# SCI 80 HAND SANITIZER WIPES- alcohol cloth 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 Wipes

- 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.

## 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 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

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. Discard wipe in trash receptacle after use. Do not flush. Children under 6 years of age whould be supervised when using this product.

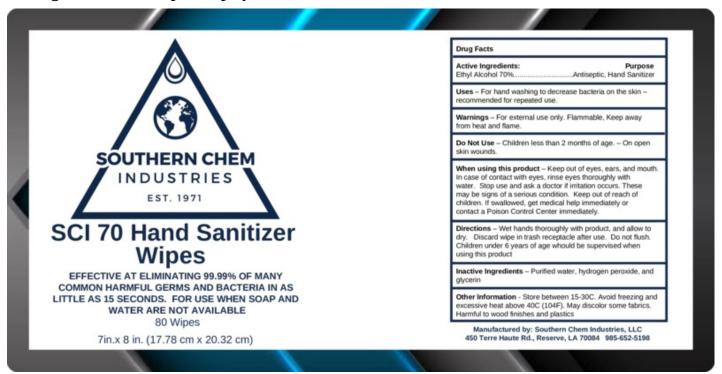
### Other information

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

## **Inactive ingredients**

glycerin, hydrogen peroxide, purified water USP

## Package Label - Principal Display Panel



#### SCI 80 HAND SANITIZER WIPES

alcohol cloth

Product Information				
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:55549-006	
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			
HYDRO GEN PERO XIDE (UNII: BBX060AN9V)	0.125 mL in 100 mL			
WATER (UNII: 059QF0KO0R)				

Packaging		

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:55549-006- 80	320 mL in 1 CANISTER; Type 0: Not a Combination Product	03/30/2020	
2	NDC:55549-006-25	500 mL in 1 CANISTER; Type 0: Not a Combination Product	03/30/2020	
3	NDC:55549-006-30	1200 mL in 1 PAIL; Type 0: Not a Combination Product	03/30/2020	
4	NDC:55549-006-40	1600 mL in 1 PAIL; Type 0: Not a Combination Product	08/01/2020	
5	NDC:55549-006-70	2800 mL in 1 PAIL; Type 0: Not a Combination Product	08/01/2020	
6	NDC:55549-006- 60	640 mL in 1 CANISTER; 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(55549-006)	

Revised: 8/2020 Southern Chem Industries LLC