

SCI 80 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.

80%

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) (80%, 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.

The firm does not add other active or inactive ingredients. Different or additional ingredients may impact the quality and potency of the product.

Active Ingredient(s)

Alcohol 80% 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 and flame.

Do not use

- in children less than 2 months of age
- on open skin wounds

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 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

- Place enough product on hands to cover all surfaces. Rub hands together until dry.
- Supervise children under 6 years of age when using this product to avoid swallowing.

Other information

Store between 15-30C Avoid freezing and excessive heat above 40C (104F). May discolor some fabrics. Harmful to wood finishes and plastics.

Inactive ingredients



SCI 80 Hand Sanitizer

*EFFECTIVE AT ELIMINATING 99.99% OF MANY COMMON HARMFUL GERMS & BACTERIA IN AS LITTLE AS 15 SECONDS FOR USE WHEN SOAP AND WATER ARE NOT AVAILABLE

hydrogen peroxide, purified water USP

Package Label - Principal Display Panel

Drug Facts	
Active Ingredients	Purpose
Ethyl Alcohol 80%	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 or rash occurs. These may be signs of serious condition. Keep out of reach of children. If swallowed, get medical help 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, fragrance, 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.	

Manufactured by:

Southern Chem Industries LLC
450 Terre Haute Rd. Reserve, LA 70084
985-652-5198

glycerin,



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NDC: 55549-001-32

or

1892 mL NDC: 55549-001-64

or

3785 mL NDC: 55549-001-01

or

118927 mL NDC: 55549-001-05

or

208198 mL NDC: 55549-001-55

or

946353 mL NDC: 55549-001-25

or

1135500 mL NDC: 55549-001-30

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946 mL

SCI 80 HAND SANITIZER

alcohol liquid

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:55549-001
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		
FRAGRANCE LAVENDER & CHIA F-153480 (UNII: SXS9CO2TZK)		1 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:55549-001-32	946 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	03/30/2020	
2	NDC:55549-001-01	3785 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	03/30/2020	
3	NDC:55549-001-05	18927 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	03/30/2020	
4	NDC:55549-001-64	1892 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	03/30/2020	
5	NDC:55549-001-25	946353 mL in 1 CONTAINER, FLEXIBLE INTERMEDIATE BULK; Type 0: Not a Combination Product	03/30/2020	
6	NDC:55549-001-30	1135500 mL in 1 CONTAINER, FLEXIBLE INTERMEDIATE BULK; Type 0: Not a Combination Product	03/30/2020	
7	NDC:55549-001-55	208198 mL in 1 DRUM; 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(55549-001)