

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[s]

Ethyl alcohol 75% v/v

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 eyes, rinse eyes thorough 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 (59-86F)

Avoid freezing and excessive heat above 40C (104F)

Inactive ingredients

Glycerin, purified water, carbomer, triethanolamine.

Package Labeling

Drug Facts	
Active ingredient(s) Ethyl Alcohol 70% v/v	Purpose(s) 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 or on open skin wounds.	
When using this product keep out of eyes, ears, and mouth. In case of contact with eyes, 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 eye contact.	
Other Information Store between 15-30°C (59-86°F) Avoid freezing and excessive heat above 40°C (104°F)	
Inactive ingredients Glycerin, purified water, carbomer, triethanolamine.	

Schutz Wellness

HAND SANTIZER

**Kills
99.9%
of bacteria**

Ethyl Alcohol 70% GL

**Topical Solution
16.9 fl Oz/500 ml**

www.schutzwellness.com

Manufactured by
Rose Girl S.A. de C.V.
San Jose Del Real 23B
Lomas Verdes Quinta Seccion
Naucalpan Estado de Mexico
Code 52126
RG 1885021F3
Made in Mexico



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SCHUTZ WELLNESS HAND SANITIZER

alcohol gel

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:79207-000
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
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ALCOHOL (UNII: 3K9958V90M) (ALCOHOL - UNII:3K9958V90M)	ALCOHOL	0.75 mL in 1 mL
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Inactive Ingredients

Ingredient Name	Strength
GLYCERIN (UNII: PDC6A3C0OX)	
WATER (UNII: 059QF0K00R)	
CARBOMER HOMO POLYMER, UNSPECIFIED TYPE (UNII: 0A5MM307FC)	
TROLAMINE (UNII: 9O3K93S3TK)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:79207-000-01	500 mL in 1 BOTTLE; Type 0: Not a Combination Product	07/15/2020	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part333E	07/15/2020	

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

Revised: 8/2020

Rose Girl, S.A. de C.V.