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





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)

.ot#:	
NDC#:	

Made in USA Before handling this material, read accompanied Safety DataSheet for more detailed safety, health, and environmental data.

rug Facts	0.01
ctive ingredient[s]	Purpose
conol T08v/v	antise ptic
se(s)	24
nd Samilier no field reduce Galeeria (fax) potentially cancalate discuse. For lateration source and water are not available.	
arnina s	
remernal use only. Filam mapile, Kee plaway from heat or filame	
anotuse .	
In on littiren less than 2 months of age	
on open at In wounds	
nen using this product tree our of eyes, exis, and mourh, in ease of Conract with eyes, vinseleyes the roughly with water.	
op useand ask a doctor Fireius is not usshoot us. Firetr may be signs of a serious condition.	
ap out of mich of dalldram. If swallowed, get medical field or contact a Pobon Control Control (gft) away.	
lrections .	
Place enough production hands to cover all surfaces. Rup hands together until dry.	
Supervise children under 6 years of age when using this product to avoid awallowing.	
ther Information	
\$10 @ perween 15-30C \$5966FI	
Avoid freezing and excessive near above 40C [104F]	
active ingredients carbonier, trietnanolamine, water, glycerin	



LOT#:	
NDC#+	

Gel Hand Sanitizer

Alcohol Antiseptic 70% Topical Solution

Hand Sanitizer
Non-sterile Solution

<u>Drug Facts</u>	
Active ingredient[s]	Purpo:
Active ingredient[s]	i ui po
Alcohol 70%/v	.Antisept
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 graduct 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 rach 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 nandling this material, read accompanied 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



LOT#:	
NDC#+	

Gel Hand Sanitizer

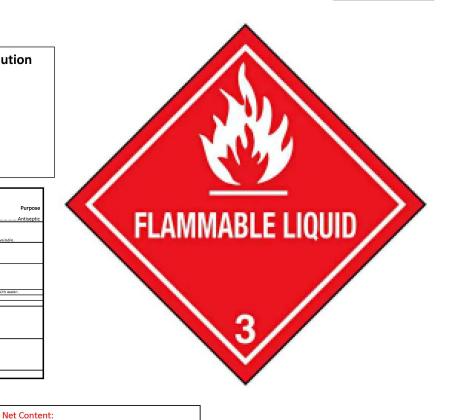
Alcohol Antiseptic 70% Topical Solution

Hand Sanitizer
Non-sterile Solution

<u>Drug Facts</u>	
Active ingredient[s]	urpose
Alcohol 70%/vAni	tiseptic
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 one skin wounds	
On open skin wounds When using this groduct 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 rach 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 nandling this material, read accompanied Safety Data Sheet for more detailed safety, health, and environmental data.

DOT info: UN1170, Ethanol Solution, 3, PGII



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



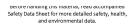
LOT#:		_
NDC#+		

Gel Hand Sanitizer

Alcohol Antiseptic 70% Topical Solution

Hand Sanitizer
Non-sterile Solution

<u>Drug Facts</u>
Active ingredient[s] Purpose
Alcohol 70%/v
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. These may be signs of a serious condition.
Keep out of rach 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





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

Net Content:

DOT info: UN1170, Ethanol Solution, 3, PGII

GEL HAND SANITIZER

gel hand sanitizer gel

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:79975-012
5 1		` ,	

Route of Administration TOPICAL

Active Ingredient/Active Moiety

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

Strength
0.5 mL in 100 mL
0.37 mL in 100 mL

Packaging					
#	Item Code	Package Description	Marketing Start Date	Marketing End Date	
1	NDC:79975-012- 02	1249 186 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