NATURAL CONCEPTS ALCOHOL-FREE HAND SANITIZER- benzalkonium chloride gel
Apollo Health and Beauty Care 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

Antiseptic

Uses

to help reduce bacteria on the skin. For use when soap and water are not available.

Warnings

For external use only.

When using this product

avoid contact with eyes. If contact occurs, rinse eyes thoroughly with water.

Do not use
- on children less than 2 months of age
- on open skin wounds

Stop use and ask a doctor if

irritation develops.

Keep out of reach of children.

If swallowed, call or contact a Poison Control Center or get medical help right away.

Directions
- put enough product in your palm to cover hands, rub hands together for at least 30 seconds. Allow to dry.
- Children under 6 years should be supervised when using this product.

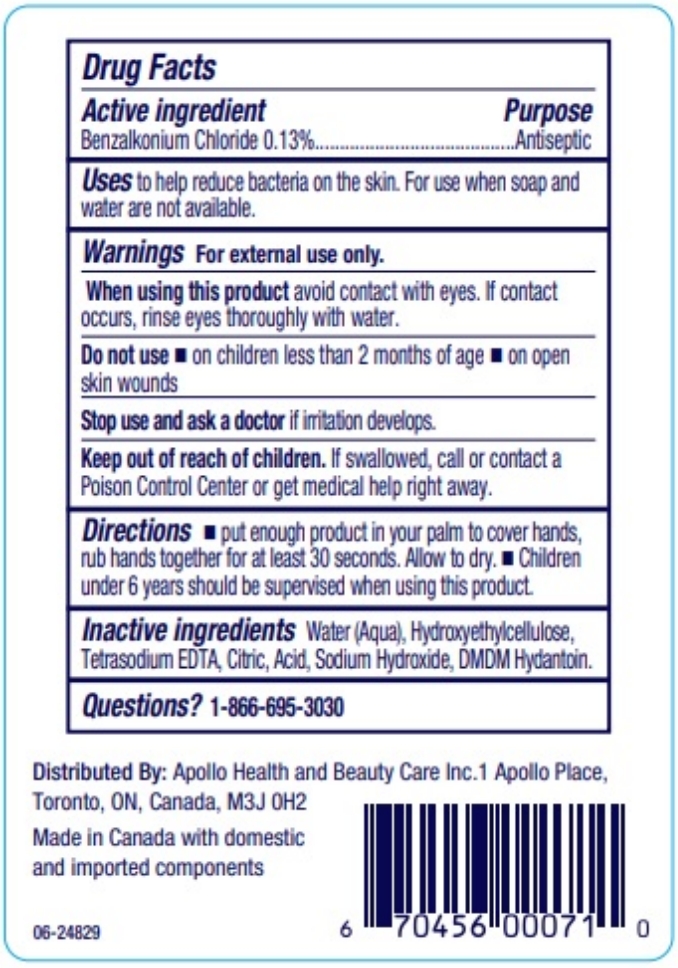
Inactive ingredients

Water (Aqua), Hydroxyethylcellulose, Tetrasodium EDTA, Citric Acid, Sodium Hydroxide, DMDM Hydantoin.

Questions?

1-866-695-3030

Label copy



NATURAL CONCEPTS ALCOHOL-FREE HAND SANITIZER

benzalkonium chloride gel

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:63148-512
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)	
HYPROMELLOSES (UNII: 3NXW29V3WO)	
EDETATE SODIUM (UNII: MP1J8420LU)	
CITRIC ACID MONOHYDRATE (UNII: 2968PHW8QP)	

SODIUM HYDROXIDE (UNII: 55X04QC32I)	
DMDM HYDANTOIN (UNII: BYR0546TOW)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:63148-512-37	3785 mL in 1 PACKAGE; Type 0: Not a Combination Product	07/16/2020	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part333E	07/16/2020	

Labeler - Apollo Health and Beauty Care Inc. (201901209)

Registrant - Apollo Health and Beauty Care Inc. (201901209)

Establishment

Name	Address	ID/FEI	Business Operations
Apollo Health and Beauty Care Inc.		201901209	manufacture(63148-512)

Revised: 7/2020 Apollo Health and Beauty Care Inc.