

HAND SANITIZER- alcohol gel
Zephyr Technologies, 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.

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.

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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

glycerin, hydrogen peroxide, purified water USP

Package Label - Principal Display Panel

CLINICALLY TESTED - NON-IRRITATING ENRICHED WITH MOISTURIZERS

◆◆ Clinically Proven ◆◆
to Kill **99.99%** of Germs ◆◆



Instant

HAND SANITIZER

FRAGRANCE FREE



WITH **80%** ALCOHOL



Environmentally Sensitive Formula

WARNINGS: Keep out of the reach of children and pets, store in a cool, dry place, free from direct sunlight, the product can cause irritation in people sensitive to ethyl alcohol, avoid splashing in the eyes, close the container tightly after each use to avoid evaporation, do not ingest. When using this product, keep it out of the eyes, ears and mouth. In case of contact with eyes, rinse eyes thoroughly with water.

INGREDIENTS: Ethyl Alcohol, Distilled Water, Glycerine, Carbomer, Aloe vera, Citrus, Triethanolamine, Hydrogen peroxide.

HOW TO USE: Apply the Antibacterial Gel on the hands, rub for at least 30 seconds, distribute evenly and allow to dry.

Net Cont.
1 Gallon / 3.785 L / 128 oz



www.nuwelt.com

3785.41 mL NDC: 79153-001-03



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ENRICHED WITH MOISTURIZERS



Instant

HAND SANITIZER

FRAGRANCE FREE



Environmentally Sensitive Formula

Net Cont. **1 L / 33.8 oz**



Instant

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CLINICALLY TESTED - NON-IRRITATING ENRICHED WITH MOISTURIZERS



Instant

HAND SANITIZER

FRAGRANCE FREE



Environmentally Sensitive Formula

Net Cont. 500 ml / 16.9 oz

HAND SANITIZER

alcohol gel

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:79153-001
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
ALCOHOL (UNII: 3K9958V90M) (ALCOHOL - UNII:3K9958V90M)	ALCOHOL	80 mL in 100 mL

Inactive Ingredients

Ingredient Name	Strength
GLYCERIN (UNII: PDC6A3C0OX)	1.45 mL in 100 mL
HYDROGEN PEROXIDE (UNII: BBX060AN9V)	0.125 mL in 100 mL
WATER (UNII: 059QF0KO0R)	

Packaging

Marketing Start	Marketing End
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#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:79 153-001-01	500 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	07/08/2020	
2	NDC:79 153-001-02	1000 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	07/08/2020	
3	NDC:79 153-001-03	3785.41 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	07/08/2020	
4	NDC:79 153-001-04	250 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	09/24/2020	

Marketing Information

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

Labeler - Zephyr Technologies, Inc (012865619)

Registrant - Zephyr Technologies, Inc. (012865619)

Revised: 9/2020

Zephyr Technologies, Inc