

## **SANI STAND 70% GEL UNSCENTED- alcohol gel**

### **Narrativo**

*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.*

-----

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 70% v/v. Purpose: Antiseptic, hand sanitizer

### **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, carbomer

## Package Label - Principal Display Panel

3785 mL NDC: 78327-0002-01

DRUG FACTS
<b>ACTIVE INGREDIENTS: PURPOSE</b> Ethyl Alcohol 70%.....Antiseptic, Hand Sanitizer
<b>USES:</b> For hand washing to decrease bacteria on the skin - recommended for repeated use.
<b>Warnings:</b> For external use only - Flammable. Keep away from heat and flame.
<b>DO NOT USE:</b> Children less than 2 months of age - on open skin wounds.
<b>WHEN USING THIS PRODUCT:</b> 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 serious condition. Keep out of reach of children. If swallowed, get medical help or contact a Poison Control Center immediately.
<b>DIRECTIONS:</b> Wet hands thoroughly with product, and allow to dry without wiping. For children under six, use only under adult supervision.
<b>INACTIVE INGREDIENTS:</b> Purified water, Hydrogen peroxide, Glycerin, Carbomer
<b>OTHER INFORMATION:</b> Store between 15-30C. Avoid freezing and excessive heat above 40C (104F). May discolor some fabrics. Harmful to wood finishes and plastics.



70% ALCOHOL  
**HAND SANITIZER**  
UNSCENTED

1 GAL (3785mL)

Sani Stand  
50 W Broadway Ste 333  
Salt Lake City, UT 84101

NDC 78327-0002-1



**SANI STAND 70% GEL UNSCENTED**

alcohol gel

**Product Information**

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:78327-0002
<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	70 mL in 100 mL

**Inactive Ingredients**

<b>Ingredient Name</b>	<b>Strength</b>
CARBOXYPOLYMETHYLENE (UNII: 0A5MM307FC)	4 mL in 100 mL
GLYCERIN (UNII: PDC6A3C0OX)	1.45 mL in 100 mL
HYDROGEN PEROXIDE (UNII: BBX060AN9V)	0.125 mL in 100 mL
WATER (UNII: 059QF0KO0R)	

**Packaging**

#	<b>Item Code</b>	<b>Package Description</b>	<b>Marketing Start Date</b>	<b>Marketing End Date</b>
1	NDC:78327-0002-1	3785 mL in 1 BOTTLE; Type 0: Not a Combination Product	03/30/2020	

**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	03/30/2020	

**Labeler** - Narrativo (084615891)**Registrant** - Narrativo (084615891)**Establishment**

<b>Name</b>	<b>Address</b>	<b>ID/FEI</b>	<b>Business Operations</b>
Narrativo		084615891	manufacture(78327-0002)

Revised: 6/2020

Narrativo