

GEL HAND SANITIZER- gel hand sanitizer 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

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. Glycerol (0.5% v/v).
- c. Carbomer (0.37% 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

glycerin, hydrogen peroxide, purified water USP

Package Label - Principal Display Panel

236mL NDC:79975-012-08



3785mL NDC: 79975-012-05



145 49 Minetta St. Houston, TX 77035
 Phone: 713.380.2134

Gel Hand Sanitizer (Sample)

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)	Purpose
Alcohol 70%v/v	Antiseptic
Use(s)	
Hand sanitizer to help reduce bacteria virus assembly, to reduce disease transmission and reduce and neutralize.	
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 doctor if irritation or redness occurs. If more than 2 weeks of symptoms persist.	
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. Use only 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 expose to heat above 40C (104F) 	
Inactive ingredients carboxymethylcellulose, methylparaben, water, glycerin	

18927 mL NDC: 79975-012-04



LOT#: _____

NDC#: _____

Gel Hand Sanitizer

Alcohol Antiseptic 70% Topical Solution

**Hand Sanitizer
Non-sterile Solution**

Drug Facts	
Active ingredient(s)	Purpose
Alcohol 70%w/v	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 thoroughly with water.	
Stop use and ask a doctor if irritation or rash occurs. There 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, water, glycerin	



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

Net Content:

DOT info: UN1170, Ethanol Solution, 3, PGII

14549 Minetta St., Houston, TX 77035

PHONE: (713) 380-2134

208197 mL NDC: 79975-012-03



LOT#: _____

NDC#: _____

Gel Hand Sanitizer

Alcohol Antiseptic 70% Topical Solution

**Hand Sanitizer
Non-sterile Solution**

Drug Facts

Active ingredient(s)	Purpose
Alcohol 70%w/v	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 thoroughly with water.	
Stop use and ask a doctor if irritation or rash occurs. There 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, water, glycerin	



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

Net Content:

DOT info: UN1170, Ethanol Solution, 3, PGII

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

1249186 mL NDC: 79975-012-02



LOT#: _____

NDC#: _____

Gel Hand Sanitizer

Alcohol Antiseptic 70% Topical Solution

**Hand Sanitizer
Non-sterile Solution**

Drug Facts	
Active ingredient(s)	Purpose
Alcohol 70%w/v	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 thoroughly with water.	
Stop use and ask a doctor if irritation or rash occurs. There 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, water, glycerin	



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

Net Content:
DOT info: UN1170, Ethanol Solution, 3, PGII

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

GEL HAND SANITIZER

gel hand sanitizer gel

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:79975-012
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
ALCOHOL (UNII: 3K9958 V90M) (ALCOHOL - UNII:3K9958 V90M)	ALCOHOL	70 mL in 100 mL

Inactive Ingredients

Ingredient Name	Strength
GLYCERIN (UNII: PDC6A3C0OX)	0.5 mL in 100 mL
CARBOMER COPOLYMER TYPE C (ALLYL PENTAERYTHRITOL CROSSLINKED) (UNII: 1N11AG4X4L)	0.37 mL in 100 mL
WATER (UNII: 059QF0KO0R)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:79975-012-02	1249186 mL in 1 CONTAINER; Type 0: Not a Combination Product	10/20/2020	
2	NDC:79975-012-03	208197 mL in 1 DRUM; Type 0: Not a Combination Product	10/20/2020	
3	NDC:79975-012-04	18927 mL in 1 PAIL; Type 0: Not a Combination Product	10/20/2020	
4	NDC:79975-012-05	3785 mL in 1 JUG; Type 0: Not a Combination Product	10/20/2020	
5	NDC:79975-012-08	236 mL in 1 BOTTLE; Type 0: Not a Combination Product	11/12/2020	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part333A	10/20/2020	

Labeler - Solugen Blending, LLC (117590261)

Establishment

Name	Address	ID/FEI	Business Operations
Minetta		117590261	manufacture(79975-012)

Establishment

Name	Address	ID/FEI	Business Operations
Slaton		117605218	manufacture(79975-012)

Revised: 11/2020

Solugen Blending, LLC