

**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.*

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**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 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 or comments?**

1-866-695-3030

Label copy



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<b>Active ingredient</b> Benzalkonium Chloride 0.13%	<b>Purpose</b> Antiseptic
<b>Uses</b> to help reduce bacteria on the skin. For use when soap and water are not available.	
<b>Warnings</b> <b>For external use only.</b> <b>When using this product</b> avoid contact with eyes. If contact occurs, rinse eyes thoroughly with water. <b>Do not use</b> ■ on children less than 2 months of age ■ on open skin wounds <b>Stop use and ask a doctor</b> if irritation develops.	
<b>Keep out of reach of children.</b> If swallowed, call a contact a Poison Control Centre or get medical help right away.	
<b>Directions</b> ■ 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.	
<b>Inactive ingredients</b> Water (Aqua), Hydroxypropyl Guar, Tetrasodium EDTA, Citric Acid, Sodium Hydroxide, DMDM Hydantoin.	
<b>Questions?</b> 1-866-695-3030	

MADE IN CANADA WITH DOMESTIC AND IMPORTED COMPONENTS  
 DISTRIBUTED AND MANUFACTURED BY:  
 APOLLO HEALTH AND BEAUTY CARE INC. TORONTO, ON, CANADA, M3J 0H2



06-24657

**NATURAL CONCEPTS ALCOHOL-FREE HAND SANITIZER**

benzalkonium chloride gel

**Product Information**

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:63148-512
<b>Route of Administration</b>	TOPICAL		

**Active Ingredient/Active Moiety**

Ingredient Name	Basis of Strength	Strength
<b>BENZALKONIUM CHLORIDE</b> (UNII: F5UM2KM3W7) (BENZALKONIUM - UNII:7N6JUD5X6Y)	BENZALKONIUM CHLORIDE	1.3 mg in 1 mL

**Inactive Ingredients**

Ingredient Name	Strength
WATER (UNII: 059QF0KO0R)	
HYDROXYPROPYL GUAR (2500-4500 MPAS AT 1%) (UNII: 3A1I7376TC)	
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:63148-512-10	236 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	04/14/2020	
2	NDC:63148-512-04	59 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	04/14/2020	
3	NDC:63148-512-34	946 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	04/14/2020	

### Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part333E	04/14/2020	

**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: 4/2020

Apollo Health and Beauty Care Inc.