

## **SAVIOUR PLUS HAND SANITIZER- alcohol gel**

### **WILSHIRE LABORATORIES PRIVATE LIMITED**

*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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#### **Saviour Plus 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 80% 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**

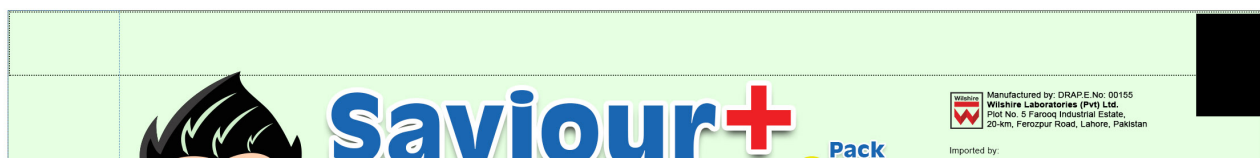
- Store between 15-30C (59-86F)
- Avoid freezing and excessive heat above 40C (104F)


### **Inactive ingredients**

glycerin, hydrogen peroxide, purified water USP

### **Package Label - Principal Display Panel**

# Actual Size





Kills **99.99%** Germs without water

**Junior**  
One Time Use

Lá Originale Corp. U.S.A.  
La Originale Rockvill Center,  
NY11870  
Tollfree No. 1-888-945-7473

<b>Drug Facts</b>		<b>Stop use and ask a doctor</b> if irritation or rash occurs. These may be a signs of a serious condition.
Active Ingredient	Purpose	
Alcohol 80% v/v	Antiseptic	<b>Keep out of reach of children.</b> If swallowed, get medical help contact a Poison Control Center right away.
<b>Uses</b> Hand Sanitizer to help reduce bacteria that potentially can cause disease. Use when soap and water are not available.		
<b>Warnings</b> External use only. Flammable: Keep away from fire or flame.		<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.
<b>Do not use</b> In children less than 2 month of age. on open skin wounds		
<b>When using this product</b> keep out of eyes, ears and mouth. In case of contact with rinse eyes thoroughly with water.		<b>Inactive ingredients</b> Glycerin, Hydrogen peroxide, purified water USP.
		<b>Other information</b> Store between 15-30 °C (59-86°F). Avoid freezing and excessive heat above 40 °C (104°F).

NDC NO. 78813-002-80  
Lot No:  
Mfg. Date: AUG 2020  
Best Before: AUG 2022  
Once open use within 30 days  
Best Before: Within 2 Years  
Once open use within 30 days

002 mL NDC: 78813-002-80

## SAVIOR PLUS HAND SANITIZER

alcohol gel

### Product Information

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:78813-002
<b>Route of Administration</b>	TOPICAL		

### Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
ALCOHOL (UNII: 3K9958V90M) (ALCOHOL - UNII:3K9958V90M)	ALCOHOL	1.667 mL in 2 mL

### Inactive Ingredients

Ingredient Name	Strength
GLYCERIN (UNII: PDC6A3C0OX)	0.0365 mL in 2 mL

<b>HYDROGEN PEROXIDE</b> (UNII: BBX060AN9V)	0.005 mL in 2 mL
<b>WATER</b> (UNII: 059QF0KO0R)	0.291 mL in 2 mL

### Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:78813-002-80	2 mL in 1 POUCH; Type 0: Not a Combination Product	03/30/2020	

### Marketing Information

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

**Labeler** - WILSHIRE LABORATORIES PRIVATE LIMITED (645383407)

**Registrant** - WILSHIRE LABORATORIES PRIVATE LIMITED (645383407)

### Establishment

Name	Address	ID/FEI	Business Operations
WILSHIRE LABORATORIES PRIVATE LIMITED		645383407	manufacture(78813-002)

Revised: 1/2022

WILSHIRE LABORATORIES PRIVATE LIMITED