

HAND SANITIZER- alcohol liquid
Blind Industries and Services of Maryland

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)

Ethyl Alcohol 70%. 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.

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

Inactive ingredients

glycerin, purified water USP, Acrylates/C10 Alkyl Acrylate, Aloe Barbadensis Leaf Juice, Tocopherol Acetate, Lavendula Latifolia, Triethanolamine

236 mL

236 mL NDC: 77941-236-24

<p>Drug Facts</p> <p>Active Ingredient Purpose Ethyl Alcohol 70% Antimicrobial</p> <p>Use Helps reduce bacteria and viruses on the skin that could cause disease. Recommended for repeated use. Do not ingest, for topical use only.</p> <p>Warnings Flammable. Keep away from fire or flame. For external use only.</p> <p>Stop use and see doctor if irritation or rash appears/lasts.</p> <p>When using this product do not use in or near the eyes. In case of contact rinse eyes thoroughly with water.</p> <p>Keep out of reach of children. If swallowed get medical help or contact a Poison Control Center right away. Not recommended for infants.</p>	 <p>MIRACLE HEALTH®</p> <p>HAND SANITIZER GEL with ALOE</p> <p>Kills 99.9% of Germs*</p> <p>8 Fl Oz (236 ml)</p>	<p>Directions Place enough product in your palm to cover hands. Rub hands together until dry. Children under 6 years of age should be supervised when using this product.</p> <p>Other Information Do not store above 110°F (43°C). May discolor certain fabrics or surfaces.</p> <p>Inactive Ingredients Water Acrylates/C10 Alkyl Acrylate, Aloe Barbadensis Leaf Juice, Glycerin, Tocopherol Acetate, Lavendula Latifolia, Triethanolamine</p> <p><small>*Effective at eliminating 99.9% of many common germs and harmful bacteria.</small></p> <p>Miracle Health Company LLC 1422 Scales Street, Raleigh, NC 27608 1-800-795-2618</p>  
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500 mL

500 mL NDC: 77941-500-24

Drug Facts

Active Ingredient	Purpose
Ethyl Alcohol 70%	Antimicrobial

Use Helps reduce bacteria and viruses on the skin that could cause disease. Recommended for repeated use. Do not ingest, for topical use only.

Warnings Flammable. Keep away from fire or flame. For external use only.

Stop use and see doctor if irritation or rash appears/lasts.

When using this product do not use in or near the eyes. In case of contact rinse eyes thoroughly with water.

Keep out of reach of children. If swallowed, get medical help or contact a Poison Control Center right away. Not recommended for infants.



**MIRACLE
HEALTH®**
HAND SANITIZER
GEL with ALOE
Kills 99.9% of Germs*
16.9 Fl Oz (500 ml)

Directions Place enough product in your palm to cover hands. Rub hands together until dry. Children under 6 years of age should be supervised when using this product.

Other Information Do not store above 110°F (43°C). May discolor certain fabrics or surfaces.

Inactive ingredients water, Acrylates/C10-18 Alkyl Acrylate, Aloe Barbadensis Leaf Juice, Glycerin, Tocopherol Acetate, Lavandula Latifolia, Triethanolamine.

*Effective at eliminating 99.9% of many common germs and harmful bacteria.

Miracle Health Company LLC
1422 Scales Street, Raleigh, NC 27608
1-800-795-2818

**HAND SANITIZER**

alcohol liquid

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:77941-236
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
ALCOHOL (UNII: 3K9958V90M) (ALCOHOL - UNII:3K9958V90M)	ALCOHOL	70 mL in 100 mL

Inactive Ingredients

Ingredient Name	Strength
GLYCERIN (UNII: PDC6A3C0OX)	1.45 mL in 100 mL
WATER (UNII: 059QF0K00R)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:77941-236-24	236 mL in 1 BOTTLE; Type 0: Not a Combination Product	05/22/2020	

Marketing Information

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

HAND SANITIZER

alcohol liquid

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:77941-500	
Route of Administration	TOPICAL			
Active Ingredient/Active Moiety				
Ingredient Name		Basis of Strength	Strength	
ALCOHOL (UNII: 3K9958V90M) (ALCOHOL - UNII:3K9958V90M)		ALCOHOL	70 mL in 100 mL	
Inactive Ingredients				
Ingredient Name		Strength		
WATER (UNII: 059QF0K00R)				
GLYCERIN (UNII: PDC6A3C0OX)		1.45 mL in 100 mL		
Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:77941-500-24	500 mL in 1 BOTTLE; Type 0: Not a Combination Product	06/01/2020	
Marketing Information				
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date	
OTC monograph not final	part333A	03/30/2020		

Labeler - Blind Industries and Services of Maryland (074925017)

Registrant - Blind industries and service of Maryland (074925017)

Establishment

Name	Address	ID/FEI	Business Operations
Blind Industries and Services of Maryland		074925017	manufacture(77941-500, 77941-236)

Revised: 5/2020

Blind Industries and Services of Maryland