p>d. Phone only <input type="checkbox"/> Yes <input type="checkbox"/> No</p> <p>e. Supplier Web Site only <input type="checkbox"/> Yes <input type="checkbox"/> No</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><b>Expedited Freight Charges or Other Designated Drop Ship Fees:</b></p>											
<p>Expedited freight fees billed with each order: <input type="checkbox"/> Yes <input type="checkbox"/> No</p> <p>Drop Ship service fee billed with each order: <input type="checkbox"/> Yes <input type="checkbox"/> No</p> <p>Drop Ship miscellaneous fees billed: <input type="checkbox"/> Yes <input type="checkbox"/> No</p> <p>Comments: <input style="width:100%;" type="text"/></p>											
<p><b>Class of Trade Restriction:</b></p>											
<p>No restriction: Select YES if sold to retail pharmacy, hospitals, clinics and physician offices <input type="checkbox"/> Yes <input type="checkbox"/> No</p> <p>Restricted to retail pharmacy only: <input type="checkbox"/> Yes <input type="checkbox"/> No</p> <p>Restricted to hospital, clinics, and physician offices only: <input type="checkbox"/> Yes <input type="checkbox"/> No</p> <p>Restricted from US territories? (explain in comments) <input type="checkbox"/> Yes <input type="checkbox"/> No</p> <p>Comments: <input style="width:100%;" type="text"/></p>											
<p><b>Other Data Information Required to Process PO:</b></p>											
<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><b>Miscellaneous Notes:</b></p>											
<p><input style="width:100%; height:100%;" type="text"/></p>											
<p><b>Overnight and Priority Overnight PO Processing</b></p>											
<p><b>Overnight receipt available:</b> <input type="checkbox"/> Yes <input type="checkbox"/> No</p> <p>PO Receipt cut off time: <input type="text"/> 12:00pm <input type="text"/> Central</p> <p>Days of week overnight is available:</p> <table border="1" style="display: inline-table; border-collapse: collapse;"> <tr><td>Monday</td><td><input checked="" type="checkbox"/></td></tr> <tr><td>Tuesday</td><td><input checked="" type="checkbox"/></td></tr> <tr><td>Wednesday</td><td><input checked="" type="checkbox"/></td></tr> <tr><td>Thursday</td><td><input checked="" type="checkbox"/></td></tr> <tr><td>Friday</td><td><input type="checkbox"/></td></tr> </table>		Monday	<input checked="" type="checkbox"/>	Tuesday	<input checked="" type="checkbox"/>	Wednesday	<input checked="" type="checkbox"/>	Thursday	<input checked="" type="checkbox"/>	Friday	<input type="checkbox"/>
Monday	<input checked="" type="checkbox"/>										
Tuesday	<input checked="" type="checkbox"/>										
Wednesday	<input checked="" type="checkbox"/>										
Thursday	<input checked="" type="checkbox"/>										
Friday	<input type="checkbox"/>										
<p><b>Priority Overnight receipt available:</b> <input type="checkbox"/> Yes <input type="checkbox"/> No</p> <p>PO Receipt Cut off time: <input type="text"/> 12:00pm</p>											
<p><b>Saturday Overnight receipt available:</b> <input type="checkbox"/> Yes <input type="checkbox"/> No</p> <p>PO Receipt Cut off time: <input type="text"/> 12:00pm</p> <p>Phone #: <input type="text"/> 855-225-8244</p> <p>Fax #: <input type="text"/> 815-624-7687</p> <p>EDI: <input type="text"/></p> <p>Other fees apply: <input type="checkbox"/> Yes <input type="checkbox"/> No</p>											
<p><b>Return Instructions</b></p>											
<p>Contact # if product is received damaged: <input type="text"/> 855-225-8244</p> <p>Is product returnable for credit: <input type="checkbox"/> Yes <input type="checkbox"/> No</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"/> Yes <input type="checkbox"/> No</p> <p>If so, which states? Other requirements? Comments? <input type="text"/></p> <p>Georgia, Mississippi and North Carolina. Requests can be made via fax: 815-624-7687 or email <input type="text"/></p>											
<p><b>ADDITIONAL INFORMATION</b></p>											
<p>Is product order for scheduled patient procedure? <input type="checkbox"/></p> <p>Is product order for restocking purposes? <input type="checkbox"/></p>											



## Section 1. Identification

### Identification of the product:

**Product name** Benzonatate Capsules,  
**Formula** C<sub>30</sub>H<sub>53</sub>NO<sub>11</sub>  
**Chemical Name** 2,5,8,11,14,17,20,23,26-nonaoxaocacosan-28-yl *p*-(butylamino) benzoate



**Therapeutic Category** Benzonatate capsules, a non-narcotic oral antitussive agent

### Manufacturer / supplier identification:

**Company** CSPC NBP Pharmaceutical Co.,LTD  
**Address** No.88 Yangzi Road,Economic and Technological Development Zone, Shijiazhuang, Hebei Province, P.R.China  
**Contact for information** Tel.: +86 311 83092888 Fax: +86 311 83092777  
**Emergency telephone No.** Tel.: +86 311 83092888

## Section 2. Hazard(s) Information

**Dose and Administration** Adults and Children over 10 years of age:Usual dose is one 100 mg or 200 mg capsule three times a day as needed for cough. If necessary to control cough, up to 600 mg daily in three divided doses may be given.Benzonatate Capsules should be swallowed whole. Benzonatate Capsules are not to be broken, chewed, dissolved, cut or crushed.

**ADVERSE REACTIONS** Potential Adverse Reactions to Benzonatate Capsules may include:



# Material Safety Data Sheet

Version:1.0

**CSPC** BENZONATATE CAPSULES,

Strength: 200 mg & 100 mg

**Hypersensitivity reactions** including bronchospasm, laryngospasm, cardiovascular collapse possibly related to local anesthesia from chewing or sucking the capsule.

**CNS:**sedation; headache; dizziness; mental confusion; visual hallucinations.

**GI:** constipation; nausea; GI upset.

**Dermatologic:** pruritus; skin eruptions.

**Other:** nasal congestion; sensation of burning in the eyes; vague “chilly” sensation; numbness of the chest;

## OVERDOSAGE

Intentional and unintentional overdose may result in death, particularly in children.

The drug is chemically related to tetracaine and other topical anesthetics and shares various aspects of their pharmacology and toxicology. Drugs of this type are generally well absorbed after ingestion.

## Medical Conditions

### **Hypersensitivity:**

Sever hypersensitivity reactions (including bronchospasm, laryngospasm and cardiovascular collapse) have been reported which are possibly related to local anesthesia from sucking or chewing the capsules intervention with vasopressor agents and supportive measures.

### **Psychiatric Effects:**

Isolated instances of bizzare behavior, including mental confusion and visual hallucinations, have also been reported in patients taking benzonatate capsules in combination with other prescribed drug.

## Contraindications

Severe hypersensitivity reactions (including bronchospasm, laryngospasm and cardiovascular collapse) have been reported which are possibly related to local anesthesia from sucking or



chewing the capsule instead of swallowing it. Severe reactions have required intervention with vasopressor agents and supportive measures. Isolated instances of bizarre behavior, including mental confusion and visual hallucinations, have also been reported in patients taking benzonatate capsules in combination with other prescribed drugs.

### Pregnancy Comments

Pregnancy Category C. Animal reproduction studies have not been conducted with benzonatate capsules. It is also not known whether benzonatate capsules can cause fetal harm when administered to a pregnant woman or can affect reproduction capacity. Benzonatate capsules should be given to a pregnant woman only if clearly needed.

### Pediatric Use

Safety and effectiveness in children below the age of 10 have not been established. Accidental ingestion resulting in death has been reported in children below age 10. Keep out of reach of children.

## Section 3. Composition / information on Ingredients

Component	Exposure Limit	CAS No.
<b>Principle Component :</b>		
Benzonatate	Not Found	104-31-4
<b>Inactive Ingredients :</b>		
Gelatin	Not Found	9000-70-8
Glycerin	Not Found	56-81-5
Methylparaben	Not Found	99-76-3
Propylparaben	Not Found	94-13-3

## Section 4. First - aid Measures

**General** Remove from exposure. Remove contaminated Clothing. Person developing serious hypersensitivity reaction must receive



# Material Safety Data Sheet

Version:1.0

**CSPC** BENZONATATE CAPSULES,

Strength: 200 mg & 100 mg

medical attention.

## Overdose Treatment

In case of overdose, seek medical attention immediately. Evacuate gastric contents and administer copious amounts of activated charcoal slurry. Even in the conscious patient, cough and gag reflexes may be so depressed as to necessitate special attention to protection against aspiration of gastric contents and orally administered materials. Convulsions should be treated with a short-acting barbiturate given intravenously and carefully titrated for the smallest effective dosage. Intensive support of respiration and cardiovascular-renal function is an essential feature of the treatment of severe intoxication from overdosage. Do not use CNS stimulants.

## Section 5. Fire - fighting Measures

<b>Flash point</b>	Not Found	<b>Auto-Ignition Temperature</b>	Not Found
<b>Upper Flammable Limit</b>	Not Found	<b>Lower Flammable Limit</b>	Not Found
<b>Extinguishing Media</b>	Water Spray, dry chemical, carbon dioxide or foam as appropriate for surrounding fire and material.	<b>Fire and Explosion Hazard</b>	This material is assumed to be combustible.

**Fire Fighting Procedure** As with all fires, evacuate personnel to a safe area. Fire fighter should use self- contained breathing equipment and protective clothing.

## Section 6. Accidental Release Measures

**Spill Response** Wear approved respiratory protection, chemically compatible gloves and protective clothing. Wipe up spillage or collect spillage using high efficiency vacuum cleaner. Avoid breathing dust. Place spillage in appropriately labelled container for disposal. Wash spill site.



# Material Safety Data Sheet

Version:1.0

**CSPC** BENZONATATE CAPSULES,

Strength: 200 mg & 100 mg

## Section 7. Handling and Storage

**Storage** Store at 20° to 25°C (68° to 77°F) excursions permitted between 15° to 30°C (59° to 86°F). PROTECT FROM LIGHT.

**Incompatibilities** No data available.

## Section 8. Exposure Controls / Personal Protection

**Respiratory Protection** Protection from inhalation is not normally necessary. If ventilation is inadequate or dust is likely to generate, use of suitable dust mask would be appropriate.

**Skin Protection** Skin protection is not normally necessary, however it is good practice to avoid contact with chemical to use suitable gloves when handling.

**Eye protection** Eye protection is not normally necessary. If concerned wear protective goggles or glasses. Wash hands prior to touching eye and in particular handling contact lenses.

**Protective Clothing** Protective clothing is not normally necessary, however it is good practice to use apron.

**Engineering Control** Use process enclosures, local exhaust ventilation, or other engineering controls to keep airborne levels below recommended exposure limits. If user operations generate dust, fume or mist, use ventilation to keep exposure to airborne contaminants below the exposure limit.

## Section 9. Physical and Chemical Properties

**Appearance** Benzonatate capsules USP, 200 mg and 100 mg are light yellow-colored, oval-shaped soft gelatin capsules, imprinted with “2” or “1” containing pale yellow-colored clear viscous liquid.

<b>Solubility in water</b>	No Data Available	<b>Odour</b>	Odourless
<b>Boiling point</b>	No Data Available	<b>Melting Point</b>	No Data Available
<b>Evaporation rate</b>	No Data Available	<b>Vapour density</b>	No Data Available





# Material Safety Data Sheet

Version:1.0

**CSPC** BENZONATATE CAPSULES,

Strength: 200 mg & 100 mg

<b>Reactivity in water</b>	No Data Available	<b>Evaporation rate</b>	No Data Available
<b>% Volatile by volume</b>	No Data Available	<b>Specific gravity</b>	No Data Available
<b>Vapour pressure</b>	No Data Available	<b>Other information</b>	No Data Available

## Section 10. Stability and Reactivity

<b>Condition to avoid</b>	Avoid exposure to extreme heat, light and moisture.	<b>Stable</b>	Stable under normal Ambient and anticipated storage and handling conditions.
---------------------------	---	---------------	--

<b>Decomposition</b>	No Data Available	<b>Hazardous Reaction</b>	No data available.
----------------------	-------------------	---------------------------	--------------------

### Products

**Incompatibilities** No data available.

## Section 11. Toxicological Information

**General** Handling of formulated product is not expected to cause any adverse affects.The data pertains to the ingredient in formulations, rather than this specie formulation.

**Target organ** Eye contact, Skin contact and inhalation is not great risk as this product is capsules.

**Other** No data available.

## Section 12. Ecological Information

Do not allow product to enter drinking water supplies, waste water or soil.

## Section 13. Disposal Consideration

Dispose the waste in accordance with all applicable Federal, State and local laws.

## Section 14. Transport Information

The product is not hazardous when shipping via air (IATA), ground (DOT), or sea (IMDG).

## Section 15. Regulatory Information

Generic Medicine. Approved by USFDA & the ANDA Number is 202765.



**CSPC**

# Material Safety Data Sheet

**BENZONATATE CAPSULES,**

**Strength: 200 mg & 100 mg**

**Version:1.0**

## Section 16. Other information

None.