

HAND SANITIZER- alcohol gel

One Sanitizer 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.

TOP NOW

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. Glycerol (1.45% v/v).
- c. Hydrogen peroxide (0.125% 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.

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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, hydrogen peroxide, purified water USP

Package Label - Principal Display Panel

.120 L NDC: 79516-9664-7

Drug Facts

Active Ingredients.....Purpose
Ethyl Alcohol 80%.....Antiseptic

Uses: Hand sanitizer to help decrease bacteria on the skin when water, soap & towel are not available.
Recommended for repeated use.

Warnings:
For external use only.

Flammable. Keep away from fire or flame.

Do not apply around eyes.
Do not use in ears & mouth.
When using this product, avoid contact with eyes.
In case of contact, flush eyes with water.

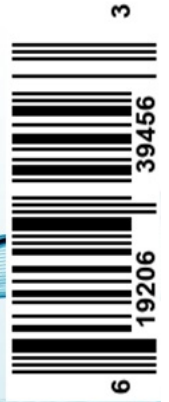
Stop use and ask a doctor if redness or irritation persists more than 72 hours.

Directions: Squirt as needed into your palms and thoroughly spread on both hands. Rub into skin until dry.

Other Information: Store at 20C (68 to 77 F)
May discolor fabrics

Inactive Ingredients:
Water, Propylene glycol, N&A essential oils

 **TOPNOW**
PRODUCTS



GEL FORMULA

HAND SANITIZER

GEL FORMULA

4oz- 120mL

TopNowProducts.com



1.893 L NDC: 79516-9664-8

Drug Facts

Active Ingredients.....Purpose
Ethyl Alcohol 80%.....Antiseptic

Uses: Hand sanitizer to help decrease bacteria on the skin when water, soap & towel are not available.
Recommended for repeated use.

Warnings:
For external use only.

Flammable. Keep away from fire or flame.

Do not apply around eyes.
Do not use in ears & mouth.
When using this product, avoid contact with eyes.
In case of contact, flush eyes with water.

Stop use and ask a doctor if redness or irritation persists more than 72 hours.

Directions: Squirt as needed into your palms and thoroughly spread on both hands. Rub into skin until dry.

Other Information: Store at 20C (68 to 77 F)
May discolor fabrics

Inactive Ingredients:
Water, Propylene glycol, N&A essential oils


PRODUCTS

GEL FORMULA

HAND SANITIZER

GEL FORMULA

1/2 GALLON

TopNowProducts.com



3.785 L NDC: 79516-9664-9

Drug Facts
Active Ingredients.....Purpose Ethyl Alcohol 80%....Antiseptic
Uses: Hand sanitizer to help decrease bacteria on the skin. When water, soap & towel are not available. Recommended for repeated use.
Warnings For External use only
Flammable. Keep away from fire or flame
Do not apply around eyes. Do not use in ears & mouth When using this product, avoid contact with eyes Incase of contact flush eyes with water
Stop use and ask a doctor if redness or irritation persists more than 72 hours Keep out of reach of children. Children must be supervised when using this product
Directions: Squirt as needed into your palms and thoroughly spread on both hands. Rub into skin until dry.
Inactive Ingredients: Water, glycerin(e), Hydroxypropyl cellulose

HAND SANITIZER

alcohol gel

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:79516-9664(NDC:65353-9664)
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
GLYCERIN (UNII: PDC6A3C0OX)	2.5 L in 100 L
HYDROGEN PEROXIDE (UNII: BBX060AN9V)	1.1 L in 100 L
WATER (UNII: 059QF0K00R)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:79516-9664-7	0.12 L in 1 BOTTLE, SPRAY; Type 0: Not a Combination Product	03/30/2020	

2	NDC:79516-9664-9	3.785 L in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	03/30/2020	
3	NDC:79516-9664-8	1.893 L in 1 BOTTLE, PLASTIC; 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 - One Sanitizer LLC (117523177)

Registrant - Brenntag North America (145865148)

Establishment

Name	Address	ID/FEI	Business Operations
One Sanitizer LLC		117523177	relabel(79516-9664)

Revised: 7/2020

One Sanitizer LLC