

## **HAND SANITIZER- alcohol gel**

### **Whish Body Products**

*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.*

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### **Hand Sanitizer**

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 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

aloe, purified water USP, isopropyl myristate, acrylates/c10-30 acrylates crosspolymer, aminomethylpropanediol, peppermint oil.

## Package Label - Principal Display Panel

<p><b>Drug Facts</b></p> <p><b>Active Ingredient(s):</b> Ethyl Alcohol 70% v/v. <b>Purpose:</b> Antiseptic</p> <p><b>Use(s):</b> Hand sanitizer to help reduce microbial presence that potentially can cause disease. For use when soap and water are not available.</p> <p><b>Warnings:</b> For external use only. Flammable. Keep away from heat or flame.</p> <p><b>Do not use:</b> • In children less than 2 months of age • on open skin wounds</p> <p>When using this product keep out of eyes, ears, and mouth. In case of contact with eyes, rinse eyes thoroughly with water.</p> <p>Stop use and ask a doctor if irritation or rash occurs. There may be signs of a serious condition.</p> <p>Keep out of reach of children. If swallowed, get medical help or contact a Poison Control Center immediately.</p> <p><b>Directions:</b> • 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.</p> <p><b>Other information:</b> • Store between 15-30°C (59-86° F) • Avoid Freezing and excessive heat above 40°C (104° F).</p> <p><b>Inactive Ingredients:</b> Water (Aqua), Isopropyl Myristate, Acrylates C10-30 Acrylates Copolymer, Aloe Barbadensis (Aloe) Leaf Juice, Aminomethylpropanediol, Mentha Piperita (Peppermint) Oil.</p>	<p><i>whish</i><sup>®</sup></p> <p>POWERFULLY EFFECTIVE NATURALS</p> <p><b>HAND SANITIZER</b></p> <p>70% ETHYL ALCOHOL</p> <p>PARABEN FREE SULFATE FREE PHTHALATE FREE DEA &amp; TEA FREE PETROCHEMICAL FREE CRUELTY FREE LEAPING BUNNY CERTIFIED</p> <p>3.79 L e 128 FL OZ</p> <p>WHISH IS DEDICATED TO THE DISCOVERY OF NATURAL INGREDIENTS WHICH ENABLE INTELLIGENT CHOICES FOR YOUR SKIN. WELCOME TO A GENTLE NEW WORLD.</p> <p>TESTED ON US, NOT ANIMALS. MADE IN THE USA. Whish Body Products, LLC Scottsdale, AZ 85260</p> <p>WWW.WHISHBEAUTY.COM 12280 0164 1 7</p>
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--- TRIM  
— BLEED

□ WHITE STOCK WITH GLOSS LAMINATION  
■ BLACK



POWERFULLY EFFECTIVE NATURALS

# HAND SANITIZER

70% ETHYL ALCOHOL

PARABEN FREE  
SULFATE FREE  
PHTHALATE FREE  
DEA & TEA FREE  
PETRO-CHEMICAL FREE  
CRUELTY FREE  
LEAPING BUNNY CERTIFIED

976 mL e 33 FL OZ

**Drug Facts**

<b>Active Ingredient(s):</b> Ethyl Alcohol 70% v/v	<b>Purpose:</b> Antiseptic
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<b>Inactive Ingredients:</b> Water (Aqua), Isopropyl Myristate, Acrylates/ C10-30 Acrylates Crosspolymer, Aloe Barbadensis (Aloe) Leaf Juice, Aminomethylpropanediol, Mentha Piperita (Peppermint) Oil.	

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BLACK



POWERFULLY EFFECTIVE NATURALS

# HAND SANITIZER

70% ETHYL ALCOHOL

PARABEN FREE • SULFATE FREE • PHTHALATE FREE • DEA & TEA FREE  
PETRO-CHEMICAL FREE • CRUELTY FREE • LEAPING BUNNY CERTIFIED

488 mL e 16.5 FL OZ

**Drug Facts**

<b>Active Ingredient(s):</b> Ethyl Alcohol 70% v/v	<b>Purpose:</b> Antiseptic
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whish

POWERFULLY EFFECTIVE NATURALS

## HAND SANITIZER

70%  
ETHYL ALCOHOL

PARABEN FREE  
SULFATE FREE  
PHYTHALATE FREE  
DEA & TEA FREE  
PETROCHEMICAL FREE  
CRUELTY FREE  
LEAPING BUNNY CERTIFIED

300 mL e 13 FL OZ

### Drug Facts

Active Ingredient(s):	Purpose:
Ethyl Alcohol 70% v/v	Antiseptic

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DOCUMENT CONTROL

FILE: HS\_4oz\_OT\_al

WHITE LABEL STOCK  
GLOSS LAM

■ = BLACK

- 118 mL NDC: 76224-6822-2
- 390 mL NDC: 76224-7822-3
- 488 mL NDC: 76224-7822-4
- 976 mL NDC: 76224-7822-5
- 3.79L NDC: 76244-7822-6

**HAND SANITIZER**

alcohol gel

**Product Information**

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:76224-6822
<b>Route of Administration</b>	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
CARBOMER HOMO POLYMER TYPE C (UNII: 4Q93RCW27E)	
MENTHA PIPERITA (UNII: 79M2M2UDA9)	
ALOE VERA LEAF (UNII: ZY81Z83H0X)	
AMINOMETHYL PROPANEDIOL (UNII: CZ7BU4QZJZ)	
WATER (UNII: 059QF0K00R)	
ISOPROPYL MYRISTATE (UNII: 0RE8K4LNJS)	

## Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:76224-6822-5	976 mL in 1 BOTTLE, PUMP; Type 0: Not a Combination Product	03/01/2020	
2	NDC:76224-6822-4	488 mL in 1 BOTTLE, PUMP; Type 0: Not a Combination Product	03/01/2020	
3	NDC:76224-6822-3	390 mL in 1 BOTTLE, PUMP; Type 0: Not a Combination Product	03/01/2020	
4	NDC:76224-6822-2	118 mL in 1 BOTTLE, PUMP; Type 0: Not a Combination Product	03/01/2020	
5	NDC:76224-6822-6	3785 mL in 1 BOTTLE, PUMP; Type 0: Not a Combination Product	03/01/2020	

## Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part333A	03/01/2020	

**Labeler** - Whish Body Products (606576952)

## Establishment

Name	Address	ID/FEI	Business Operations
Whish Body Products		606576952	manufacture(76224-6822)

Revised: 5/2020

Whish Body Products