HAND SANITIZER- benzalkonium chloride liquid Henry Schein, 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.

Drug Facts

Active Ingredient

Benzalkonium Chloride 0.39%

Purpose

Antiseptic

Uses

- for handwashing to decrease bacteria on skin without soap and water
- recommended for repeated use

Warnings

For external use only. Flammable, keep away from fire or flame

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

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

Keep out of reach of children

If ingested get medical help or contact a Poison Control Center right away

Directions

- wet hands thoroughly with product
- allow to dry without wiping
- children under 6 should be supervised while using this product

Inactive Ingredients

aloe vera, propylene glycol, fragrance, purified water, germaben II, ganex p-904 LC

Distributed by:

Distribuido por: Distribuépar:

HENRY SCHEIN, Inc.

135 Duryea Road Melville, NY 11747 USA

Made in U.S.A.

PRINCIPAL DISPLAY PANEL - 50 mL Bottle Label

Henry Schein

Hand Sanitizer

Mountain Meadow

Jabón higiénico de manos

Désinfectant pour les mains

Foaming

Alcohol Free

2 fl. oz. (50 ml)



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Reorder No. 900-4445



HAND SANITIZER

benzalkonium chloride liquid

Product Information

HUMAN OTC DRUG LABEL Product Type

Item Code (Source)

NDC:0404-4445

Route of Administration

TOPICAL

DEA Schedule

Active Ingredient/Active Moiety

Basis of Strength Ingredient Name Strength

Inactive Ingredients	
Ingredient Name	Strength
water	

benzalkonium chloride

7.49 g in 1 L

aloe vera leaf
propylene glycol
diazolidinyl urea

benzalkonium chloride (benzalkonium)

]	Packaging					
#	Item Code	Package Description	Marketing Start Date	Marketing End Date		
1	NDC:0404-4445-01	0.05 L in 1 BOTTLE, PUMP				
2	NDC:0404-4445-02	0.55 L in 1 BOTTLE, PUMP				

Marketing Information							
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date				
OTC monograph not final	part333E	0 1/30/20 13					

Labeler - Henry Schein, Inc. (012430880)

Registrant - Safetec of America, Inc. (874965262)

Establishment						
Name	Address	ID/FEI	Business Operations			
Safetec of America, Inc.		874965262	MANUFACTURE(0404-4445)			

Revised: 1/2013 Henry Schein, Inc.