

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.

70 No Fragrance Gel

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, hydrogen peroxide, carbomer, and purified water USP

Package Label - Principal Display Panel

SCI 70 HAND SANITIZER GEL

alcohol gel

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:55549-003
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
ALCOHOL (UNII: 3K9958V90M) (ALCOHOL - UNII:3K9958V90M)	ALCOHOL	80 mL in 100 mL

Inactive Ingredients

Ingredient Name	Strength
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GLYCERIN (UNII: PDC6A3C0OX)	1.45 mL in 100 mL
HYDROGEN PEROXIDE (UNII: BBX060AN9V)	0.125 mL in 100 mL
WATER (UNII: 059QF0K00R)	
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:55549-003-64	1892 mL in 1 BOTTLE; Type 0: Not a Combination Product	03/30/2020	
2	NDC:55549-003-01	3785 mL in 1 BOTTLE; Type 0: Not a Combination Product	03/30/2020	
3	NDC:55549-003-05	18927 mL in 1 PAIL; Type 0: Not a Combination Product	03/30/2020	
4	NDC:55549-003-25	946353 mL in 1 CONTAINER, FLEXIBLE INTERMEDIATE BULK; Type 0: Not a Combination Product	03/30/2020	
5	NDC:55549-003-32	946 mL in 1 BOTTLE; Type 0: Not a Combination Product	03/30/2020	
6	NDC:55549-003-55	208198 mL in 1 DRUM; Type 0: Not a Combination Product	03/30/2020	
7	NDC:55549-003-30	1135500 mL in 1 CONTAINER, FLEXIBLE INTERMEDIATE BULK; Type 0: Not a Combination Product	03/30/2020	
8	NDC:55549-003-02	74 mL in 1 PACKET; Type 0: Not a Combination Product	03/30/2020	
9	NDC:55549-003-08	236 mL in 1 BOTTLE; 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(55549-003)

Revised: 11/2020

Southern Chem Industries LLC