ANTIBACTERIAL FOAMING HAND WASH SWEET TREATS- 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.

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 Barbadensis (Aloe Vera) Leaf Extract, Benzophenone-3, Citric Acid, Cocamidopropyl Betaine, Cocamidopropylamine Oxide, , Water, Disodium EDTA, FD&C Red. No. 40 (CI16035), FD&C Yellow No. 5 (CI19140), Fragrance (Parfum), Glycerin, Hamamelis Virginiana (Witch Hazel) Extract, Methylchloroisothiazolinone, Methylisothiazolinone, Olea Europaea (Olive) Leaf Extract, Panthanol, Polysorbate 20, Propylene Glycol, Sodium Lauroamphoacetate.

ANTIBACTERIAL FOAMING HAND WASH SWEET TREATS

benzalkonium chloride liquid

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:43333-454
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: 95OOS7VE0Y)	
CITRIC ACID ACETATE (UNII: DSO12WL7AU)	
COCAMIDOPROPYL BETAINE (UNII: 5OCF3O11KX)	
COCAMIDOPROPYLAMINE OXIDE (UNII: M4SL82J7HK)	
WATER (UNII: 059QF0KO0R)	
EDETIC ACID (UNII: 9G34HU7RV0)	
FD&C RED NO. 40 (UNII: WZB9127XOA)	
FD&C YELLOW NO. 5 (UNII: I753WB2F1M)	
GLYCERIN (UNII: PDC6A3C0OX)	
WITCH HAZEL (UNII: 101I4J0U34)	

METHYLCHLOROISOTHIAZOLINONE (UNII: DEL7T5QRPN)	
METHYLISOTHIAZOLINONE (UNII: 229D0E1QFA)	
OLEA EUROPAEA LEAF (UNII: MJ95C3OH47)	
PANTHENOL (UNII: WV9CM0O67Z)	
POLYSORBATE 20 (UNII: 7T1F30V5YH)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
SODIUM LAURAMINOPROPIONATE (UNII: X5NJA9HXPU)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:43333-454-16	500 mL in 1 BOTTLE, PUMP; Type 0: Not a Combination Product		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part333E	06/25/2015	

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(43333-454)

Revised: 6/2015 Tonic Bath and Body Products Shenzhen Ltd.