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

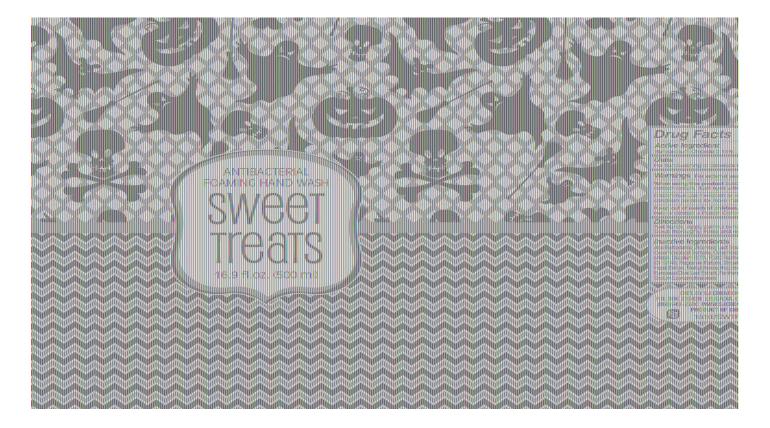
If swallowed get medical help or contact a Poison Control Center right away.

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

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Pro	duct	Infori	mation

Product TypeHUMAN OTC DRUGItem Code (Source)NDC:43333-454

Route of Administration TOPICAL

Active Ingredient/Active Moiety				
	Ingredient Name	Basis of Strength	Strength	
	BENZALKO NIUM CHLO RIDE (UNII: F5UM2KM3W7) (BENZALKO NIUM -	BENZALKONIUM	1 mg	
	UNII:7N6JUD5X6Y)	CHLORIDE	in 13 mL	

Inactive Ingredients	
Ingredient Name	Strength
ALOE VERA LEAF (UNII: ZY8 1Z8 3H0 X)	
OXYBENZONE (UNII: 950OS7VE0Y)	
CITRIC ACID ACETATE (UNII: DSO 12WL7AU)	
CO CAMIDO PRO PYL BETAINE (UNII: 50 CF3O 11KX)	
CO CAMIDO PRO PYLAMINE O XIDE (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: 10 114J0 U34)	

METHYLCHLORO ISOTHIAZO LINO NE (UNII: DEL7T5QRPN)	
METHYLISOTHIAZOLINONE (UNII: 229 D0 E1QFA)	
OLEA EUROPAEA LEAF (UNII: MJ95C3OH47)	
PANTHENOL (UNII: WV9CM0O67Z)	
POLYSORBATE 20 (UNII: 7T1F30V5YH)	
PROPYLENE GLYCOL (UNII: 6 DC9 Q16 7 V3)	
SODIUM LAURAMINO PRO PIO NATE (UNII: X5NJA9 HXPU)	

ı	Packaging				
	# I	tem Code	Package Description	Marketing Start Date	Marketing End Date
	1 ND 16	C:43333-454-	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.		528 19 70 42	manufacture(43333-454)	

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