

SANITIZER ACE-SA001- benzalkonium chloride liquid
ACE CHEM SOLUTIONS

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.

This sanitizer is manufactured using only the following United States Pharmacopoei (USP) grade ingredients in the preparation of the product (percentage in the final product formulation) consistent with World Health Organization (WHO):

Belzankonium Chloride (0.2% volume/volume (v/v)) in an aqueous solution).

Alcohol (isopropylic alcohol) (10% v/v)

Sterile distilled water or boiled cold water.

This firm does not add other active or inactive ingredients. Different or additional ingredients may impact the quality and potency of the product.

Benzalkonium Chloride. Purpose: Antiseptic

Antiseptic, Hands, Surface and Cloths Sanitizer.

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

For external use only.

in children less than 2 months of age

on open skin wounds

When using this product keep out eyes, ears, 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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Place enough product on hands or surfaces to cover all. Rub hands together untill dry.

Supervise children under 6 years of age when using this products to avoid swallowing.

Store between 15-30C (59-86F)

Avoiding freezing and excessive heat above 40C (104F)

Isopropylic Alcohol, purified water USP.

250 ml NDC: 77308-003-01

Drug Facts	
Active ingredient[s] Benzalkonium Chloride 0.2% v/v	Purpose Antiseptic
Use[s] 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 	
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 or surfaces to cover all . 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 Isopropyl Alcohol, purified water USP	

1 L NDC: 77308-003-03

Drug Facts	
Active ingredient[s] Benzalkonium Chloride 0.2% v/v	Purpose Antiseptic
Use[s] 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 	
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 or surfaces to cover all . 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 Isopropyl Alcohol, purified water USP	

4 L NDC: 77308-003-04

Drug Facts	
Active ingredient[s] Benzalkonium Chloride 0.2% v/v	Purpose Antiseptic
Use[s] 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 	
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 or surfaces to cover all . 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 Isopropyl Alcohol, purified water USP	

SANITIZER ACE-SA001

benzalkonium chloride liquid

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:77308-003
Route of Administration	CUTANEOUS		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
BENZALKONIUM CHLORIDE (UNII: F5UM2KM3W7) (BENZALKONIUM - UNII:7N6JUD5X6Y)	BENZALKONIUM CHLORIDE	2 g in 1 L

Inactive Ingredients

Ingredient Name	Strength
ISOPROPYL ALCOHOL (UNII: ND2M416302)	0.1 L in 1 L
WATER (UNII: 059QF0K00R)	0.899 L in 1 L

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:77308-003-01	0.25 L in 1 BOTTLE; Type 0: Not a Combination Product	06/29/2020	
2	NDC:77308-003-03	1 L in 1 BOTTLE; Type 0: Not a Combination Product	06/29/2020	
3	NDC:77308-003-04	4 L in 1 BOTTLE, PLASTIC; 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 - ACE CHEM SOLUTIONS (951577314)

Establishment

Name	Address	ID/FEI	Business Operations
ACE CHEMS SOLUTIONS		951577314	manufacture(77308-003)

Revised: 6/2020

ACE CHEM SOLUTIONS