

SCI 70 HAND SANITIZER GEL- 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.

Fragrance Gel

- 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
- f. Fragrance

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Active Ingredient(s)

Alcohol 70% v/v. Purpose: Antiseptic

Purpose

Antiseptic, Hand Sanitizer

Use

For Hand-washing to decrease bacteria on skin - recommended for repeat 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)

Inactive ingredients

Purified water, hydrogen peroxide, Carbomer, fragrance and Glycerin

Package Label - Principal Display Panel



Drug Facts	
Active Ingredients: Ethyl Alcohol 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 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 years of age, use only under adult supervision.	
Inactive Ingredients — Purified water, hydrogen peroxide, carbomer, fragrance and glycerin.	
Other Information — Store between 15-30C. Avoid freezing and excessive heat above 40C (104F). May discolor some fabrics. Harmful to wood finished and plastics.	
Questions Or Comments? Call (985) 652-5198, M-F	



MANUFACTURED AND DISTRIBUTED BY:
Swakem Clean Industries, LLC
310 West Hesse Rd.,
Bossier, LA 70064
(985) 652-5198

46 mL NDC: 55549-002-32

or

1892 mL NDC: 55549-002-64

or

3785 mL NDC: 55549-002-01

or

118927 mL NDC: 55549-002-05

or

118927 mL NDC: 55549-002-55

or

946353 mL NDC: 55549-002-25

or

1135500 mL NDC: 55549-002-30

SCI 70 HAND SANITIZER GEL

alcohol gel

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:55549-002
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
GLYCERIN (UNII: PDC6A3C0OX)	1.45 mL in 100 mL
HYDROGEN PEROXIDE (UNII: BBX060AN9V)	0.125 mL in 100 mL
WATER (UNII: 059QF0K00R)	
FRAGRANCE LAVENDER & CHIA F-153480 (UNII: SXS9CO2TZK)	1 mL in 100 mL
METHACRYLIC ACID - ETHYL ACRYLATE COPOLYMER (4500 MPA.S) (UNII: T967IEU43C)	4 mL in 100 mL

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:55549-002-32	946 mL in 1 BOTTLE; Type 0: Not a Combination Product	03/30/2020	
2	NDC:55549-002-64	1892 mL in 1 BOTTLE; Type 0: Not a Combination Product	03/30/2020	
3	NDC:55549-002-01	3785 mL in 1 BOTTLE; Type 0: Not a Combination Product	03/30/2020	
4	NDC:55549-002-05	18927 mL in 1 PAIL; Type 0: Not a Combination Product	03/30/2020	
5	NDC:55549-002-55	208198 mL in 1 DRUM; Type 0: Not a Combination Product	03/30/2020	
6	NDC:55549-002-25	946353 mL in 1 CONTAINER, FLEXIBLE INTERMEDIATE BULK; Type 0: Not a Combination Product	03/30/2020	
7	NDC:55549-002-30	1135500 mL in 1 CONTAINER, FLEXIBLE INTERMEDIATE BULK; Type 0: Not a Combination Product	03/30/2020	
8	NDC:55549-002-02	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(55549-002)

Revised: 10/2020

Southern Chem Industries LLC