

H2ONE- alcohol gel
Plantium International, 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) (75%, 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 (1.50% v/v).
- c. Carbomer 1.50% v/v
- d. Triethanolamine .75% v/v
- e. Aloe .25% v/v
- f. Vitmine E .25% v/v
- g. Lanvender Oil .25%
- h. Sterile distilled water or boiled cold water.

Active Ingredient(s)

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

purified water, Isopropal Alchoal, Carbomer, glycerin, Triethanolamine, Aloe, Vitimine C, Lavander Oil

Package Label - Principal Display Panel



500 mL NDC: 76730-385-25

H2ONE

alcohol gel

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:76730-675
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
ALCOHOL (UNII: 3K9958V90M) (ALCOHOL - UNII:3K9958V90M)	ALCOHOL	75 mL in 100 mL

Inactive Ingredients

Ingredient Name	Strength
GLYCERIN (UNII: PDC6A3C0OX)	1.75 mL in 100 mL
TROLAMINE (UNII: 9O3K93S3TK)	0.75 mL in 100 mL
WATER (UNII: 059QF0KO0R)	

ALOE (UNII: V5VD430 YW9)	0.16 mL in 100 mL
ISOPROPYL ALCOHOL (UNII: ND2M416 302)	80 mL in 100 mL
.ALPHA.-TOCOPHEROL, DL- (UNII: 7QWA1RIO01)	0.25 mL in 100 mL
POLYACRYLIC ACID (8000 MW) (UNII: 73861X4K5F)	1.5 mL in 100 mL

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:76730-675-50	500 mL in 1 BOTTLE, PUMP; Type 0: Not a Combination Product	03/30/2020	
2	NDC:76730-675-33	975 mL in 1 BOTTLE, PUMP; Type 0: Not a Combination Product	03/30/2020	
3	NDC:76730-675-10	3785 mL in 1 BOTTLE, PUMP; 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 - Plantium International, Inc (014607385)

Establishment

Name	Address	ID/FEI	Business Operations
Plantium International, Inc		014607385	manufacture(76730-675)

Revised: 8/2020

Plantium International, Inc