

SCI 70 HAND SANITIZER- alcohol liquid
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 Liquid No Fragrance

- 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.

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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, and Glycerin

Package Label - Principal Display Panel

SCI 70 HAND SANITIZER			
alcohol liquid			
Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:55549-009
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		
GLYCERIN (UNII: PDC6 A3C0 OX)	1.45 mL in 100 mL		
HYDROGEN PEROXIDE (UNII: BBX060 AN9V)	0.125 mL in 100 mL		
WATER (UNII: 059QF0K00R)			
Packaging			

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:55549-009-32	946 mL in 1 BOTTLE; Type 0: Not a Combination Product	03/30/2020	
2	NDC:55549-009-64	1892 mL in 1 BOTTLE; Type 0: Not a Combination Product	03/30/2020	
3	NDC:55549-009-01	3785 mL in 1 BOTTLE; Type 0: Not a Combination Product	03/30/2020	
4	NDC:55549-009-05	18927 mL in 1 PAIL; Type 0: Not a Combination Product	03/30/2020	
5	NDC:55549-009-55	208198 mL in 1 DRUM; Type 0: Not a Combination Product	03/30/2020	
6	NDC:55549-009-25	946353 mL in 1 CONTAINER, FLEXIBLE INTERMEDIATE BULK; Type 0: Not a Combination Product	03/30/2020	
7	NDC:55549-009-30	1135500 mL in 1 CONTAINER, FLEXIBLE INTERMEDIATE BULK; 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(55549-009)

Revised: 10/2020

Southern Chem Industries LLC