

HAND SANITIZER- ethanol alcohol liquid
Almil Nutritional 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.

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. Isopropyl Alcohol (75%, 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)

Isopropyl Alcohol 75% 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

glycerin, hydrogen peroxide, purified water USP

Package Label - Principal Display Panel

tightly closed. Ground/bond container and receiving equipment. Use explosion-proof electrical/ventilating/lighting/equipment, etc. Use only non-sparking tools. Take precaution any measures to prevent static discharge. Avoid breathing dust/fume/gas/mist/vapors/spray. Wash hands and exposed body parts thoroughly after handling. Use only outdoors or in a well-ventilated area. Wear protective gloves/protective clothing/eye protection/face protection. IF ON SKIN (or hair): Remove/Take off immediately all contaminated clothing. Rinse skin with water or shower. IF INHALED: Remove victim to fresh air and keep comfortable for breathing. IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses if present and easy to do so- continue rinsing. Call a POISON CENTER or a doctor/physician if you feel unwell. If eye irritation persists get medical advice/attention. In case of fire: Use dry sand, dry chemical or alcohol-resistant foam to extinguish. Store in a well ventilated place. Keep container tightly closed. Keep cool. Store locked up. Dispose of contents/container to an approved waste disposal facility.

Ingredients: 70% alcohol, Purified Water USP

570 W Lambert road, Unit G,
Brea, CA 92821

PHONE NUMBER: 909-856-9666
WWW.ALMILUSA.COM

DANGER



7 93897 22936 3

3750mL

NDC: 53325-124-01



AN ALMIL
Nutritional
Products, Inc.



70% PLUS ALCOHOL
Flammable Liquid

Highly flammable liquid and vapor. Causes serious eye irritation. May cause dizziness or drowsiness.

Keep away from heat, hot surfaces, sparks, open flames, and other ignition sources. No smoking. Keep container tightly closed. Ground/bond container and receiving equipment. Use

NET WT.: 3.75 Liters (1 Gal)

3750mL

NDC: 53325-124-01

HAND SANITIZER

ethanol alcohol liquid

Product Information

Product Type

HUMAN OTC DRUG

Item Code (Source)

NDC:53325-124

Route of Administration TOPICAL

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
ISOPROPYL ALCOHOL (UNII: ND2M416302) (ISOPROPYL ALCOHOL - UNII:ND2M416302)	ISOPROPYL ALCOHOL	75 mL in 100 mL

Inactive Ingredients

Ingredient Name	Strength
HYDROGEN PEROXIDE (UNII: BBX060AN9V)	25 mL in 100 mL

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:53325-124-01	3750 mL in 1 BOTTLE; 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 - Almil Nutritional Products, Inc. (153736301)

Registrant - Almil Nutritional Products, Inc. (153736301)

Establishment

Name	Address	ID/FEI	Business Operations
Almil Nutritional Products, Inc.		153736301	label(53325-124) , manufacture(53325-124) , repack(53325-124)

Revised: 6/2020

Almil Nutritional Products, Inc.