

**HAND SANITIZER- alcohol liquid**  
**Value Products 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.*

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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) (70%, 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 (3% v/v).
- c. Hydrogen peroxide (0.13% 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

glycerin, hydrogen peroxide, purified water USP

## Description

HAND SANITIZER 70 is a premium pH balanced formula that is mild on skin, yet tough enough to meet USDA efficacy guidelines for E3 hand sanitizers. HAND SANITIZER 70 contains emollients which leave your hands feeling soft and moisturized. HAND SANITIZER 70 is intended for use as a no-rinse hand sanitizer.

## Precautionary Statement

Keep away from heat/open flames/hot surfaces - no smoking. Keep container tightly closed. Take precautionary measures against static discharge.

## Package Label - Principal Display Panel

Hand Sanitizer

Antimicrobial Hand Sanitizer

For Industrial Use Only Keep Out of Reach of Children

Net Contents: 1 US Gallon

Code # 2655

<b>PRIDE LINE</b>			
<b>HAND SANITIZER</b>			
<b>ANTIMICROBIAL HAND SANITIZER</b>			
<b>FOR INDUSTRIAL USE ONLY</b> <b>KEEP OUT OF THE REACH OF CHILDREN</b>			
<b>DRUG FACTS</b> <table border="1"><tr><td><b>Active ingredient</b> Alcohol 70% v/v</td><td><b>Purpose</b> Antiseptic</td></tr></table>	<b>Active ingredient</b> Alcohol 70% v/v	<b>Purpose</b> Antiseptic	<b>DESCRIPTION</b> HAND SANITIZER is a premium pH balanced formula that is mild on skin, yet tough enough to meet USDA efficacy guidelines for E3 hand sanitizers. HAND SANITIZER contains emollients which leave your hands feeling soft and moisturized. HAND SANITIZER is intended for use as a no-rinse hand sanitizer.
<b>Active ingredient</b> Alcohol 70% v/v	<b>Purpose</b> Antiseptic		
<b>Use:</b> Hand sanitizer to help reduce bacteria that potentially can cause disease. For use when soap and water are not available.	 		
<b>Warnings:</b> For external use only. Flammable. Keep away from heat or flame.			
<b>Do not use:</b> <ul style="list-style-type: none"><li>• on children less than 2 months of age</li><li>• on open skin wounds</li></ul>	<b>PRECAUTIONARY STATEMENTS:</b> Keep away from heat/open flames/hot surfaces - no smoking. Keep container tightly closed. Take precautionary measures against static discharge.		
<b>When using this product</b> keep out of eyes, ears, and mouth. In case of contact with eyes, rinse eyes thoroughly with water.			
<b>Stop use and ask a doctor</b> if irritation or rash occurs. These may be signs of a serious condition.			
<b>Keep out of reach of children.</b> If swallowed, get medical help or contact a Poison Control Center right away.			
<b>Directions</b> <ul style="list-style-type: none"><li>• Place enough product on hands to cover all surfaces. Rub hands together until dry.</li><li>• Supervise children under 6 years of age when using this product to avoid swallowing.</li></ul>			
<b>Other information</b> <ul style="list-style-type: none"><li>• Store between 15-30C (59-86F)</li><li>• Avoid freezing and excessive heat above 40C(104F)</li></ul>			
<b>Inactive ingredients:</b> glycerin, hydrogen peroxide, purified water			
<b>Net contents:</b> <ul style="list-style-type: none"><li>• 1 US Gallon</li></ul>			

**Value Products Inc.**  
Chemical Compounding & Packaging

2128 Industrial Dr • Stockton, CA 95206 • tel: (209)-983-4000 fax: (209) 983-4080 • www.ValueProductsInc.com CODE# 2655

# HAND SANITIZER

alcohol liquid

## Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:77715-2655
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)	3 mL in 100 mL
HYDROGEN PEROXIDE (UNII: BBX060AN9V)	0.13 mL in 100 mL
WATER (UNII: 059QF0KO0R)	

## Product Characteristics

Color		Score	
Shape		Size	
Flavor		Imprint Code	
Contains			

## Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:77715-2655-1	3785 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	03/30/2020	

**DRUG FACTS**

Active ingredient	Purpose
Alcohol 70% v/v	Antiseptic

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**Net contents:**

- 1 U.S. Gallon

# PRIDE LINE

  

# HAND SANITIZER

## ANTIMICROBIAL HAND SANITIZER

  

FOR INDUSTRIAL USE ONLY  
KEEP OUT OF THE REACH OF CHILDREN

**DESCRIPTION**

HAND SANITIZER is a premium pH balanced formula that is mild on skin, yet tough enough to meet USDA efficacy guidelines for E3 hand sanitizers. HAND SANITIZER contains emollients which leave your hands feeling soft and moisturized. HAND SANITIZER is intended for use as a no-rinse hand sanitizer.



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## Marketing Information

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

**Labeler** - Value Products Inc (050514124)

## Establishment

Name	Address	ID/FEI	Business Operations
Enter Establishment Name		050514124	manufacture(77715-2655)

Revised: 5/2020

Value Products Inc