

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



Alcohol Based
Hand Sanitizer Gel

EFFECTIVE AT ELIMINATING 99.99% OF MANY
COMMON HARMFUL GERMS AND BACTERIA IN AS
LITTLE AS 15 SECONDS. FOR USE WHEN SOAP
AND WATER ARE NOT AVAILABLE
1 Gal (128oz)

Made in the USA

Drug Fact	
Active Ingredients: Ethanol 70%.....	Purpose Antiseptic, Hand Sanitizer
Uses – For hand washing to decrease bacteria on the skin – recommended for repeated use.	
Warnings – For external use only. Flammable, Keep away from heat and flame.	
Do Not Use – 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 occurs. These may be signs of a serious condition. Keep out of reach of children. If swallowed, get medical help immediately or contact a Poison Control Center immediately	
Directions – Wet hands thoroughly with product, and allow to dry without wiping. For children under six, use only under adult supervision.	
Inactive Ingredients – Purified water, hydrogen peroxide, Carbomer, and glycerin	
Other information - Store between 15-30C. Avoid freezing and excessive heat above 40C (104F). May discolor some fabrics. Harmful to wood finishes and plastics	

Distributed by: SX Industries, Inc
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covid19.sxindustries.com | (781) 828-7111

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: 3K9958V90M) (ALCOHOL - UNII:3K9958V90M)	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	
HYDROGEN PEROXIDE (UNII: BBX060AN9V)			0.125 mL in 100 mL	
WATER (UNII: 059QF0KO0R)				
Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
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)