## HAND SANITIZER- benzalkonium chloride gel Alpine Industries

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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## **Alpine Benzalkonium Citrus**

## **Active Ingredient(s)**

Benzalkonium Chloride 0.13% Purpose: Antimicrobial

## **Purpose**

Antiseptic, Hand Sanitizer

#### Use

Hand Sanitizer to help reduce bacteria that potentially can cause disease. For use when soap and water are not available.

## **Warnings**

For external use only. Flammable. Keep away from heat or flame

#### Do not use

- in children less than 2 months of age
- on open skin wounds

When using this product keep out of eyes, ears, and mouth. In case of contact with eyes, rinse eyes thoroughly with water.

Stop use and ask a doctor if irritation or rash occurs. These may be signs of a serious condition.

Keep out of reach of children. If swallowed, get medical help or contact a Poison Control Center right away.

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Keep out of reach of children. If swallowed, get medical help or contact a Poison Control Center right away.

#### **Directions**

- Place enough product on hands to cover all surfaces. Rub hands together until dry.
- Supervise children under 6 years of age when using this product to avoid swallowing.

## Other information

- Store between 15-30C (59-86F)
- Avoid freezing and excessive heat above 40C (104F)

# **Inactive ingredients**

Water, Potassium Cocoate, Cetrimonium Chloride, Fragrance

## Package Label - Principal Display Panel

140mL NDC: 78224-003-01



237mL NDC 78224-003-02



3.79L NDC: 78224-003-03



#### **Brug Facts**

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- recommended for

#### Warnings For external use or

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#### Directions

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- Rub ihomoghly ox
- Rub hands jugethe
- Supervise children.

- Other information
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  Avoid freezing and

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## **HAND SANITIZER**

benzalkonium chloride gel

#### **Product Information**

HUMAN OTC DRUG **Product Type** Item Code (Source) NDC:78224-003

**Route of Administration TOPICAL** 

#### **Active Ingredient/Active Moiety Ingredient Name Basis of Strength** Strength BENZALKONIUM CHLORIDE (UNII: F5UM2KM3W7) (BENZALKONIUM -**BENZALKONIUM** $0.13 \, q$ in 100 mL UNII:7N6JUD5X6Y) **CHLORIDE**

Inactive Ingredients				
Ingredient Name	Strength			
TRIETHYL CITRATE (UNII: 8Z96QXD6UM)				
POTASSIUM COCOATE (UNII: F8U72V8ZXP)				
CETRIMONIUM CHLORIDE (UNII: UC9PE95IBP)				
WATER (UNII: 059QF0KO0R)				
ORANGE OIL (UNII: AKN3KSD11B)				

P	Packaging					
#	Item Code	Package Description	Marketing Start Date	Marketing End Date		
1	NDC:78224- 003-01	140 mL in 1 BOTTLE; Type 0: Not a Combination Product	06/29/2020			
2	NDC:78224- 003-02	237 mL in 1 BOTTLE; Type 0: Not a Combination Product	06/29/2020			
3	NDC:78224- 003-03	3785 mL in 1 PACKET; Type 0: Not a Combination Product	06/29/2020			

Marketing Information					
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date		
OTC monograph not final	part333A	06/29/2020			

# Labeler - Alpine Industries (095207423)

Revised: 5/2021 Alpine Industries