

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.

Fragrance

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.

- e. Fragrance

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 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 should 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, and Fragrance

Package Label - Principal Display Panel

Drug Facts	
Active Ingredients: Ethyl Alcohol 80%.....	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 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.	
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 should be supervised when using this product	
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 finishes and plastics	
Manufactured by: Southern Chem Industries, LLC 450 Terre Haute Rd., Reserve, LA 70084 985-652-5198	

SCI 80 HAND SANITIZER WIPES

alcohol cloth

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:55549-005
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 LEMON ORC2001060 (UNII: K1725A7G95)	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:55549-005-80	480 mL in 1 CANISTER; Type 0: Not a Combination Product	03/30/2020	
2	NDC:55549-005-25	750 mL in 1 CANISTER; Type 0: Not a Combination Product	03/30/2020	
3	NDC:55549-005-30	1800 mL in 1 PAIL; Type 0: Not a Combination Product	03/30/2020	
4	NDC:55549-005-40	2400 mL in 1 PAIL; Type 0: Not a Combination Product	08/01/2020	
5	NDC:55549-005-70	4200 mL in 1 PAIL; Type 0: Not a Combination Product	08/01/2020	
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(55549-005)