

**SCI 70 GEL HAND SANITIZER- alcohol gel**  
**Southern Chem Industries LLC**

*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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**70 No Fragrance Gel No HP**

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) (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. Carbomer

**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 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.

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, carbomer, and purified water USP

## Package Label - Principal Display Panel



Drug Facts	
<b>Active Ingredients:</b> Ethyl Alcohol 70%.....	<b>Purpose</b> 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 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.	
<b>Directions</b> — Wet hands thoroughly with product and allow to dry without wiping. For children under six years of age, use only under adult supervision.	
<b>Inactive Ingredients</b> — Purified water, carbomer, and glycerin.	
<b>Other Information</b> — Store between 15-30C. Avoid heating and excessive heat above 40C (104F). May discolor some fabrics. Harmful to wood finishes and plastics.	
<b>Questions Or Comments?</b> Call (985) 652-5196, M-F	



MANUFACTURED AND DISTRIBUTED BY:  
Wellness Care Solutions, LLC  
450 Tenth Street St.,  
Bossier, LA 70004  
(985) 652-5196

## SCI 70 GEL HAND SANITIZER

alcohol gel

### Product Information

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:55549-017
<b>Route of Administration</b>	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

<b>GLYCERIN</b> (UNII: PDC6A3C0OX)	1.45 mL in 100 mL
<b>WATER</b> (UNII: 059QF0KO0R)	
<b>METHACRYLIC ACID - ETHYL ACRYLATE COPOLYMER (4500 MPA.S)</b> (UNII: T967IEU43C)	4 mL in 100 mL

### Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:55549-017-64	1892 mL in 1 BOTTLE; Type 0: Not a Combination Product	03/30/2020	
2	NDC:55549-017-01	3785 mL in 1 BOTTLE; Type 0: Not a Combination Product	03/30/2020	
3	NDC:55549-017-05	18927 mL in 1 PAIL; Type 0: Not a Combination Product	03/30/2020	
4	NDC:55549-017-25	946353 mL in 1 CONTAINER, FLEXIBLE INTERMEDIATE BULK; Type 0: Not a Combination Product	03/30/2020	
5	NDC:55549-017-32	946 mL in 1 BOTTLE; Type 0: Not a Combination Product	03/30/2020	
6	NDC:55549-017-55	208198 mL in 1 DRUM; Type 0: Not a Combination Product	03/30/2020	
7	NDC:55549-017-30	1135500 mL in 1 CONTAINER, FLEXIBLE INTERMEDIATE BULK; Type 0: Not a Combination Product	03/30/2020	
8	NDC:55549-017-02	74 mL in 1 PACKET; 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** - Southern Chem Industries LLC (056025778)

**Registrant** - Southern Chem Industries LLC (056025778)

### Establishment

Name	Address	ID/FEI	Business Operations
Southern Chem Industries LLC		056025778	manufacture(55549-017)

Revised: 10/2020

Southern Chem Industries LLC