

SHSNH6-3600- isopropyl alcohol gel
Shotwell Hydrogenics, 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.

SHSNH6-3600 Antiseptic Gel Topical Solution HAND SANITIZER

Drug Facts

Active ingredients(s)

Isopropyl Alcohol 70% v/v

Purpose

Antiseptic

Use(s)

Hand sanitizer to help reduce bacteria that potentially can cause disease. For use when soap and water are not available

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 for a doctor if irritation 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(59-86F)

- Avoid freezing and excessive heat above 40C(104F)

Inactive ingredients

deionized water, polyethylene glycol, AMP-acrylates vinyl isodecanoate crosspolymer, glycerin

Packaging

| | |
|---|-----------------------------------|
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SHSNH6-3600

Isopropyl Alcohol 70%

Antiseptic Gel

Topical Solution

HAND SANITIZER

Tote
1249 Liters

| | |
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SHSNH6-3600

Isopropyl Alcohol 70%

Antiseptic Gel

Topical Solution

HAND SANITIZER

Tote
2 ounces

| | | | |
|--|----------------|---------------------------|---------------|
| SHSNH6-3600 | | | |
| isopropyl alcohol gel | | | |
| Product Information | | | |
| Product Type | HUMAN OTC DRUG | Item Code (Source) | NDC:73870-506 |
| Route of Administration | TOPICAL | | |
| Active Ingredient/Active Moiety | | | |

| Ingredient Name | | Basis of Strength | Strength | |
|--|--|---|----------------------|--------------------|
| ISOPROPYL ALCOHOL (UNII: ND2M416302) (ISOPROPYL ALCOHOL - UNII:ND2M416302) | | ISOPROPYL ALCOHOL | 70 L in 100 L | |
| Inactive Ingredients | | | | |
| Ingredient Name | | | Strength | |
| WATER (UNII: 059QF0KO0R) | | | | |
| POLYETHYLENE GLYCOL, UNSPECIFIED (UNII: 3WJQ0SDW1A) | | | | |
| AMINOMETHYLPROPANOL (UNII: LU49E6626Q) | | | | |
| ACRYLATES/VINYL ISODECANOATE CROSSPOLYMER (10000 MPA.S NEUTRALIZED AT 0.5%) (UNII: 2N8MDB79NA) | | | | |
| GLYCERIN (UNII: PDC6A3C0OX) | | | | |
| Packaging | | | | |
| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
| 1 | NDC:73870-506-33 | 1249 L in 1 CONTAINER; Type 0: Not a Combination Product | 06/24/2020 | |
| 2 | NDC:73870-506-02 | 0.059 L in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product | 03/16/2021 | |
| Marketing Information | | | | |
| Marketing Category | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date | |
| OTC monograph not final | part333A | 06/24/2020 | | |

Labeler - Shotwell Hydrogenics, LLC (108985732)

Establishment

| Name | Address | ID/FEI | Business Operations |
|---------------------------|---------|-----------|------------------------|
| Shotwell Hydrogenics, LLC | | 108985732 | manufacture(73870-506) |

Revised: 3/2021

Shotwell Hydrogenics, LLC