BENZOCLEAN HAND SANITIZER- benzalkonium chloride gel
GADAL Laboratories, 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.

BENZOCLEAN™ HAND SANITIZER

Drug Facts

Active Ingredient

Benzalkonium Chloride 0.13%

Purpose

Antiseptic

Use ▪ For handwashing to decrease bacteria on the skin.

Warnings **For external use only. Do not use** ▪ in the eyes **Stop use and ask a doctor if** ▪ irritation and redness develop ▪ if condition persists for more than 72 hours.

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

Directions ▪ Place enough product in your palm to thoroughly cover your hands. ▪ Rub hands together briskly until dry. ▪ No rinsing required. No towels needed.

Other information Store at room temperature.

Inactive ingredients Water (Aqua), Aloe Barbadensis Leaf Juice, Disodium EDTA, DMDM Hydantoin, Fragrance, Glycerin, Hydroxyethylcellulose, Sodium Chloride, Tocopheryl Acetate.

ADVANCED

MOISTURIZING

LONG-LASTING GEL

WITH ALOE VERA & VITAMIN E

KILLS 99.9% OF GERMS

*Kills Most Viruses

*Moisturizes & Leaves

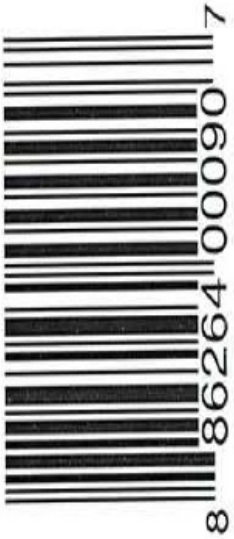
Hands Feeling Smooth

MADE IN THE **USA**

GMP GOOD MANUFACTURING PRACTICE QUALITY PRODUCT

Distributed by: PCO Foods • 1110 Powers Place Alpharetta, GA, 30009 • pcofoods.com **Questions or comments:** sales@pcofoods.com

Packaging



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8 FL OZ (236.5 ML)

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DRUG FACTS LABEL

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BENZOCLEAN HAND SANITIZER

benzalkonium chloride gel

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:53113-090
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety		
Ingredient Name	**Basis of Strength**	**Strength**
BENZALKONIUM CHLORIDE (UNII: F5UM2KM3W7) (BENZALKONIUM - UNII:7N6JUD5X6Y)	BENZALKONIUM CHLORIDE	0.13 g in 100 mL

Inactive Ingredients	
Ingredient Name	**Strength**
WATER (UNII: 059QF0KO0R)	
ALOE VERA LEAF (UNII: ZY81Z83H0X)	
EDETATE DISODIUM ANHYDROUS (UNII: 8NLQ36F6MM)	
DMDM HYDANTOIN (UNII: BYR0546TOW)	
GLYCERIN (UNII: PDC6A3C0OX)	
HYDROXYETHYL CELLULOSE, UNSPECIFIED (UNII: T4V6TWG28D)	
SODIUM CHLORIDE (UNII: 451W47IQ8X)	
.ALPHA.-TOCOPHEROL ACETATE (UNII: 9E8X80D2L0)	

Packaging				
#	**Item Code**	**Package Description**	**Marketing Start Date**	**Marketing End Date**
1	NDC:53113-090-08	236.5 mL in 1 BOTTLE; Type 0: Not a Combination Product	07/01/2020	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part333A	07/01/2020	

Labeler - GADAL Laboratories, Inc (841305639)

Establishment

Name	Address	ID/FEI	Business Operations
GADAL Laboratories, Inc		841305639	manufacture(53113-090)