



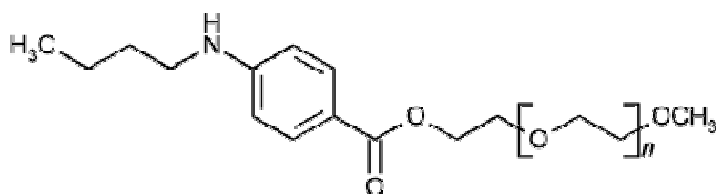
Section 1. Identification

Identification of the product:

Product name Benzonatate Capsules, USP

Formula $C_{30}H_{53}NO_{11}$

Chemical Name 2,5,8,11,14,17,20,23,26-nonaoxaocacosan-28-yl *p*-(butylamino) benzoate



Therapeutic Category Benzonatate capsules, USP, 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:



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.
Principle Component :		
Benzonatate	Not Found	104-31-4
Inactive Ingredients :		
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



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

Flash point	Not Found	Auto-Ignition Temperature	Not Found
Upper Flammable Limit	Not Found	Lower Flammable Limit	Not Found
Extinguishing Media	Water Spray, dry chemical, carbon dioxide or foam as appropriate for surrounding fire and material.	Fire and Explosion Hazard	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.



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 are light yellow-colored, oval-shaped soft gelatin capsules, imprinted with “2” containing pale yellow-colored clear viscous liquid.		
Solubility in water	No Data Available	Odour	Odourless
Boiling point	No Data Available	Melting Point	No Data Available
Evaporation rate	No Data Available	Vapour density	No Data Available



Safety Data Sheet

Version:1.0

CSPC BENZONATATE CAPSULES, USP

Strength: 200 mg

Pack Size: 500 Capsules per bottle

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

Section 10. Stability and Reactivity

Condition to avoid	Avoid exposure to extreme heat, light and moisture.	Stable	Stable under normal Ambient and anticipated storage and handling conditions.
Decomposition	No Data Available	Hazardous Reaction	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.



Safety Data Sheet

Version:1.0

CSPC BENZONATATE CAPSULES, USP

Strength: 200 mg

Pack Size: 500 Capsules per bottle

Section 16. Other information

None.