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

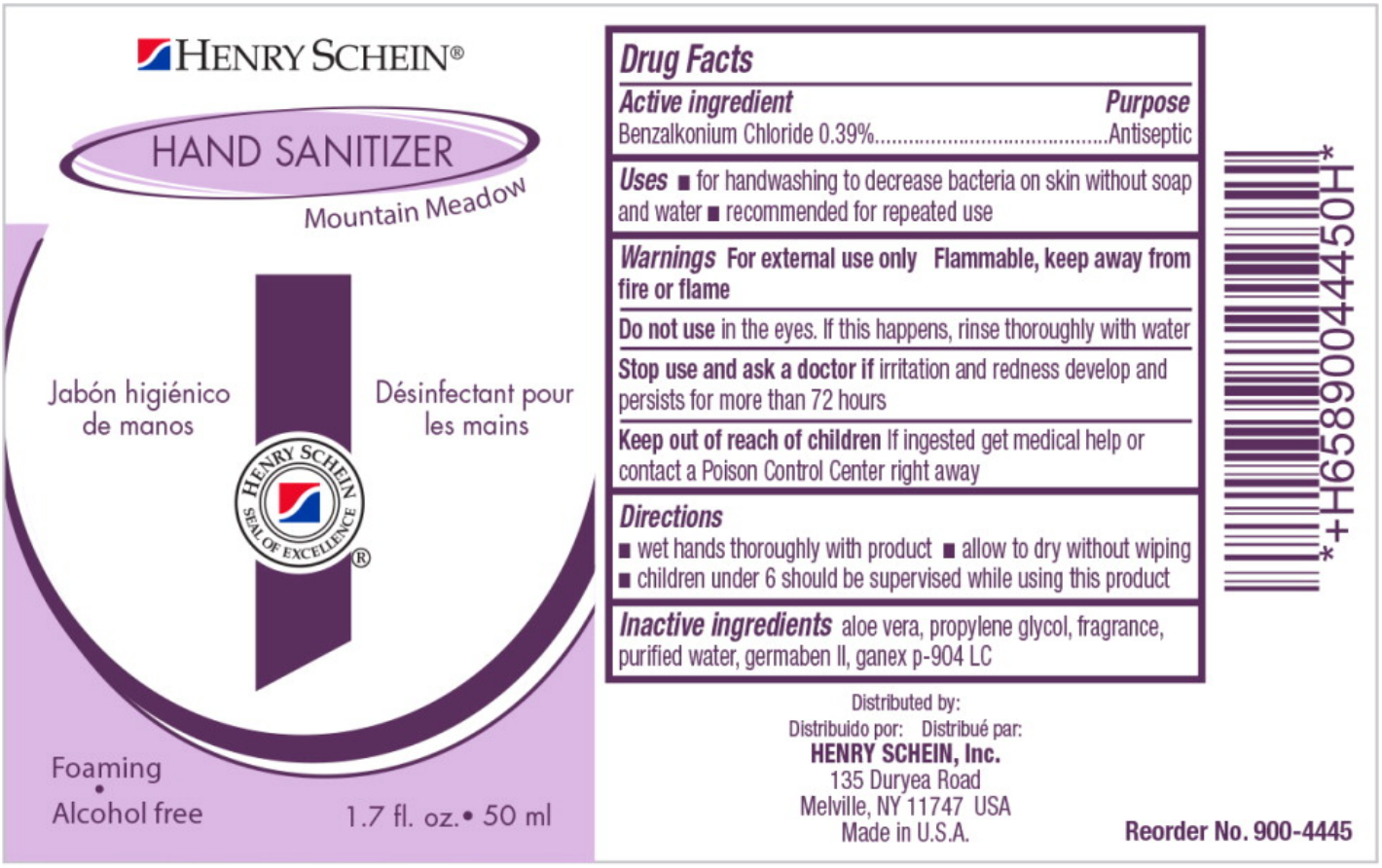
Jabón higiénico
de manos

Désinfectant pour
les mains

Foaming

Alcohol Free

1.7 fl. oz. (50 ml)



HAND SANITIZER

benzalkonium chloride liquid

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:0404-4445
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety		
Ingredient Name	**Basis of Strength**	**Strength**

benzalkonium chloride (UNII: F5UM2KM3W7) (benzalkonium - UNII:7N6JUD5X6Y)	benzalkonium chloride	7.49 g in 1 L

Inactive Ingredients

Ingredient Name	Strength
water (UNII: 059QF0KO0R)	
aloe vera leaf (UNII: ZY81Z83H0X)	
propylene glycol (UNII: 6DC9Q167V3)	
diazolidinyl urea (UNII: H5RIZ3MPW4)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:0404-4445-01	0.05 L in 1 BOTTLE, PUMP; Type 0: Not a Combination Product		
2	NDC:0404-4445-02	0.55 L in 1 BOTTLE, PUMP; 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	01/30/2013	

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.