

SAVIOUR PLUS- 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.

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.

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

65mm

65mm

97mm

97mm

Drug Facts	
Active Ingredient	Purpose
Alcohol 80% v/v	Antiseptic
Uses	
Hand Sanitizer to help reduce bacteria that potentially can cause disease. Use when soap and water are not available.	
Warnings	
External use only. Flammable: Keep away from fire or flame.	
Do not use	
In children less than 2 month of age. on open skin wounds	
When using this product keep out of eyes, ears and mouth. In case of contact with rinse eyes throughly with water.	
Stop use and ask a doctor if irritation or rash occurs. These may be a signs of a serious condition.	
Keep out of reach of children. If swallowed, get medical help contact a Poison Control Center right away.	
Directions	
Place enough product on hands to cover all surfaces. Rub hands together untill dry. Supervise children under 6 years of age when using this product to avoid swallowing.	
Inactive ingredients	
Glycerin, Hydrogen peroxide, purified water USP.	
Other Information	
Store between 15-30 °C (59-86F). Avidod freezing and excessive heat above 40 C (104F).	

Printing area 55mm x85mm

15 mL NDC:78813-080-15

SAVIOUR PLUS

alcohol gel

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:78813-080
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
ALCOHOL (UNII: 3K9958V90M) (ALCOHOL - UNII:3K9958V90M)	ALCOHOL	12.5 mL in 15 mL

Inactive Ingredients

Ingredient Name	Strength
GLYCERIN (UNII: PDC6A3C00X)	0.274 mL in 15 mL
HYDROGEN PEROXIDE (UNII: BBX060AN9V)	0.038 mL in 15 mL
WATER (UNII: 059QF0K00R)	2.18 mL in 15 mL

Product Characteristics

Color		Score	
Shape		Size	
Flavor		Imprint Code	
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:78813-080-15	15 mL in 1 POUCH; Type 0: Not a Combination Product	03/30/2020	

65mm

65mm

97mm

97mm

Wilshire

Hand Sanitizer Gel

Saviour+ 15ml

Kills **99.99%** Germs without water

NDC NO. 78813-080-15
 Lot No:
 Mfg. Date: AUG 2020
 Best Before: AUG 2022
 Once open use within 30 days

Imported by:
La Originale Corp. U.S.A.
 La Originale Rockwell Center,
 WY11579
 Tollfree No. 1-888-945-7473

DRAP.E.No: 00155

Manufactured by:
Wilshire Laboratories (Pvt) Ltd.
 Plot No. 5 Farooq Industrial Estate,
 20-km, Sherazgar Road, Lahore, Pakistan.
 www.wilshirelabs.com

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

Printing area 55mm x85mm

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
WLSHIRE LABORATORIES PRIVATE LIMITED		645383407	manufacture(78813-080)

Revised: 1/2022

WLSHIRE LABORATORIES PRIVATE LIMITED