

ANTISEPTIC- benzalkonium chloride liquid
Total Resources International

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 ingredients

Benzalkonium Chloride 0.13%

Purpose

First Aid Antiseptic

Uses

- Antiseptic cleansing of face, hands and body to decrease bacteria on skin without soap and water

Warnings

For external use only

Do not use in the eyes. If this happens, rinse thoroughly with water.

Stop use and ask doctor if irritation or redness develop and persists for more than 72 hours

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

Directions

- tear open packet, unfold and use as a washcloth. Allow hands to dry without wiping.

Inactive ingredients

alcohol, water

PRINCIPAL DISPLAY PANEL – packet label

NDC 55550-200-00

Antiseptic
Towelette

Benzalkonium Chloride/
First Aid Antiseptic

1 SINGLE-USE
PREMOISTENED TOWELETTE



Drug Facts	
Active ingredients	Purpose
Benzalkonium Chloride 0.13%	First Aid Antiseptic
Uses ■ Antiseptic cleansing of face, hands and body to decrease bacteria on skin without soap and water	
Warnings	
For external use only.	
Do not use in the eyes. If this happens, rinse thoroughly with water.	
Stop use and ask a doctor if irritation or redness develop and persists for more than 72 hours	
Keep out of reach of children If swallowed get medical help or contact a Poison Control Center right away	
Directions ■ tear open packet, unfold and use as a washcloth. Allow hands to dry without wiping.	
Inactive ingredients alcohol, water	
Dist. By: Total Resources International • Walnut, CA 91789 ITEM #00TOW94185USA Rev.02 Made In USA	

ANTISEPTIC

benzalkonium chloride liquid

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:55550-200
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
alcohol (UNII: 3K9958V90M)	
water (UNII: 059QF0K00R)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:55550-200-00	2.5 mL in 1 PACKET; Type 0: Not a Combination Product		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part333E	07/01/2013	

Labeler - Total Resources International (790160535)

Registrant - Safetec of America, Inc. (874965262)

Establishment

Name	Address	ID/FEI	Business Operations
Safetec of America, Inc.		874965262	MANUFACTURE(55550-200)

Revised: 7/2013

Total Resources International