GEL HAND SANITIZER WITH SIGNATURE SCENT- gel hand sanitizer with signature scent 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 with Signature Scent

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. Fragrance (0.3% v/v)
- e. 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)

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.

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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, Carbomer, Fragrance, purified water USP

Package Label - Principal Display Panel

236mL NDC: 79975-013-08



1249186 mL NDC: 79975-013-05



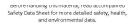
LOT#:		
NDC#:		

Gel Hand Sanitizer with Signature Scent

Alcohol Antiseptic 70% Topical Solution

Hand Sanitizer
Non-sterile Solution

<u>Drug Facts</u>	
Active ingredient[s]	Purpose
Alcohol 70%v/v	Antiseptio
Use[s]	
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Other Information	
- Stare between 15-30C (59-86F)	
Avoid freezing and excessive heat above 40C (104F)	
Inactive ingredients carbomer, triethanglamine, water, glycerin	



Net Content:

DOT info: UN1170, Ethanol Solution, 3, PGII



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

208197 mL NDC: 79975-013-04



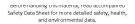
LOT#:	
NDC#·	

Gel Hand Sanitizer with Signature Scent

Alcohol Antiseptic 70% Topical Solution

Hand Sanitizer
Non-sterile Solution

<u>Drug Facts</u>	
Active ingredient[s]	Purpose
Alcohol 70%v/v	Antiseptic
Use[s]	
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Directions	
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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	



Net Content:

DOT info: UN1170, Ethanol Solution, 3, PGII



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

18927 mL NDC: 79975-013-05



14549 MinettaSt. Houston, TX 77035 Phone: 713 380.2134

Gel Hand Sanitizer with Signature Scent

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



128 Fluid Oz. (3785.41 ml)

Lot#:	
NDC#:	
W	

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] slooks170Ne(v) A	Purpose ntiseptic
Use[5] the Samuer to tell reduce between that exercise care cause disease. For the whoir source and varior are not available.	
Warning 5 Resident use only. Remmable. Neep away from heat or fame	
Conctuse - in children less then 2 months ofege - on open skin wounds	
When using this product focus out of cycs, care, and mouth. In case of Contact with cycs, wise cycs choosing by with various.	
Step use and lask address of invalues, or local decirity. Here may be signs of a schools condition.	
Responsible and children. If swallboad, got would all hole or concept after a Concel Concer high away.	
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Other Information Sare beven 15-70: 19-968 - Hold Trading and existive has hove 40: 11949	
Inactive ingred is not component triggered with water about in terrors	

GEL HAND SANITIZER WITH SIGNATURE SCENT

gel hand sanitizer with signature scent gel

Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:79975-013
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)	0.125 mL in 100 mL
WATER (UNII: 059QF0KO0R)	

Product Characteristics				
Color	white (Colorless)	Score		
Shape		Size		
Flavor		Imprint Code		
Contains				

P	Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date	
1	NDC:79975-013-04	18927 mL in 1 PAIL; Type 0: Not a Combination Product	10/20/2020		
2	NDC:79975-013-05	3785 mL in 1 JUG; Type 0: Not a Combination Product	10/20/2020		
		208197 mL in 1 DRUM; Type 0: Not a Combination Product	10/20/2020		
4	NDC:79975-013-02	1249 186 mL in 1 TANK; Type 0: Not a Combination Product	10/20/2020		
5	NDC:79975-013- 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(79975-013)		

Establishment					
Name	Address	ID/FEI	Business Operations		
Slaton		117605218	manufacture(79975-013)		

Revised: 11/2020 Solugen Blending, LLC