

HAND SANITIZER- ethyl alcohol gel
Olympic Mountain Products, Inc.

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.

Essenza 8.5 oz Hand Sanitizer (62%)

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:

Alcohol (ethanol) (USP or Food Chemical Codex (FCC) grade) (62%, volume/volume (v/v)) in an aqueous solution denatured according to Alcohol and Tobacco Tax and Trade Bureau regulations in 27 CFR part 20.

Water (35.31 % v/v)

Glycerin (2.0 % v/v)

Carbomer (0.35 % v/v)

PEG-40 Hydrogenated Castor Oil (0.2 % v/v)

Chloroxylenol (0.1 % v/v)

Sodium Hydroxide (0.04 % 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)

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.

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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

Water, Glycerin, Carbomer, Peg-40
Hydrogenated Castor Oil,
Chloroxyleneol, Sodium Hydroxide.

Package Label

251 mL NDC: 75951-8099-8



ESSENZA

**HAND
SANITIZER**



MOISTURIZING

NO RINSE FORMULA

8.5 FL OZ (250 ML)



HAND SANITIZER

Drug Facts

Active Ingredients: Ethyl Alcohol, 62%
Benzyl Alcohol

Hand sanitizer helps reduce the number of germs on your hands. 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.
Do not use on open wounds.

Use only for external use. Keep out of eyes, ears, and mouth. In case of contact with eyes, rinse eyes thoroughly with water.

Do not use with a barrier. If irritation or rash occurs, there may be some of a allergic reaction.

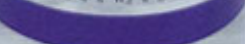
Keep out of reach of children. If treatment, get medical help or contact Poison Control Center.

Other information:
Store between 15-30°C (59-86°F).
Keep away from heat and excessive heat (above 120°C/248°F).

Inactive ingredients:
Glycerin, Propyl Hydrogenated Castor Oil, Cellulose Acrylate, Sodium Hydroxide.

Questions or Comments? 1-800-837-2861

Manufactured by: Ogenius Mountain Products
10000 10th Street, Kent, WA 98043
www.ogenius.com Made in China





ANTIBACTERIAL
**HAND
SANITIZER**



NO RINSE FORMULA

8.5 FL OZ (251 ML)

HAND SANITIZER

Drug Facts

Active Ingredient: Ethyl Alcohol 62%
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

- on 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.

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 15-30 C (59-86 F)
- Avoid freezing and excessive heat above 40 C (104 F)

Inactive ingredients

Water, Glycerin, Carbomer, Peg-40 Hydrogenated Castor Oil, Chloroxylenol, Sodium Hydroxide.

Questions or Comments? 1-800-937-2545



Distributed by: Olympic Mountain Products
8655 South 208th Street, Kent, WA 98031
www.MyEssenza.com **Made in China**



Please Recycle



HAND SANITIZER

ethyl alcohol gel

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:75951-8099
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
ALCOHOL (UNII: 3K9958V90M) (ALCOHOL - UNII:3K9958V90M)	ALCOHOL	62 mL in 100 mL

Inactive Ingredients

Ingredient Name	Strength
CARBOMER HOMO POLYMER, UNSPECIFIED TYPE (UNII: 0A5MM307FC)	0.35 mL in 100 mL
WATER (UNII: 059QF0KO0R)	35.31 mL in 100 mL
CHLOROXYLENOL (UNII: 0F32U78V2Q)	0.1 mL in 100 mL
SODIUM HYDROXIDE (UNII: 55X04QC32I)	0.04 mL in 100 mL
POLYOXYL 40 HYDROGENATED CASTOR OIL (UNII: 7YC686GQ8F)	0.2 mL in 100 mL

GLYCERIN (UNII: PDC6A3C0OX)

2 mL in 100 mL

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:75951-8099-8	251 mL 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 - Olympic Mountain Products, Inc. (103355350)

Revised: 6/2020

Olympic Mountain Products, Inc.