

**HAND SANITIZER- gel hand sanitizer 70% v/v gel
Solugen Blending, 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.

Gel Hand Sanitizer 70%

This is a hand sanitizer manufactured according to the Temporary Policy for Preparation of Certain Alcohol-Based Hand Sanitizer Products During the Public Health Emergency (CoViD-19); Guidance for Industry.

The hand sanitizer is manufactured using only the following United States Pharmacopoeia (USP) grade ingredients in the preparation of the product (percentage in final product formulation) consistent with World Health Organization (WHO) recommendations:

- a. Alcohol (ethanol) (USP or Food Chemical Codex (FCC) grade) (70%, volume/volume (v/v)) in an aqueous solution denatured according to Alcohol and Tobacco Tax and Trade Bureau regulations in 27 CFR part 20.
- b. Carbomer (0.4% v/v).
- c. Triethanolamine (0.2% v/v).
- d. Sterile distilled water or boiled cold water.

The firm does not add other active or inactive ingredients. Different or additional ingredients may impact the quality and potency of the product.

Active Ingredient(s)

Alcohol 70% v/v. Purpose: Antiseptic

Purpose

Antiseptic, Hand Sanitizer

Use

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.

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

carbomer, triethanolamine, purified water USP

Package Label - Principal Display Panel

1249 L NDC: 79975-010-02



LOT#: _____

NDC#: _____

Gel Hand Sanitizer

Alcohol Antiseptic 70% Topical Solution

**Hand Sanitizer
Non-sterile Solution**



Drug Facts	
Active ingredient[s] Alcohol 70% 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 <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 at 1-800-222-1222.	
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 40C (104F)	
Inactive ingredients carbomer, triethanolamine, purified water USP	

Made in USA

Before handling this material, read accompanied Safety Data Sheet for more detailed safety, health, and environmental data.

Net Weight:

DOT info: UN1170, Ethanol Solution, 3, PGI

Solugen Blending, LLC
14549 Minetta St., Houston, TX 77035
PHONE: (713) 380-2134

208 L NDC: 79975-010-03



LOT#: _____

NDC#: _____

Gel Hand Sanitizer

Alcohol Antiseptic 70% Topical Solution

**Hand Sanitizer
Non-sterile Solution**



Drug Facts	
Active ingredient(s) Alcohol 70% (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	
<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 at 1-800-222-1222.	
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 40C (104F) 	
Inactive ingredients carbomer, triethanolamine, purified water USP	

Made in USA

Before handling this material, read accompanied Safety Data Sheet for more detailed safety, health, and environmental data.

Net Weight:

DOT info: UN1170, Ethanol Solution, 3, PGII

Solugen Blending, LLC
14549 Minetta St., Houston, TX 77035
PHONE: (713) 380-2134

19 L NDC: 79975-010-04



LOT#: _____

NDC#: _____

Gel Hand Sanitizer

Alcohol Antiseptic 70% Topical Solution

**Hand Sanitizer
Non-sterile Solution**



Drug Facts	
Active Ingredient(s) Alcohol 70% (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	
<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 at 1-800-222-1222.	
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 40C (104F) 	
Inactive ingredients carbomer, triethanolamine, purified water USP	

Made in USA

Before handling this material, read accompanied Safety Data Sheet for more detailed safety, health, and environmental data.

Net Weight:

DOT info: UN1170, Ethanol Solution, 3, PGI

Solugen Blending, LLC
14549 Minetta St., Houston, TX 77035
PHONE: (713) 380-2134

3.78 L NDC: 79975-010-09



solugen 14549 Minetta St. Houston, TX 77035
Phone: 713.380.2134

Gel Hand Sanitizer (Sample not for Resale)

Alcohol Antiseptic 70% Topical Gel Hand Sanitizer Non-sterile Solution

128 Fluid Oz. (3785.41 ml)

Lot#: _____

NDC#: _____

Made in USA

Before handling this material, read accompanied Safety Data Sheet for more detailed safety, health, and environmental data.

Drug Facts	
Active ingredient(s) Alcohol 70% v/v	Purpose Antiseptic
Use(s) Use alcohol sanitizer to help reduce bacteria and viruses that cause disease. To use when you are sick or you are around someone who is sick.	
Warnings For external use only. Flammable. Keep away from heat or flame.	
DO NOT USE In children less than 2 months of age. Do not get in your eyes.	
Directions When using the product, take care of your eyes, ears, and mouth. In case of contact with eyes, use clean water to flush out soap. Wash hands with water and soap for 20 seconds. Avoid touching your face. Wash out of reach of children. If swallowed, get medical help or call a poison control center right away.	
Other information Store between 15-30C (59-86F). Avoid freezing and excessive heat above 40C (104F). Inactive ingredients: carbomer, triethanolamine, purified water.	

HAND SANITIZER

gel hand sanitizer 70% v/v gel

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:79975-010
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
ALCOHOL (UNII: 3K9958V90M) (ALCOHOL - UNII:3K9958V90M)	ALCOHOL	70 mL in 100 mL

Inactive Ingredients

Ingredient Name	Strength
TROLAMINE (UNII: 9O3K93S3TK)	0.2 mL in 100 mL
POLYACRYLIC ACID (450000 MW) (UNII: KD3S7H73D3)	0.4 mL in 100 mL
WATER (UNII: 059QF0K00R)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:79975-010-02	1249 186 mL in 1 CONTAINER; Type 0: Not a Combination Product	10/12/2020	
2	NDC:79975-010-03	208 197 mL in 1 CONTAINER; Type 0: Not a Combination Product	10/12/2020	
3	NDC:79975-010-04	189 27 mL in 1 CONTAINER; Type 0: Not a Combination Product	10/12/2020	
4	NDC:79975-010-09	378 5 mL in 1 CONTAINER; Type 0: Not a Combination Product	10/12/2020	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part333A	10/12/2020	

Labeler - Solugen Blending, LLC (117590261)

Establishment

Name	Address	ID/FEI	Business Operations
Solugen Blending - Minnetta		117590261	manufacture(79975-010)

Establishment

Name	Address	ID/FEI	Business Operations
Solugen Blending - Slaton		117605218	manufacture(79975-010)

Revised: 10/2020

Solugen Blending, LLC