BERKLEY JENSEN ANTIBACTERIAL HAND- benzalkonium chloride liquid
BJWC

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%

PURPOSES

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 A 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

APPLY ONTO WET HANDS. LATHER AND RINSE THOROUGHLY

OTHER INFORMATION

STORE AT ROOM TEMPERATURE

INACTIVE INGREDIENTS

WATER (AQUA), COCAMIDOPROPYL BETAINE, GLYCERIN, DECYL GLUCOSIDE, HYDROXYETHYLCELLULOSE, ALOE BARBADENSIS LEAF JUICE, FRAGRANCE (PARFUM), POLOXAMER 124, POLYQUATERNIUM-7, TETRASODIUM EDTA, CITRIC ACID, SODIUM CITRATE, CAMELLIA SINENSIS LEAF EXTRACT, SACCHAROMYCES FERMENT, TOCOPHERYL ACETATE, RETINYL PALMITATE, ASCORBYL PALMITATE, NIACINAMIDE, METHYLCHLOROISOTHIAZOLINONE, METHYLISOTHIAZOLINONE, BLUE 1 (CI 42090), RED 33 (CI 17200)

QUESTIONS OR COMMENTS?

1-800-934-1204

LABEL COPY

BERKLEY JENSEN ANTIBACTERIAL HAND

benzalkonium chloride liquid

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:68391-150
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**
WATER (UNII: 059QF0KO0R)	
COCAMIDOPROPYL BETAINE (UNII: 5OCF3O11KX)	
GLYCERIN (UNII: PDC6A3C0OX)	
DECYL GLUCOSIDE (UNII: Z17H97EA6Y)	
HYPROMELLOSES (UNII: 3NXW29V3WO)	
ALOE VERA LEAF (UNII: ZY81Z83H0X)	
POLOXAMER 124 (UNII: 1S66E28KXA)	
POLYQUATERNIUM-7 (70/30 ACRYLAMIDE/DADMAC; 1600000 MW) (UNII: 0L414VCS5Y)	

EDETATE SODIUM (UNII: MP1J8420LU)	
CITRIC ACID MONOHYDRATE (UNII: 2968PHW8QP)	
SODIUM CITRATE (UNII: 1Q73Q2JULR)	
GREEN TEA LEAF (UNII: W2ZU1RY8B0)	
.ALPHA.-TOCOPHEROL ACETATE (UNII: 9E8X80D2L0)	
VITAMIN A PALMITATE (UNII: 1D1K0N0VVC)	
ASCORBYL PALMITATE (UNII: QN83US2B0N)	
NIACINAMIDE (UNII: 25X51I8RD4)	
METHYLCHLOROISOTHIAZOLINONE (UNII: DEL7T5QRPN)	
METHYLISOTHIAZOLINONE (UNII: 229D0E1QFA)	
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:68391-150-64	1890 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	12/09/2014	

Labeler - BJWC (159082692)

Registrant - APOLLO HEALTH AND BEAUTY CARE (201901209)

Establishment

Name	Address	ID/FEI	Business Operations
APOLLO HEALTH AND BEAUTY CARE		201901209	manufacture(68391-150)

Revised: 12/2014 BJWC