

**CHEMSTATION ALCOHOL FREE HAND SANITIZER- benzalkonium chloride liquid
CHEMSTATION SOUTHERN CALIFORNIA, 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.

Active ingredient

Benzalkonium Chloride 0.14 v/v

Purpose

Antiseptic

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.

Do not use

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

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.

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

purified water USP, glycerin, cocamidopropyl diethylamine, and Cocamidopropyl betaine

Product label

**Chemstation Alcohol-Free
Hand Sanitizing Spray
Antiseptic Hand Wash
0.14% Topical Solution**

**Hand Sanitizer
Non-sterile Solution**

1 gallon/3.785 L

Drug Facts	
Active ingredient	Purpose
Benzalkonium Chloride 0.14 v/v.....	Antiseptic
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.	
Do not use	
<ul style="list-style-type: none"> • in children less than 2 months of age • on open skin wounds • in eyes 	
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.	
Directions	
<ul style="list-style-type: none"> • 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	
<ul style="list-style-type: none"> • Store between 15-30C (59-86F) • Avoid freezing and excessive heat above 40C (104F) 	
Inactive ingredients purified water USP, glycerin, cocamidopropyl diethylamine, and Cocamidopropyl betaine	

Manufactured for
Chemstation of Southern California, Inc.
14699 El Molino Street
Fontana , CA 92335

Expiration date: _____ Lot number: _____

CHEMSTATION ALCOHOL FREE HAND SANITIZER

benzalkonium chloride liquid

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:80291-002
---------------------	----------------	---------------------------	---------------

Route of Administration TOPICAL

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
BENZALKONIUM CHLORIDE (UNII: F5UM2KM3W7) (BENZALKONIUM - UNII:7N6JUD5X6Y)	BENZALKONIUM CHLORIDE	1.4 mg in 1 mL

Inactive Ingredients

Ingredient Name	Strength
WATER (UNII: 059QF0KO0R)	
GLYCERIN (UNII: PDC6A3C0OX)	
COCAMIDOPROPYL BETAINE (UNII: 5OCF3O11KX)	
COCAMIDOPROPYL DIMETHYLAMINE PROPIONATE (UNII: 83750MLC4A)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:80291-002-01	59 mL in 1 BOTTLE; Type 0: Not a Combination Product	08/28/2020	
2	NDC:80291-002-02	118 mL in 1 BOTTLE; Type 0: Not a Combination Product	08/28/2020	
3	NDC:80291-002-03	236 mL in 1 BOTTLE; Type 0: Not a Combination Product	08/28/2020	
4	NDC:80291-002-04	3.785 mL in 1 BOTTLE; Type 0: Not a Combination Product	08/28/2020	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part333A	08/28/2020	

Labeler - CHEMSTATION SOUTHERN CALIFORNIA, INC. (825479186)

Establishment

Name	Address	ID/FEI	Business Operations
CHEMSTATION SOUTHERN CALIFORNIA, INC.		825479186	manufacture(80291-002)

Revised: 8/2020

CHEMSTATION SOUTHERN CALIFORNIA, INC.