

PURE SOURCE HAND SANITIZER- alcohol gel

Pure Source, 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.

PURE SOURCE Hand Sanitizer

Drug Facts

Active ingredient

Ethyl Alcohol 70% v/v

Purpose

Antiseptic

Uses

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 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 (59-86F)
- Avoid freezing and excessive heat above 40°C (104°F)

Inactive ingredients

Acrylates/C10-30 Alkyl Acrylate Crosspolymer, Aloe Barbadensis Leaf (Aloe Vera Gel) Juice, Aminomethylpropanediol, Aqua (Deionized Water), Ethylhexylglycerin, Glycerin, Phenoxyethanol, Polysorbate-20

Questions? (866) 565-575

□ **Package Labeling: 8 oz (65121-069-08)**



The label features a light blue background with a darker blue horizontal band across the middle. At the top center is a circular logo with a yellow sun, blue waves, and a white anchor. Below the logo, the text 'PURE SOURCE' is written in a bold, blue, sans-serif font. The words 'Hand Sanitizer' are written in a large, blue, cursive font with white outlines and small white stars. A dark blue button with the text 'REFRESHING GEL' is positioned below the main title. In the bottom left corner, there is a 'made in USA' logo with a star and stripes, followed by the manufacturer's name and contact information. The bottom right corner contains a 'Drug Facts' table. The background of the label has a pattern of light blue circles.

PURE SOURCE

Hand Sanitizer

REFRESHING GEL

8 fl. oz (237ml)

made in USA

Manufactured By:
Pure Source, LLC
9750 NW 17th Street, Miami, FL 33172
Phone: (305) 477-8111
Email: info@thepuresource.com
www.thepuresource.com

Drug Facts	
Active ingredient	Purpose
Ethyl Alcohol 70% v/v.....	Antiseptic
Uses 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 <ul style="list-style-type: none">■ 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 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: <ul style="list-style-type: none">■ 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: <ul style="list-style-type: none">■ Store between 15-30C (59-86F)■ Avoid freezing and excessive heat above 40°C (104°F)	
Inactive ingredients: Acrylates/C10-30 Alkyl Acrylate Crosspolymer, Aloe Barbadensis Leaf (Aloe Vera Gel) Juice, Aminomethylpropanediol, Aqua (Deionized Water), Ethylhexylglycerin, Glycerin, Phenoxyethanol, Polysorbate-20	
Questions? (866) 565-5750	

Package Labeling: 4 oz (65121-069-04)



PURE SOURCE

Hand Sanitizer



Manufactured By:
Pure Source, LLC

9750 NW 17th Street, Miami, FL 33172

Phone: (305) 477-8111

Email: info@thepuresource.com

www.thepuresource.com

REFRESHING GEL

4 fl. oz (118ml)

Drug Facts

Active ingredient	Purpose
Ethyl Alcohol 70% v/v.....	Antiseptic

Uses
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 thoroughly with water.

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Inactive ingredients: Acrylates/C10-30 Alkyl Acrylate Crosspolymer, Aloe Barbadensis Leaf (Aloe Vera Gel) Juice, Aminomethylpropanediol, Aqua (Deionized Water), Ethylhexylglycerin, Glycerin, Phenoxyethanol, Polysorbate-20

Questions? (866) 565-5750

PURE SOURCE HAND SANITIZER

alcohol gel

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:65121-069
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
CARBOMER INTERPOLYMER TYPE A (ALLYL SUCROSE CROSSLINKED) (UNII: 59TL3WG5CO)	
ALOE VERA LEAF (UNII: ZY81Z83H0X)	
AMINOMETHYLPROPANEDIOL (UNII: CZ7BU4QZJZ)	

WATER (UNII: 059QF0KO0R)	
ETHYLHEXYLGLYCERIN (UNII: 147D247K3P)	
GLYCERIN (UNII: PDC6A3C0OX)	
PHENOXYETHANOL (UNII: HIE492ZZ3T)	
POLYSORBATE 20 (UNII: 7T1F30V5YH)	

Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:65121-069-08	237 mL in 1 CYLINDER; Type 0: Not a Combination Product	04/20/2020	
2	NDC:65121-069-04	118 mL in 1 CYLINDER; Type 0: Not a Combination Product	04/20/2020	

Marketing Information			
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part333E	04/20/2020	

Labeler - Pure Source, LLC (080354456)