

## **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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### **275 Gallon Tote**

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



**PREMIUM**

**HAND  
SANITIZER**

**Alcohol 75% v/v**



Net 275 gallon (104IL)

<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> <b>For external use only.</b> <b>Flammable, keep away from heat and flame.</b> <b>Do not use</b> in the eyes. In case of contact, rinse eyes thoroughly with water. <b>Stop use and ask a doctor if</b> irritation and redness develop and persists for more than 72 hours. <b>Keep out of reach of children.</b> 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 800-986-9240 602-698-9111  
WWW.HEALINGSOLUTIONS.COM  
MADE IN CHINA

0275 Gallon Tote NDC: 77813-001-07

**HAND SANITIZER**

alcohol gel

### Product Information

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:778 13-001
<b>Route of Administration</b>	TOPICAL		

### Active Ingredient/Active Moiety

<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

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

### Packaging

#	<b>Item Code</b>	<b>Package Description</b>	<b>Marketing Start Date</b>	<b>Marketing End Date</b>
1	NDC:778 13-001-07	1040875 mL in 1 CONTAINER, FLEXIBLE INTERMEDIATE BULK; Type 0: Not a Combination Product	05/22/2020	

### Marketing Information

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

**Labeler** - Healing Solutions (080526617)

**Registrant** - Healing Solutions (080526617)

### Establishment

<b>Name</b>	<b>Address</b>	<b>ID/FEI</b>	<b>Business Operations</b>
Healing Solutions		080526617	manufacture(778 13-001)

### Establishment

<b>Name</b>	<b>Address</b>	<b>ID/FEI</b>	<b>Business Operations</b>
Jiangsu Oppeal Daily Cosmetics Corp. Ltd.		544096556	manufacture(778 13-001)

