HEALTHY ACCENTS ANTIBACTERIAL WHITE TEA- benzalkonium chloride liquid DZA BRANDS 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.

DRUG FACTS

ACTIVE INGREDIENT

BENZALKONIUM CHLORIDE 0.13%

PURPOSE

ANTIBACTERIAL

USES

HELPS ELIMINATE BACTERIA ON HANDS

WARNINGS

FOR EXTERNAL USE ONLY

WHEN USING THIS PRODUCT

AVOID CONTACT WITH EYES. IN CASE OF CONTACT, RINSE WITH WATER

STOP USE AND ASK DOCTOR IF

IRRITATION OR REDNESS DEVELOPS AND LASTS

KEEP OUT OF REACH OF CHILDREN

IN CASE OF ACCIDENTAL INGESTION, GET MEDICAL HELP OR CONTACT A POISON CONTROL CENTER IMMEDIATELY

DIRECTIONS

PUMP ONTO DRY HANDS. WORK INTO A RICH FOAMY LATHER, RINSE THOROUGHLY AND DRY

OTHER INFORMATION

STORE AT ROOM TEMPERATURE

INACTIVE INGREDIENTS

WATER (AQUA), COCAMIDOPROPYL BETAINE, POLYSORBATE 20, GLYCERIN, FRAGRANCE (PARFUM), CAMELLIA SINENSIS LEAF EXTRACT, ALOE BARBADENSIS LEAF JUICE, SODIUM CITRATE, XANTHAN GUM, TETRASODIUM EDTA, POLYQUATERNIUM-7, DECYL GLUCOSIDE, CITRIC ACID, METHYLCHLOROISOTHIAZOLINONE, METHYLISOTHIAZOLINONE, EXT. VIOLET 2 (CI 60730)

LABEL COPY



HEALTHY ACCENTS ANTIBACTERIAL WHITE TEA

benzalkonium chloride liquid

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Product Type HUMAN OTC DRUG Item Code (Source) NDC:55316-102

Route of Administration TOPICAL

Active Ingredient/Active Moiety

Ingredient NameBasis of StrengthStrengthBENZALKONIUM CHLORIDE (UNII: F5UM2KM3W7) (BENZALKONIUM -
UNII:7N6JUD5X6Y)BENZALKONIUM
CHLORIDE1.3 mg
in 1 mL

Inactive Ingredients	
Ingredient Name	Strength
WATER (UNII: 059QF0KO0R)	
COCAMIDO PRO PYL BETAINE (UNII: 50 CF3011KX)	
POLYSORBATE 20 (UNII: 7T1F30V5YH)	
GLYCERIN (UNII: PDC6 A3C0 OX)	
GREEN TEA LEAF (UNII: W2ZU1RY8B0)	
ALOE VERA LEAF (UNII: ZY8 1Z8 3H0 X)	
SODIUM CITRATE (UNII: 1Q73Q2JULR)	
XANTHAN GUM (UNII: TTV12P4NEE)	

EDETATE SO DIUM (UNII: MP1J8420 LU)	
POLYQUATERNIUM-7 (70/30 ACRYLAMIDE/DADMAC; 1600000 MW) (UNII: 0L414VCS5Y)	
DECYL GLUCOSIDE (UNII: Z17H97EA6Y)	
CITRIC ACID MONO HYDRATE (UNII: 2968 PHW8 QP)	
METHYLCHLORO ISO THIAZO LINO NE (UNII: DEL7T5QRPN)	
METHYLISOTHIAZOLINONE (UNII: 229 D0 E1QFA)	
EXT. D&C VIOLET NO. 2 (UNII: G5UX3K0728)	

ı	Packaging			
	# Item Code	Package Description	Marketing Start Date	Marketing End Date
	1 NDC:55316-102-08	221 mL in 1 BOTTLE, PLASTIC		

Marketing Information				
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date	
OTC monograph not final	part333E	0 2/0 3/20 15		

Labeler - DZA BRANDS LLC (090322194)

Registrant - APOLLO HEALTH AND BEAUTY CARE (201901209)

Establishment						
Name	Address	ID/FEI	Business Operations			
APOLLO HEALTH AND BEAUTY CARE		201901209	manufacture(55316-102)			

Revised: 2/2015 DZA BRANDS LLC