ANTIBACTERIAL- chloroxylenol 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

Chloroxylenol (PCMX) 0.6%

Purpose

Antiseptic

Uses

For handwashing to decrease bacteria on skin. Recommended for repeated use.

Warnings

For external use only.

When using this product

- supervise children under 6
- do not use in the eyes. If contact occurs, rinse thoroughly with water.

Stop use and ask doctor if irritation or redness develop and persist 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

Wet hands and forearms. Apply 5 milliliters (teaspoonful) or palmful to hands and forearms. Scrub thoroughly for 30 seconds. Rinse and repeat.

Inactive ingredients

aloe vera, cocamide DEA, cocamidopropyl betaine, fragrance, germaben II, propylene glycol, purified water, sodium chloride, sodium laureth sulfate, tetrasodium EDTA, vitamin E acetate

PRINCIPAL DISPLAY PANEL – 550 mL (18.6 fl. oz.) bottle

Henry Schein

Antibacterial

HAND SOAP

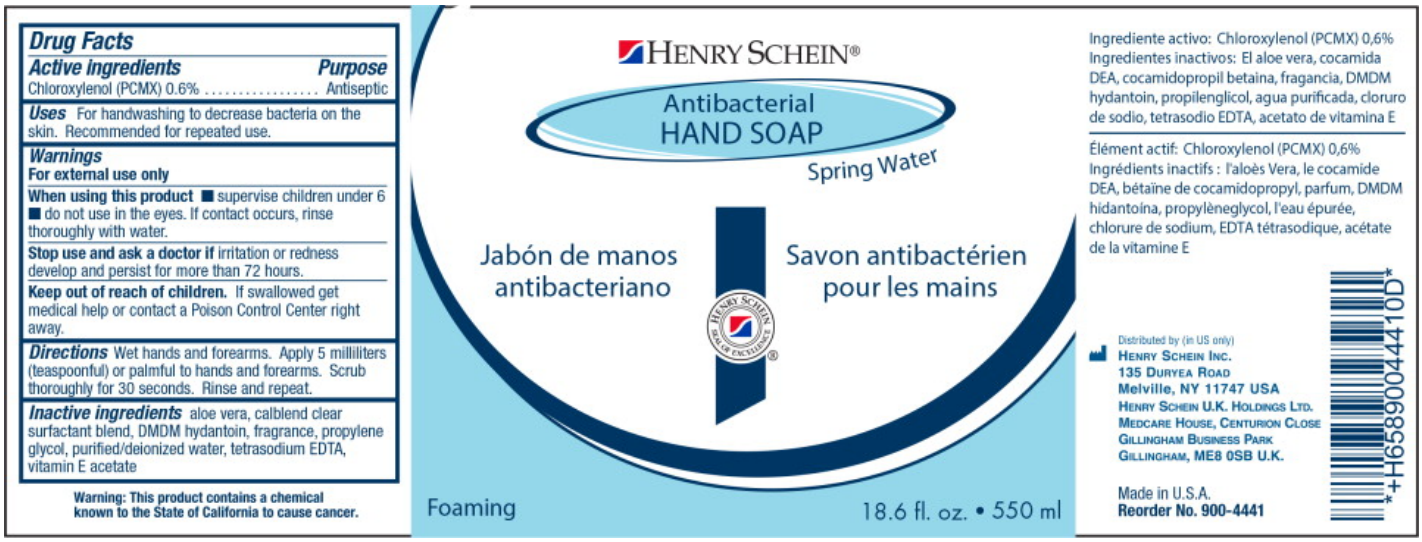
Spring Water

Jabón de manos
antibacteriano

Savon antibactérien
pour les mains

Foaming

18.6 fl. oz. • 550 ml



ANTIBACTERIAL

chloroxylenol liquid

Product Information

Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:0404-4441
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
chloroxylenol (UNII: 0F32U78V2Q) (chloroxylenol - UNII:0F32U78V2Q)	chloroxylenol	6.046 g in 1 L

Inactive Ingredients

Ingredient Name	Strength
aloe vera leaf (UNII: ZY81Z83H0X)	
coco diethanolamide (UNII: 92005F972D)	
cocamidopropyl betaine (UNII: 5OCF3O11KX)	
propylene glycol (UNII: 6DC9Q167V3)	
water (UNII: 059QF0KO0R)	
edetate sodium (UNII: MP1J8420LU)	
.alpha.-tocopherol acetate (UNII: 9E8X80D2L0)	
DMDM Hydantoin (UNII: BYR0546TOW)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:0404-4441-01	0.55 L in 1 BOTTLE; 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	part333A	01/31/2013	

Labeler - Henry Schein, Inc. (012430880)

Registrant - Safetec of America, Inc. (874965262)

Establishment

Name	Address	ID/FEI	Business Operations
Safetec of America, Inc.		874965262	MANUFACTURE(0404-4441)

Revised: 3/2016 Henry Schein, Inc.