

SCHUTZ WELLNESS HAND SANITIZER- alcohol gel
Rose Girl S.A De C.V

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.

Schutz Wellness Hand Sanitizer

Drug Facts

Active Ingredient

Ethyl Alcohol 70%

Purpose

Antiseptic

Use[s]

Hand sanitizer to help reduce bacteria that potentially can cause disease. For use when soap and water are not available.

Warnings

For external use only. Flammable. Keep away from heat or flame

Do not use

- in children less than 2 months of age
- on open skin wounds

When using this product

keep out of eyes, ears and mouth. In case of contact with eye, rinse eyes thoroughly with water.

Stop use and ask a doctor

if irritation or rash occurs. These may be signs of a serious condition.

Keep out of reach of children.

If swallowed, get medical help or contact a Poison Control Center right away.

Directions

- Place enough product on hands to cover all surfaces. Rub hands together until dry.
- Supervise children under 6 years of age when using this product to avoid swallowing.

Other Information

- Store between 15-30C (59-86)
- Avoid freezing and excessive heat above 40C (104F)

Inactive Ingredients

glycerin, water USP, carbomer, TEA.

Package Labeling:

HAND SANITIZER

KILLS 99% OF GERMS

ORIGINAL SCENT



0 052089 144137



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Components
Ethyl alcohol ——— 2.66 lts. Glycerin ——— 15.8 ml.
TEA ——— 2.2 ml. Water ——— 960 ml.
Carbomer ——— 11 gr.

128 FL OZ (3,785 ml)

DISTRIBUTED USA BY PMC DISTRIBUTION
TEL: 520-891-4413 MADE IN MEXICO
3001 E COPPER ST, TUCSON, AZ 85716

SCHUTZ WELLNESS HAND SANITIZER			
alcohol gel			
Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:79207-001
Route of Administration	TOPICAL		
Active Ingredient/Active Moiety			
Ingredient Name	Basis of Strength	Strength	
ALCOHOL (UNII: 3K9958V90M) (ALCOHOL - UNII:3K9958V90M)	ALCOHOL	0.7 mL in 1 mL	
Inactive Ingredients			

Ingredient Name	Strength
TEA LEAF (UNII: GH42T47V24)	
CARBOMER HOMO POLYMER, UNSPECIFIED TYPE (UNII: 0A5MM307FC)	
GLYCERIN (UNII: PDC6A3C0OX)	
WATER (UNII: 059QF0KO0R)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:79207-001-01	3785 mL in 1 BOTTLE; Type 0: Not a Combination Product	07/20/2020	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part333E	07/20/2020	

Labeler - Rose Girl S.A De C.V (951579303)

Revised: 7/2020

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