

HAND SANITIZER- alcohol gel
SOFi Paper Products LLC

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.

Hand Sanitizer

Drug Facts

Active Ingredient

Ethyl alcohol 70%

Purpose

Antiseptic

Use

- Hand sanitizer to help reduce bacteria on the skin

Warnings

Flammable, Keep away from fire or flame.

For external use only

When using this product

do not use in or near the eyes. In case of contact, rinse eyes thoroughly with water.

Stop use and ask a doctor

if irritation or rash appears and lasts.

Keep out of reach of children.

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

Directions

- Put enough product in your palm to cover hands and rub hands together briskly until dry.
- Children under 6 years of age should be supervised when using.

Other Information

- Store below 110°F (43°C)
- May discolor certain fabrics or surfaces

Inactive Ingredients:

Water, Triethanolamine, Carbopol, Tween 20, Glycerin, Aloe

Package Labeling:78227-000-01

Drug Facts

Active Ingredient	Purpose
Ethyl alcohol 70%	Antiseptic

Use - Hand sanitizer to help reduce bacteria on skin

Warnings

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Inactive Ingredients: Water, Triethanolamine, Carbopol, Tween 20, Glycerin, Aloe

MANUFACTURED IN USA
DIST. BY SOFI PAPER PRODUCTS LLC
MIAMI, FL 33177.
SUPPORT@SOFIPAPERPRODUCTS.COM

HAND SANITIZER



KILLS **99.99%** OF MOST
ILLNESS CAUSING GERMS

70% ALCOHOL



WITH MOISTURIZING
ALOE VERA

8 fl. oz (236 ml)

This fast-drying, antiseptic hand sanitizer kills 99.99% of most germs and bacteria. With natural glycerin and aloe vera, our fragrance free gel formula leave skin feeling soft and smooth.



Package Labeling:78227-000-02

HAND SANITIZER

KILLS **99.99%** OF MOST
ILLNESS CAUSING GERMS

70% ALCOHOL



WITH MOISTURIZING
ALOE VERA

8.45 fl oz (250 ml)

Drug Facts

Active Ingredient

Ethyl alcohol 70%

Purpose

Antiseptic

Use • Hand sanitizer to help reduce bacteria on skin

Warnings

Flammable. Keep away from fire or flame.

For external use only

When using this product do not use in or near the eyes. In case of contact, rinse eyes thoroughly with water.

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MIAMI, FL, 33177

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Package Labeling:78227-000-03

Drug Facts

Active Ingredient	Purpose
Ethyl alcohol 70%	Antiseptic
Use - Hand sanitizer to help reduce bacteria on skin	
Warnings	
Flammable. Keep away from fire or flame.	
For external use only	
When using this product do not use in or near the eyes. In case of contact, rinse eyes thoroughly with water.	
Stop use and ask a doctor if irritation or rash appears and lasts	
Keep out of reach of children. If swallowed, get medical help or contact a Poison Control Center right away.	
Directions - Put enough product in your palm to cover hands and rub hands together briskly until dry. - Children under 6 years of age should be supervised when using	
Other information - Store below 110°F (43°C) - May discolor certain fabrics or surfaces	
Inactive ingredients: Water, Triethanolamine, Carbopol, Tween 20, Glycerin, Aloe	

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HAND SANITIZER



KILLS **99.99%** OF MOST
ILLNESS CAUSING GERMS

70% ALCOHOL



WITH MOISTURIZING
ALOE VERA

1 gallon (3785 ml)

This fast-drying, antiseptic hand sanitizer kills 99.99% of most germs and bacteria. With natural glycerin and aloe vera, our fragrance free gel formula leave skin feeling soft and smooth.



HAND SANITIZER

alcohol gel

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:78227-000
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
WATER (UNII: 059QF0KO0R)	
TROLAMINE (UNII: 9O3K93S3TK)	
CARBOMER HOMO POLYMER, UNSPECIFIED TYPE (UNII: 0A5MM307FC)	
POLYSORBATE 20 (UNII: 7T1F30V5YH)	
GLYCERIN (UNII: PDC6A3C0OX)	
ALOE (UNII: V5VD430YW9)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:78227-000-01	236 mL in 1 BOTTLE; Type 0: Not a Combination Product	05/25/2020	
2	NDC:78227-000-02	250 mL in 1 BOTTLE; Type 0: Not a Combination Product	05/25/2020	
3	NDC:78227-000-03	3785 mL in 1 BOTTLE; Type 0: Not a Combination Product	06/01/2020	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part333E	05/25/2020	

Labeler - SOFi Paper Products LLC (117491636)

Revised: 6/2020

SOFi Paper Products LLC