

SIMPLY SAFE HAND SANITIZER- alcohol gel
CMM CAPITAL, 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.

CMM Capital, LLC Simply Safe 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) (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. Water (18.85% v/v).
- c. Glycerin (0.4% v/v).
- d. Hydroxypropyl Cellulose (0.75% v/v).
- e. Hydroxypropyl MethylCellulose (0.75% v/v).

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)

Ethyl 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.

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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, water, hydroxypropyl cellulose, hydroxypropyl methylcellulose

Package Label - Principal Display Panel



118 mL NDC: 79661-001-04

NEW Genesis Enterprises

Simply Safe Hand Sanitizer

80% Alcohol Antiseptic
Moisturizing Gel

Non-sterile Solution

1 Gal. (3.79 L)



DRUG FACTS

Active ingredient(s)
Ethyl Alcohol 80% v/v.....

Use(s)
Hand sanitizer to help reduce
For use when soap and water

Warnings
For external use only. Flamm

Do not use
• On children less than 2 mo
• On open skin wound.

When using this product
In case of contact with eyes,

Stop use and ask a doctor
These may be signs of serio

Keep out of reach of child
help or contact a Poison Cor

Directions
• Place enough product on h
• Rub hands together until d
• Supervise children under 6
using the product to avoid

Other information
• Store between 15—30°C (E
• Avoid freezing and excess

Inactive ingredient(s)
Glycerin, *hydroxypropyl cell
methylcellulose, water (*may

Distributed by New Genesis
3262 W Highway 67 - Clebur
361-701-7699

NEW Genesis Enterprises

Simply Safe Hand Sanitizer

80% Alcohol Antiseptic
Moisturizing Gel

Non-sterile Solution

32 OZ (946 ml)



DRUG

Active
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Use(s)
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NEW Genesis Enterprises

Simply Safe

Hand Sanitizer

80% Alcohol Antiseptic
Moisturizing Gel

Non-sterile Solution

20 OZ (591 ml)



DRUG

Active

Use(s)
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NEW Genesis Enterprises

Simply Safe

Hand Sanitizer

80% Alcohol Antiseptic
Moisturizing Gel

Non-sterile Solution

10 OZ (295 ml)



DRUG FACT

Active Ingredient(s)
Ethyl Alcohol 80% w/v

Use(s)
Hand sanitizer to help
For use when soap is

Warnings
For external use only.

Do not use
• On children less than
• On open skin wounds

When using this product
In case of contact with

Stop use and ask a doctor
These may be signs of

Keep out of reach of children
help or contact a Poison

Directions
• Place enough product
• Rub hands together
• Supervise children using the product

Other information
• Store between 15°C
• Avoid freezing and

Inactive ingredients
Glycerin, hydroxypropyl
methylcellulose, water

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361-701-7999



DRUG FACTS

Active Ingredient(s)
Ethyl Alcohol 80% v/v

Use(s)
Hand sanitizer to help reduce bacteria. For use when soap and water are not available.

Warnings
For external use only. Flammable. Keep away from heat or flame.

Do not use
• On children less than 2 months of age.
• On open skin wound.

When using this product keep out of reach of children. If swallowed, get medical help or contact a Poison Control Center right away.

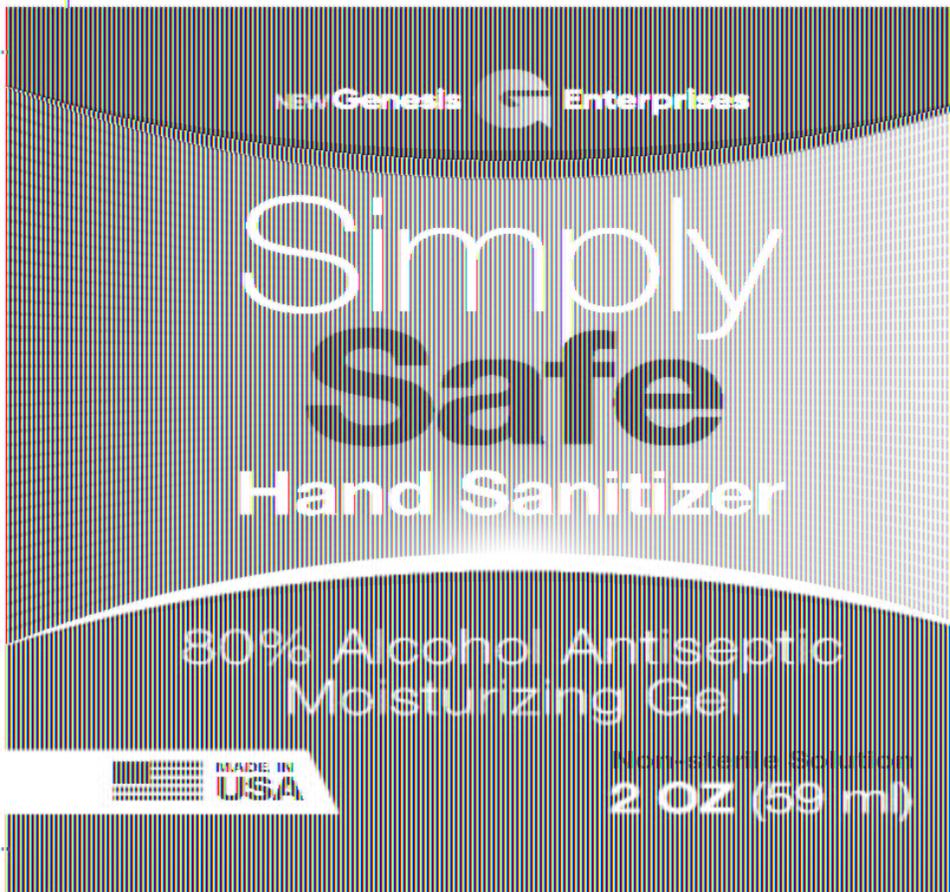
Stop use and ask a doctor if irritation occurs. These may be signs of serious allergic reaction.

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 the product to avoid swallowing.

Other information
• Store between 15–30°C (59–86°F).
• Avoid freezing and excessive heat.

Inactive ingredient(s)
Glycerin, hydroxypropyl cellulose, methylcellulose, water (may or may not contain).



DRUG FACTS

Active Ingredient(s)
Ethyl Alcohol 80% v/v

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Inactive ingredient(s)
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Distributed by New Genesis Enterprises
3262 W Highway 67
Cleburne, TX 76033
361-701-7699

SIMPLY SAFE HAND SANITIZER
alcohol gel

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:79661-001
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
ALCOHOL (UNII: 3K9958V90M) (ALCOHOL - UNII:3K9958V90M)	ALCOHOL	96 mL in 100 mL

Inactive Ingredients

Ingredient Name	Strength
GLYCERIN (UNII: PDC6A3C0OX)	4.8 mL in 100 mL
HYPROMELLOSE 2208 (100 MPA.S) (UNII: B1QE5P712K)	9 mL in 100 mL
WATER (UNII: 059QF0K00R)	1.2 mL in 100 mL
HYDROXYPROPYL CELLULOSE, UNSPECIFIED (UNII: 9XZ8H6N6OH)	9 mL in 100 mL

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:79661-001-04	120 mL in 1 BOTTLE, DISPENSING; Type 0: Not a Combination Product	03/30/2020	
2	NDC:79661-001-08	240 mL in 1 BOTTLE, DISPENSING; Type 0: Not a Combination Product	03/30/2020	
3	NDC:79661-001-02	60 mL in 1 BOTTLE, DISPENSING; Type 0: Not a Combination Product	03/30/2020	
4	NDC:79661-001-10	300 mL in 1 BOTTLE, DISPENSING; Type 0: Not a Combination Product	03/30/2020	
5	NDC:79661-001-20	600 mL in 1 BOTTLE, DISPENSING; Type 0: Not a Combination Product	03/30/2020	
6	NDC:79661-001-32	960 mL in 1 BOTTLE, DISPENSING; Type 0: Not a Combination Product	03/30/2020	
7	NDC:79661-001-01	3785 mL in 1 BOTTLE, DISPENSING; Type 0: Not a Combination Product	03/30/2020	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part333A	03/30/2020	

Labeler - CMM CAPITAL, LLC (005409676)