

## **HAND SANITIZER- alcohol gel Healing Solutions**

*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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### **Half Gallon**

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.

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, hydrogen peroxide, purified water USP

**Package Label - Principal Display Panel**

Front

Healing  
Solutions<sup>®</sup>

PREMIUM

HAND  
SANITIZER

Alcohol 75% v/v



Net 1 half gallon (1893ml)

Back

<b>Drug Facts</b>	
<b>Active Ingredient</b>	<b>Purpose</b>
Ethyl Alcohol 75.0% v/v.....	Antimicrobial
<b>Uses</b> • for handwashing to decrease bacteria on the skin • recommended for repeated use.	
<b>Warnings</b> For external use only.	
<b>Flammable, keep away from heat and flame.</b>	
Do not use in the eyes. In case of contact, rinse eyes thoroughly with water.	
Stop use and ask a doctor if irritation and redness develop and persist for more than 72 hours.	
Keep out of reach of children. If swallowed, get medical help or contact a Poison Control Center right away.	
<b>Directions</b> • wet hands thoroughly with product briskly rub hands together until dry • supervise children under 6 years in the use of this product.	
<b>Other Information</b> • store at 20°C to 25°C (68° to 77°F) • may discolor certain fabrics.	
<b>Inactive Ingredients:</b> Water, Glycerin, Carbomer, Aloe Vera, **Triethanolamine, **Aminomethyl propanol, Vitamin E.	

\* Effective at eliminating 99.99% of many common harmful germs & bacteria.  
 \*\* May contain Triethanolamine and/or Aminomethyl propanol.  
 DISTRIBUTED BY HEALING SOLUTIONS, LLC - 4703 W BRILL ST,  
 PHOENIX, AZ 85043 800-986-9210 602-698-9111  
 WWW.HEALINGSOLUTIONS.COM  
 MADE IN CHINA

NDC 77813-001-05

<b>HAND SANITIZER</b>			
alcohol gel			
<b>Product Information</b>			
<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:77813-001
<b>Route of Administration</b>	TOPICAL		
<b>Active Ingredient/Active Moiety</b>			
	<b>Ingredient Name</b>	<b>Basis of Strength</b>	<b>Strength</b>
	ALCOHOL (UNII: 3K9958V90M) (ALCOHOL - UNII:3K9958V90M)	ALCOHOL	75 mL in 100 mL

## Inactive Ingredients

Ingredient Name	Strength
CARBOMER 934 (UNII: Z135WT9208)	
TROLAMINE (UNII: 9O3K93S3TK)	
ALPHA-TOCOPHEROL (UNII: H4N855PNZ1)	
ALOE VERA LEAF (UNII: ZY81Z83H0X)	
GLYCERIN (UNII: PDC6A3C0OX)	
WATER (UNII: 059QF0KO0R)	

## Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:77813-001-05	1893 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	07/06/2020	

## Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part333A	05/22/2020	

**Labeler** - Healing Solutions (080526617)

**Registrant** - Healing Solutions (080526617)

## Establishment

Name	Address	ID/FEI	Business Operations
Healing Solutions		080526617	manufacture(77813-001)

## Establishment

Name	Address	ID/FEI	Business Operations
Jiangsu Oppeal Daily Cosmetics Corp. Ltd.		544096556	manufacture(77813-001)

Revised: 7/2020

Healing Solutions