

**ADVANCED GEL HAND SANITIZER WITH SIGNATURE SCENT- advanced 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.

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) (80%, 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 (0.5% v/v).
- c. Triethanolamine (0.5% 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 80% 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

Cabomer, triethanolamine, fragrance, purified water USP

Package Label - Principal Display Panel

1249L NDC: 79975-009-02



LOT#: _____
NDC#: 79975-009-02

Advanced Gel Hand Sanitizer with Signature Scent

Alcohol Antiseptic 80% Topical Gel

Hand Sanitizer

Non-sterile Solution

Drug Facts	
Active ingredient(s)	Purpose
Alcohol 80% 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 at 1-800-232-1232.	
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, fragrance, purified water USP	



Made in USA

Before handling this material, read accompanying 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

Drug Facts	
Active ingredient[s] Alcohol 80% 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, fragrance, purified water USP	

ADVANCED GEL HAND SANITIZER WITH SIGNATURE SCENT				
advanced gel hand sanitizer with signature scent gel				
Product Information				
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:79975-009	
Route of Administration	TOPICAL			
Active Ingredient/Active Moiety				
Ingredient Name		Basis of Strength	Strength	
ALCOHOL (UNII: 3K9958V90M) (ALCOHOL - UNII:3K9958V90M)		ALCOHOL	80 L in 100 L	
Inactive Ingredients				
Ingredient Name			Strength	
CARBOMER HOMO POLYMER TYPE A (ALLYL PENTAERYTHRITOL CROSSLINKED) (UNII: F68VH75CJC)			0.5 L in 100 L	
TROLAMINE (UNII: 9O3K93S3TK)			0.5 L in 100 L	
WATER (UNII: 059QF0K00R)			20 L in 100 L	
Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:79975-009-02	1249 L in 1 CONTAINER, FLEXIBLE INTERMEDIATE BULK; Type 0: Not a Combination Product	10/01/2020	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part333A	10/01/2020	

Labeler - Solugen Blending, LLC (117590261)

Establishment

Name	Address	ID/FEI	Business Operations
Minetta		117590261	manufacture(79975-009)

Establishment

Name	Address	ID/FEI	Business Operations
Slaton		117605218	manufacture(79975-009)

Revised: 9/2020

Solugen Blending, LLC