SPRING GROVE UNSCENTED HAND SANITIZER- spring grove unscented hand sanitizer solution Saalfeld Paper

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.

Spring Grove Unscented Hand Sanitizer

Ethyl Alcohol 62% v/v......Antibacterial Agent

Water, Glycerin, Propylene Glycol, Isopropyl Myristate, Aloe Barbadensis Leaf, Tocopheryl Acetate (Vitamin E), Carbomer, Aminomethyl Propanol.

For hand cleaning to decrease bacteria on skin.

For external use only.

Flammable. Keep away from heat or flame.

Do not use in the eyes. In case of contact, rinse thoroughly.

Stop and ask a doctor if irritation and redness appears and lasts.

Keep out of reach of children. If swallowed, contact a physician or poison center.

To decrease bacteria on skin, apply a small amount to palm. Briskly rub, covering hands with product until dry. Children should be supervised when using this product.

For hand cleaning to decrease bacteria on skin.

Do not use in the eyes. In case of contact, rinse thoroughly.

Stop and ask a doctor if irritation and redness appears and lasts.

Keep out of reach of children. If swallowed, contact a physician or poison center.

Keep out of reach of children. If swallowed, contact a physician or poision center.

LA782R



BACK LABEL typically prints on white stock

spring grove unscented hand sanitizer solution

Product Information

Product Type HUMAN OTC DRUG Item Code (Source) NDC:61827-056

Route of Administration TOPICAL

Active Ingredient/Active Moiety

Ingredient Name		Basis of Strength	Strength
	ALCOHOL (UNII: 3K9958V90M) (ALCOHOL - UNII:3K9958V90M)	ALCOHOL	62.5 mL in 100 mL

Inactive Ingredients			
Ingredient Name	Strength		
POLYACRYLIC ACID (250000 MW) (UNII: 9G2MAD7J6W)			
WATER (UNII: 059QF0KO0R)			
GLYCERIN (UNII: PDC6 A3C0 OX)			
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)			
ISOPROPYL MYRISTATE (UNII: 0 RE8K4LNJS)			
AMINOMETHYLPROPANOL (UNII: LU49E6626Q)			
ALOE VERA LEAF (UNII: ZY8 1Z8 3H0 X)			
ALPHA-TOCOPHEROL ACETATE (UNII: 9E8X80D2L0)			

Packaging

1				
	# Item Code	Package Description	Marketing Start Date	Marketing End Date
	1 NDC:61827-056-08	237 mL in 1 BOTTLE, PUMP		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part333A	11/05/2013	

Labeler - Saalfeld Paper (803116487)

Establishment				
Name	Address	ID/FEI	Business Operations	
Kutol Products Company, Inc.		004236139	manufacture(61827-056), analysis(61827-056), pack(61827-056)	

Revised: 1/2014 Saalfeld Paper