FRESH WATER- benzalkonium chloride soap
Spa Dent 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.

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 thoroughly 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

- use to refill a hand soap pump bottle.
- From pump bottle, apply onto wet hands.
- Lather and rinse thoroughly.

Other Information

Store at room temperature

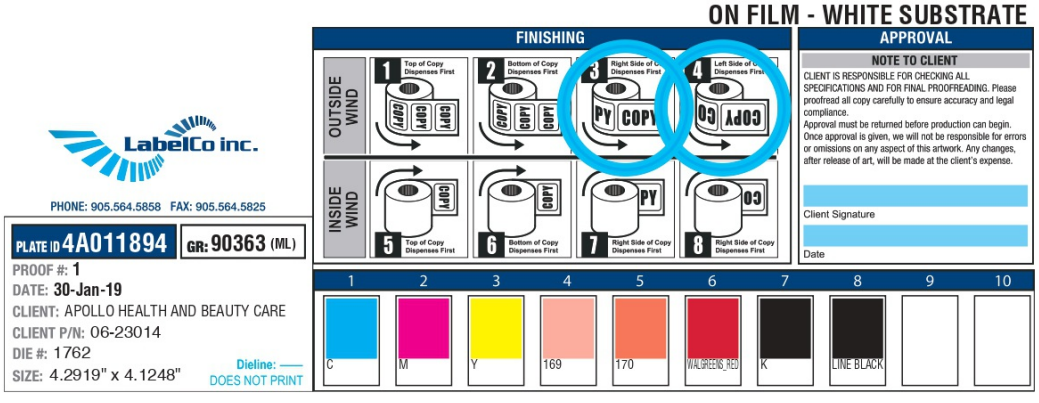
Inactive Ingredients

Water (Aqua), Lauramidopropylamine Oxide, Glycerin, Cetrimonium Chloride, Sodium Chloride, Cocamide MEA, PEG-120 Methyl Glucose Dioleate, Fragrance (Parfum), Citric Acid, Tetrasodium EDTA, Sodium Sulfate, Methylchloroisothiazolinone, Methylisothiazolinone, Red 40 (CI 16035), Yellow 5 (CI 19140), Red 33 (CI 17200).

Questions or comments ?

1-800-925-4733

PDP04



FRESH WATER

benzalkonium chloride soap

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:79147-022
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety		
Ingredient Name	**Basis of Strength**	**Strength**
BENZALKONIUM CHLORIDE (UNII: F5UM2KM3W7) (BENZALKONIUM - UNII:7N6JUD5X6Y)	BENZALKONIUM CHLORIDE	130 mg in 100 mL

Inactive Ingredients	
Ingredient Name	**Strength**
WATER (UNII: 059QF0KO0R)	
LAURAMIDOPROPYLAMINE OXIDE (UNII: I6KX160QTV)	
GLYCERIN (UNII: PDC6A3C0OX)	
CETRIMONIUM CHLORIDE (UNII: UC9PE95IBP)	
SODIUM CHLORIDE (UNII: 451W47IQ8X)	
COCO MONOETHANOLAMIDE (UNII: C80684146D)	
PEG-120 METHYL GLUCOSE DIOLEATE (UNII: YM0K64F20V)	
FRAGRANCE CLEAN ORC0600327 (UNII: 329LCV5BTF)	
CITRIC ACID MONOHYDRATE (UNII: 2968PHW8QP)	
EDETATE SODIUM (UNII: MP1J8420LU)	
SODIUM SULFATE (UNII: 0YPR65R21J)	
METHYLCHLOROISOTHIAZOLINONE (UNII: DEL7T5QRPN)	
METHYLISOTHIAZOLINONE (UNII: 229D0E1QFA)	
FD&C RED NO. 40 (UNII: WZB9127XOA)	
FD&C YELLOW NO. 5 (UNII: I753WB2F1M)	
D&C RED NO. 33 (UNII: 9DBA0SBB0L)	

Packaging				
#	**Item Code**	**Package Description**	**Marketing Start Date**	**Marketing End Date**
1	NDC:79147-022-04	1660 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	07/13/2021	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part333A	07/13/2021	

Labeler - Spa Dent Inc (203478896)

Registrant - Apollo Health and Beauty Care (201901209)

Establishment

Name	Address	ID/FEI	Business Operations
Spa Dent Inc		203478896	manufacture(79147-022)

Revised: 7/2021

Spa Dent Inc