

# Material Safety data sheet

## BENZONATATE CAPSULES, USP

**Strength:** 100 mg.

**Pack Size:** 100 and 500 Capsules per bottle

**Revision No.:** 00

**Strength:** 200 mg.

**Pack Size:** 100 Capsules per bottle

### EMERGENCY OVERVIEW

Benzonatate Capsules, USP contain Benzonatate and excipients generally considered to be non-toxic and non-hazardous in small quantities and under conditions of normal occupational exposure.

## Section 1. Identification of the substance

### Identification of the product

<b>Product name:</b>	Benzonatate Capsules, USP
<b>Formula:</b>	C <sub>30</sub> H <sub>53</sub> NO <sub>11</sub>
<b>Chemical Name:</b>	2,5,8,11,14,17,20,23,26-nonaoxaocacosan-28-yl <i>p</i> -(butylamino) benzoate
<b>Therapeutic Category</b>	Benzonatate capsules, USP, a non-narcotic oral antitussive agent

### Manufacturer / supplier identification

<b>Company:</b>	<b>Cadila Healthcare Ltd. Ahmedabad, India</b>
<b>Contact for information:</b>	Tel.: +91 79 6868100 Fax: +91 79 3750319
<b>Emergency telephone No.</b>	Tel.: +91 79 6868100

## Section 2. 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
Non-crystallizing sorbitol solution	Not Found	50-70-4
Methylparaben	Not Found	99-76-3
Propylparaben	Not Found	94-13-3

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### Section 3. Health Hazards Information

**Dose and Administration** Adults and Children over 10: Usual dose is one 100 mg or 200 mg capsule t.i.d. as required. If necessary, up to 600 mg daily may be given.

**Adverse Effects** 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.

**Over Dose Effect** 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 absorbed after ingestion.

If capsules are chewed or dissolved in the mouth, oropharyngeal anesthesia will develop rapidly. CNS stimulation may cause restlessness and tremors which may proceed to clonic convulsions followed by profound CNS depression.

Overdose may result in death.

**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** 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 pregnant woman only if clearly needed.

**Pregnancy Category** C

### Section 4. First aid measures

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

**Overdose Treatment** 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 overdose.

Do not use CNS stimulants.

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### Section 5. Fire – fighting measures

<b>Flash point</b>	Not Found	<b>Upper Flammable Limit:</b>	Not Found
<b>Auto-Ignition Temperature:</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. As with all dry powders it is advisable to ground mechanical equipment in contact with the dry material to dissipate the potential build up of static electricity.
<b>Fire Fighting Procedure</b>	As with all fires, evacuate personnel to a safe area. Fire fighter should use self-contained breathing equipment and protective clothing.		

### Section 6. Storage / Spill / Disposal Measures

<b>Storage</b>	Store at 20° - 25°C (68° - 77°F) Dispense in a tight, light-resistant container.
<b>Spill Response</b>	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.
<b>Disposal</b>	Dispose the waste in accordance with all applicable Federal, State and local laws.

### Section 7. Exposure controls and personal protection

<b>Respiratory Protection</b>	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.
<b>Skin Protection</b>	Skin protection is not normally necessary, however it is good practice to avoid contact with chemical to use suitable gloves when handling.
<b>Eye protection</b>	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.
<b>Protective Clothing</b>	Protective clothing is not normally necessary, however it is good practice to use apron.

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### Section 8. Physical and chemical properties

<b>Appearance</b>	Benzonatate capsules USP, 100 mg are light yellow-colored, round-shaped soft gelatin capsules, imprinted with "Z" containing pale yellow-colored clear viscous liquid.		
	Benzonatate capsules USP, 200 mg are light yellow-colored, round-shaped soft gelatin capsules, imprinted with "β" containing pale yellow-colored clear viscous liquid.		
<b>Odour</b>	Odourless	<b>Melting Point</b>	No Data Available
<b>Solubility in water</b>	No Data Available	<b>Vapour density</b>	No Data Available
<b>Boiling point</b>	No Data Available	<b>Evaporation rate</b>	No Data Available
<b>Evaporation rate</b>	No Data Available	<b>Specific gravity</b>	No Data Available
<b>Reactivity in water</b>	No Data Available	<b>Vapour pressure</b>	No Data Available
<b>% Volatile by volume</b>	No Data Available		
<b>Other information</b>	No Data Available		

### Section 9. Physical Hazards

<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 Products</b>	No Data Available	<b>Hazardous Reaction</b>	No data available.
<b>Incompatibilities</b>	No data available.		

### Section 10. Toxicological information

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

Rare instances of deliberate or accidental overdose have resulted in death.

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### Section 11. Ecological information

No data available on Ecotoxicity

### Section 12. Other information

None

**Date of issue:** 03/07/2007

**Supersedes edition of:** New Edition

The information contained herein is based on the state of our knowledge. It Characterises the product with regard to the appropriate safety precautions. It does not represent a guarantee of the properties of the product.