

**ANTIBACTERIAL FOAMING HAND WASH - benzalkonium chloride liquid  
Tonic Bath and Body Products Shenzhen Ltd.**

*Disclaimer: Most OTC drugs are not reviewed and approved by FDA, however they may be marketed if they comply with applicable regulations and policies. FDA has not evaluated whether this product complies.*

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**Drug Facts**

**Active Ingredient**

Benzalkonium Chloride 0.13%

**Uses**

For handwashing to decrease bacteria on the skin.

**Warnings**

**For external use only.**

**When using this product**

Avoid contact with eyes. If contact occurs flush eyes with water.

Discontinue use if irritation or redness develops. If condition persists for more than 72 hours, consult a doctor.

**Keep out of the reach of children**

If swallowed get medical help or contact a Poison Control Center right away.

**Directions**

Wet hands. Apply palmful to hands and forearms. Scrub thoroughly. Rinse and repeat. Dry thoroughly.

**Inactive Ingredients**

Aloe Barbadosis (Aloe Vera) Leaf Extract, Benzophenone-3, Citric Acid, Cocamidopropylamine Oxide, Cocamidopropyl Betaine, Water, Disodium EDTA, Glycerin, Hamamelis Virginiana (Witch Hazel) Extract, Methylchloroisothiazolinone, Methylisothiazolinone, Olea Europaea (Olive) Leaf Extract, Polyaminopropyl Biguanide, Propylene Glycol, Sodium Lauroamphoacetate, Thymus Vulgaris (Thyme Oil).



## ANTIBACTERIAL FOAMING HAND WASH

benzalkonium chloride liquid

### Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:43333-450
Route of Administration	TOPICAL		

### Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
BENZALKONIUM CHLORIDE (UNII: F5UM2KM3W7) (BENZALKONIUM - UNII:7N6JUD5X6Y)	BENZALKONIUM CHLORIDE	1 mg in 13 mL

### Inactive Ingredients

Ingredient Name	Strength
ALOE VERA LEAF (UNII: ZY81Z83H0X)	
OXYBENZONE (UNII: 9500S7VE0Y)	
CITRIC ACID ACETATE (UNII: DSO12WL7AU)	
COCAMIDOPROPYLAMINE OXIDE (UNII: M4SL82J7HK)	
COCAMIDOPROPYL BETAINE (UNII: 5OCF3011KX)	

<b>WATER</b> (UNII: 059QF0KO0R)
<b>EDETIC ACID</b> (UNII: 9G34HU7RV0)
<b>GLYCERIN</b> (UNII: PDC6A3C0OX)
<b>HAMAMELIS VIRGINIANA LEAF</b> (UNII: T07U1161SV)
<b>METHYLCHLOROISOTHIAZOLINONE</b> (UNII: DEL7T5QRPN)
<b>METHYLISOTHIAZOLINONE</b> (UNII: 229D0E1QFA)
<b>OLEA EUROPAEA LEAF</b> (UNII: MJ95C3OH47)
<b>POLYAMINOPROPYL BIGUANIDE</b> (UNII: 322U039GMF)
<b>PROPYLENE GLYCOL</b> (UNII: 6DC9Q167V3)
<b>SODIUM LAUROAMPHOACETATE</b> (UNII: SLK428451L)
<b>THYMUS VULGARIS LEAF</b> (UNII: GRX3499643)

### Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:43333-450-06	200 mL in 1 BOTTLE, PUMP		

### Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part333E	03/17/2015	

**Labeler** - Tonic Bath and Body Products Shenzhen Ltd. (528197042)

### Establishment

Name	Address	ID/FEI	Business Operations
Tonic Bath and Body Products Shenzhen Ltd.		528197042	manufacture(43333-450)

Revised: 3/2015

Tonic Bath and Body Products Shenzhen Ltd.