WIPE OUT ANTIBACTERIAL LIQUID HAND COCONUT VANILLA- benzalkonium chloride soap TZUMI INNOVATIONS LLC

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.

77878-027, Style: WP0024 COC

Active Ingredient(s)

Benzalkonium Chloride 0.13%

Purpose

Antibacterial

Use

For hand washing to decrease bacteria on the skin

Warnings

For external use only

When using this product do not get into eyes. If contact occurs, rinse eyes thoroughly with water Stop use and ask a doctor if irritation and redness develop, condition persists for more than 72 hours 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 for at least 15 seconds
- Rinse thoroughly and dry

Inactive ingredients

Water, Cocamidopropyl dimethylamine oxide, Citric Acid, Fragrance, Kathon, Glycerin, Fatty acyl diethanol amine, Disodium EDTA, Hydroxyethyl Cellulose (250HHR), Red 7 (CI 16255), Yellow 5 (CI 19140)

LABEL - FRONT LABEL - BACK





65mm

WIPE OUT ANTIBACTERIAL LIQUID HAND COCONUT VANILLA

benzalkonium chloride soap

Product Information				
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:77878-027	
Route of Administration	TOPICAL			

Active Ingredient/Active Moiety				
Ingredient Name	Basis of Strength	Strength		
BENZALKONIUM CHLORIDE (UNII: F5UM2KM3W7) (BENZALKONIUM - UNII:7N6JUD5X6Y)	BENZALKONIUM CHLORIDE	0.13 g in 100 mL		

Inactive Ingredients		
Ingredient Name	Strength	
HYDRO XYETHYL CELLULO SE, UNSPECIFIED (UNII: T4V6TWG28D)		
D&C RED NO. 7 (UNII: ECW0LZ41X8)		
FD&C YELLOW NO. 5 (UNII: I753WB2F1M)		

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WATER (UNII: 059QF0KO0R)	
CITRIC ACID MONOHYDRATE (UNII: 2968 PHW8 QP)	
GLYCERIN (UNII: PDC6A3C0OX)	
DISO DIUM HEDTA (UNII: KME849 MC7A)	

Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:77878-027-01	221 mL in 1 BOTTLE; Type 0: Not a Combination Product	12/23/2020	

Marketing Information			
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part333A	12/23/2020	

Labeler - TZUMI INNOVATIONS LLC (117426322)

Establishment				
Name	Address	ID/FEI	Business Operations	
Aogrand International Trade Corporation		421353092	manufacture(77878-027)	

Revised: 12/2020 TZUMI INNOVATIONS LLC