

SPASOAP ANTIBACTERIAL- benzalkonium chloride liquid

Total Body Care Inc

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.

Antibacterial Soap

Benzalkonium Chloride - 0.13%

Purpose - Antibacterial

Uses for handwashing or decrease bacteria to the skin

For external use only

Stop use and ask a doctor if irritation or redness develops

When using the product

- do not get into eyes. If contact occurs, rinse eye thoroughly with water

Keep out of reach of children

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

Directions

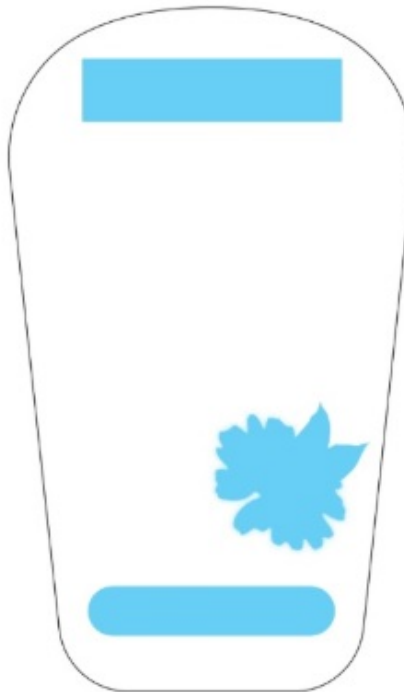
- Wet Hands
- Apply palmful to hands
- Scrub thoroughly
- Rinse

Water, Sodium Laureth Sulfate, Cocamidopropyl Betaine, Sodium Chloride, Citric Acid, Glycerin, Fragrance, Tetrasodium EDTA, Methylchloroisothiazolinone, Methylisothiazolinone, Yellow# 5 (CI 19140), Red# 4 (CI14700)

CLEAR FILM
SIZE: 4.15" X 2.4561"

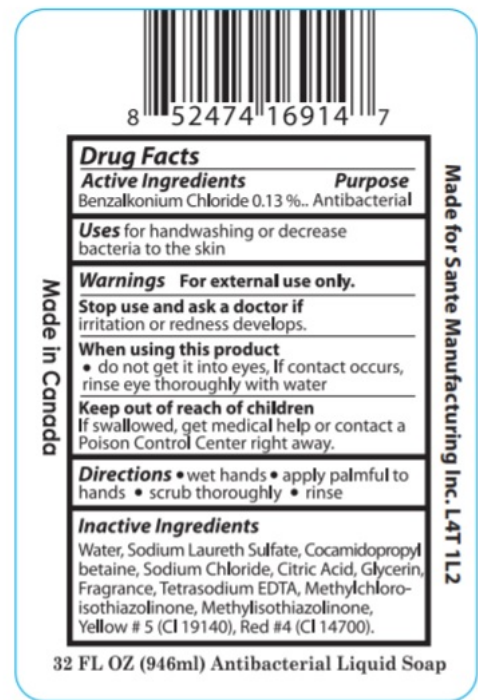


WHITE PLATE



SEMI-GLOSS PAPER
SIZE: 2.5" X 1.875"





SPASOAP ANTIBACTERIAL

benzalkonium chloride liquid

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:54369-005
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
BENZALKONIUM CHLORIDE (UNII: F5UM2KM3W7) (BENZALKONIUM - UNII:7N6JUD5X6Y)	BENZALKONIUM CHLORIDE	1.3 mg in 1 mL

Inactive Ingredients

Ingredient Name	Strength
GLYCERIN (UNII: PDC6A3C0OX)	
DITETRACYCLINE TETRASODIUM EDETATE (UNII: WX0A0IT7K5)	
METHYLCHLOROISOTHIAZOLINONE (UNII: DEL7T5QRPN)	
WATER (UNII: 059QF0KO0R)	
SODIUM LAURETH SULFATE (UNII: BPV390UAP0)	
COCAMIDOPROPYL BETAINE (UNII: 5OCF3O11KX)	
SODIUM CHLORIDE (UNII: 451W47IQ8X)	
ANHYDROUS CITRIC ACID (UNII: XF417D3PSL)	
METHYLISOTHIAZOLINONE (UNII: 229D0E1QFA)	
FD&C YELLOW NO. 5 (UNII: I753WB2F1M)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:54369-005-16	500 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	05/05/2020	
2	NDC:54369-005-60	600 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	05/05/2020	
3	NDC:54369-005-32	947 mL in 1 BOTTLE; Type 0: Not a Combination Product	05/05/2020	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part333A	05/05/2020	

Labeler - Total Body Care Inc (250919615)