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

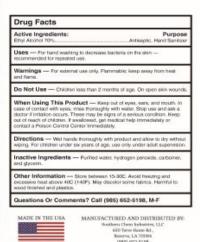
- Store between 15-30C (59-86F)
- Avoid freezing and excessive heat above 40C (104F)
- May discolor some fabrics. Harmful to wood finishes and plastics

Inactive ingredients

glycerin, hydrogen peroxide, carbomer, and purified water USP

Package Label - Principal Display Panel





SCI 70 HAND SANITIZER GEL

alcohol gel

| Prod | 11104 | Info | ито | tion |
|------|-------|------|-----|------|
| rna | IIICT | into | rma | TION |

| Product Type | HUMAN OTC DRUG | Item Code (Source) | NDC:55549-014 |
|--------------|----------------|--------------------|---------------|
| | | | |

Route of Administration TOPICAL

| Active | Ingre | dient/ | Active | Moiety |
|--------|-------|--------|--------|--------|
| | | | | |

| Ingredient Name | Basis of Strength | Strength |
|--|-------------------|-----------------|
| ALCOHOL (UNII: 3K9958V90M) (ALCOHOL - UNII:3K9958V90M) | ALCOHOL | 70 mL in 100 mL |

| Inactive Ing | reaients |
|--------------|----------|
|--------------|----------|

| Ingredient Name | Strengt | h |
|-----------------|---------|---|
| | | |

| GLYCERIN (UNII: PDC6A3C0OX) | 1.45 mL in 100 mL |
|---|--------------------|
| HYDRO GEN PERO XIDE (UNII: BBX060AN9V) | 0.125 mL in 100 mL |
| WATER (UNII: 059QF0KO0R) | |
| METHACRYLIC ACID - ETHYL ACRYLATE COPOLYMER (4500 MPA.S) (UNII: T967IEU43C) | 4 mL in 100 mL |

| P | Packaging | | | | |
|---|------------------------|--|-------------------------|-----------------------|--|
| # | Item Code | Package Description | Marketing Start Date | Marketing End Date | |
| 1 | NDC:55549 - 014-64 | 1892 mL in 1 BOTTLE; Type 0: Not a Combination Product | 03/30/2020 | | |
| 2 | NDC:55549 - 0 14-0 1 | 3785 mL in 1 BOTTLE; Type 0: Not a Combination Product | 03/30/2020 | | |
| 3 | NDC:55549 - 0 14-0 5 | 18927 mL in 1 PAIL; Type 0: Not a Combination Product | 03/30/2020 | | |
| 4 | NDC:55549 - 0 14-25 | 946353 mL in 1 CONTAINER, FLEXIBLE INTERMEDIATE BULK; Type 0: Not a Combination Product | 03/30/2020 | | |
| 5 | NDC:55549 - 014-32 | 946 mL in 1 BOTTLE; Type 0: Not a Combination Product | 03/30/2020 | | |
| 6 | NDC:55549 - 0 14-55 | 208198 mL in 1 DRUM; Type 0: Not a Combination Product | 03/30/2020 | | |
| 7 | NDC:55549 - 0 14-30 | 1135500 mL in 1 CONTAINER, FLEXIBLE INTERMEDIATE BULK; Type 0: Not a Combination Product | 03/30/2020 | | |
| 8 | NDC:55549 - 0 14-0 2 | 74 mL in 1 PACKET; 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 (55549-014) | | | |

Revised: 10/2020 Southern Chem Industries LLC