

ANTIBACTERIAL HANDWASH TROPICAL BEACH- benzalkonium chloride liquid
Universal Distribution Center 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.

ANTIBACTERIAL HANDWASH TROPICAL BEACH

Active Ingredient

Benzalkonium Chloride 0.13%

Purpose

Antibacterial

USES

for hand washing to decrease bacteria on the skin.

Warning:

Avoid contact with eyes. In case of contact flush with water. Keep out of direct sunlight. Do not drink, not edible. External use only.

Keep out of reach of children.

Directions

Pump a small amount of soap into wet hands, rub hands together to create rich lather, then rinse.

Ingredients:

Water, Sodium Laureth Sulfate, Sodium Chloride, Cocamidopropyl Betaine, Cocamide MIPA, Laureth-4, Glycerin*, Polyquaternium-7*, Fragrance, Methylchloroisothiazolinone, Methylisothiazolinone, Tetrasodium EDTA, Citric Acid, Benzophenono-4, Tocopheryl Acetate, FD&C Blue No. 1, D&C Red No. 33

*Contains one or more of these ingredients.

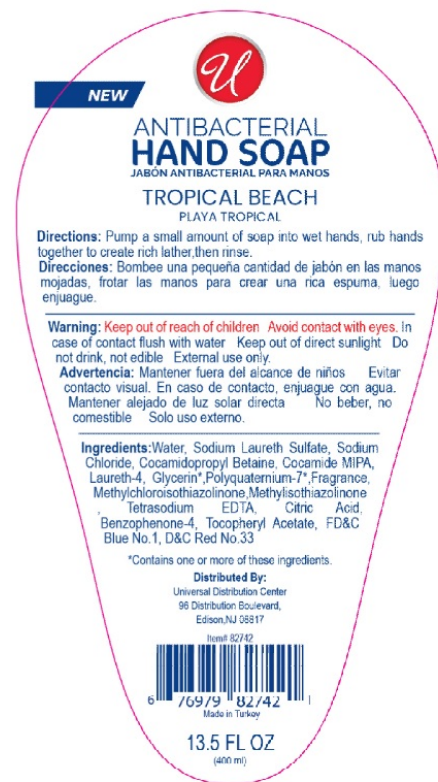
Kill Germs and Odors

Distributed By:

Universal Distribution Center
96 Distribution Boulevard,
Edison, NJ 08817

Made in Turkey

Packaging



ANTIBACTERIAL HANDWASH TROPICAL BEACH

benzalkonium chloride liquid

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:52000-043
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
WATER (UNII: 059QF0K00R)	
SODIUM LAURETH-3 SULFATE (UNII: BPV390UAP0)	
SODIUM CHLORIDE (UNII: 451W47IQ8X)	
COCAMIDOPROPYL BETAINE (UNII: 5OCF3011KX)	
COCO MONOISOPROPANOLAMIDE (UNII: 21X4Y0VTB1)	
LAURETH-4 (UNII: 6HQ855798J)	
GLYCERIN (UNII: PDC6A3C0OX)	
POLYQUATERNIUM-7 (70/30 ACRYLAMIDE/DADMAC; 1600000 MW) (UNII: 0L414VCS5Y)	
METHYLCHLOROISOTHIAZOLINONE (UNII: DEL7T5QRPN)	

METHYLISOTHIAZOLINONE (UNII: 229D0E1QFA)

EDETATE SODIUM (UNII: MP1J8420LU)

CITRIC ACID MONOHYDRATE (UNII: 2968PHW8QP)

SULISOBENZONE (UNII: 1W6L629B4K)

.ALPHA.-TOCOPHEROL ACETATE (UNII: 9E8X80D2L0)

FD&C BLUE NO. 1 (UNII: H3R47K3TBD)

D&C RED NO. 33 (UNII: 9DBA0SBB0L)

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:52000-043-01	400 mL in 1 BOTTLE; Type 0: Not a Combination Product	08/01/2018	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part333E	08/01/2018	

Labeler - Universal Distribution Center LLC (019180459)

Registrant - Universal Distribution Center LLC (019180459)

Establishment

Name	Address	ID/FEI	Business Operations
Hobi Kozmetik Imalat Sanayi Ve Ticaret Anonim Sirketi		533139227	manufacture(52000-043)

Revised: 3/2020

Universal Distribution Center LLC