

HAND SANITIZER - benzalkonium chloride gel
AMERICAN SALES COMPANY

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 INGREDIENT

BENZALKONIUM CHLORIDE 0.1%

PURPOSE

ANTIMICROBIAL

USES

TO HELP REDUCE BACTERIA ON THE SKIN. RECOMMENDED FOR REPEAT USE.

WARNINGS

FOR EXTERNAL USE ONLY.

WHEN USING THIS PRODUCT

AVOID CONTACT WITH EYES. IF CONTACT OCCURS, RINSE EYES THOROUGHLY WITH WATER.

STOP USING THIS PRODUCT AND ASK DOCTOR IF

IRRITATION OR RASH DEVELOPS AND LASTS.

KEEP OUT OF REACH OF CHILDREN

IF SWALLOWED, GET MEDICAL HELP OR CONTACT A POISON CONTROL CENTER RIGHT AWAY.

DIRECTIONS

- APPLY A SMALL AMOUNT IN YOUR PALM AND RUB HANDS TOGETHER BRISKLY UNTIL DRY.
- CHILDREN UNDER 6 SHOULD BE SUPERVISED WHEN USING THIS PRODUCT.

INACTIVE INGREDIENTS

WATER, POLYQUATERNIUM-37, HYDROXYETHYLCELLULOSE, PEG-40 HYDROGENATED CASTOR OIL, TRIDECETH-9, PROPYLENE GLYCOL, FRAGRANCE, TRIETHANOLAMINE.



Drug Facts	
Active ingredient Benzalkonium Chloride 0.1%	Purpose Antimicrobial
Uses • To help reduce bacteria on the skin. Recommended for repeat use.	
Warnings	
For external use only.	
When using this product • Avoid contact with eyes. If contact occurs, rinse eyes thoroughly with water.	
Stop using this product and ask doctor if • Irritation or rash develops and lasts.	
Keep out of reach of children. • If swallowed, get medical help or contact a Poison Control Center right away.	
Directions • Apply a small amount in your palm and rub hands together briskly until dry. • Children under 6 should be supervised when using this product.	
Inactive ingredients Water (Aqua), Polyquaternium-37, Hydroxyethylcellulose, PEG-40 Hydrogenated Castor Oil, Trideceth-9, Propylene Glycol, Fragrance (Parfum), Triethanolamine.	

DISTRIBUTED BY:
 American Sales Company
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 Lancaster, NY 14086
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 www.Care1.info

Quality guaranteed or
 your money back.

Product of Canada



HAND SANITIZER			
benzalkonium chloride gel			
Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:41520-280
Route of Administration	TOPICAL		
Active Ingredient/Active Moiety			
	Ingredient Name	Basis of Strength	Strength
	BENZALKONIUM CHLORIDE (UNII: F5UM2KM3W7) (BENZALKONIUM - UNII:7N6JUD5X6Y)	BENZALKONIUM CHLORIDE	0.1 mL in 100 mL
Inactive Ingredients			
	Ingredient Name		Strength
	WATER (UNII: 059QF0KO0R)		
	HYPROMELLOSES (UNII: 3NXW29V3WO)		
	POLYOXYL 40 HYDROGENATED CASTOR OIL (UNII: 7YC686GQ8F)		
	TRIDECETH-9 (UNII: X9HD79I514)		
	PROPYLENE GLYCOL (UNII: 6DC9Q167V3)		
	TROLAMINE (UNII: 9O3K93S3TK)		
Packaging			

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:41520-280-08	236 mL in 1 BOTTLE, PUMP		

Marketing Information			
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part333E	10/06/2011	

Labeler - AMERICAN SALES COMPANY (809183973)

Registrant - APOLLO HEALTH AND BEAUTY CARE (201901209)

Establishment

Name	Address	ID/FEI	Business Operations
APOLLO HEALTH AND BEAUTY CARE		201901209	manufacture

Revised: 10/2011

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