# SX INDUSTRIES HAND SANITIZER GEL- alcohol gel SX Industries, 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.

-----

#### 70 Gel

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 (1.45% v/v).
- c. Hydrogen peroxide (0.125% v/v).
- d. Sterile distilled water or boiled cold water.
- e. Methacrylic Acid

# Active Ingredient(s)

Alcohol 70% v/v. Purpose: Antiseptic

### **Purpose**

Antiseptic, Hand Sanitizer

#### Use

For hand washing to decrease bacteria on the skin - recommended for repeated use.

#### **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 immediately.

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**

Wet hands thoroughly with product, and allow to dry without wiping. For children under six, use only under adult supervision.

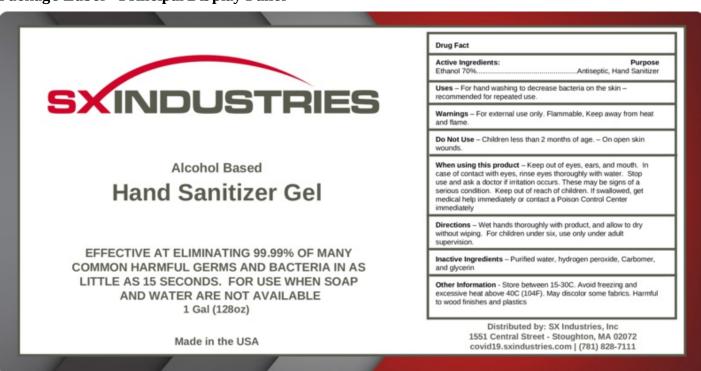
### Other information

- Store between 15-30C (59-86F)
- Avoid freezing and excessive heat above 40C (104F)
- May discolor some fabrics. Harmful to wood finishes and plastics.

## **Inactive ingredients**

glycerin, hydrogen peroxide, purified water USP

# Package Label - Principal Display Panel



#### SX INDUSTRIES HAND SANITIZER GEL

alcohol gel

Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:79767-001
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety			
Ingredient Name	Basis of Strength	Strength	
ALCOHOL (UNII: 3K9958 V90M) (ALCOHOL - UNII:3K9958 V90M)	ALCOHOL	70 mL in 100 mL	

Inactive Ingredients			
Ingredient Name	Strength		
METHACRYLIC ACID - ETHYL ACRYLATE COPOLYMER (4500 MPA.S) (UNII: T967IEU43C)	4 mL in 100 mL		
GLYCERIN (UNII: PDC6A3C0OX)	1.45 mL in 100 mL		
HYDRO GEN PERO XIDE (UNII: BBX060AN9V)	0.125 mL in 100 mL		
WATER (UNII: 059QF0KO0R)			

l	Packaging			
ı	# Item Code	Package Description	<b>Marketing Start Date</b>	Marketing End Date
ı	1 NDC:79767-001-01	3785 mL in 1 BOTTLE; Type 0: Not a Combination Product	07/14/2020	

Marketing Information				
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date	
OTC monograph not final	part333A	07/14/2020		

# **Labeler -** SX Industries, Inc. (001409374)

# **Registrant -** SX Industries, Inc. (001409374)

Establishment			
Name	Address	ID/FEI	Business Operations
SX industries, Inc.		001409374	manufacture (79767-001)

Revised: 7/2020 SX Industries, Inc.