

SHIELDTEK HAND SANITIZER- alcohol gel

Froggy's Fog 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.

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

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 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.

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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

glycerin, hydrogen peroxide, purified water USP

ShieldTEK Hand Sanitizer



The image shows the front of a 1 US Gallon (3785.41 ml) bottle of ShieldTEK Hand Sanitizer. The packaging is primarily blue and white with a large blue wave-like shape in the center containing the product name and key features. The text on the packaging includes: 'Advanced HAND SANITIZER', '70% Alcohol Based Antiseptic Gel', 'Kills 99.9% of Bacteria', 'Non-sterile Topical Solution', and '1 US Gallon (3785.41 ml)'. The ShieldTEK logo is at the top right. On the right side, there is a 'DRUG FACTS' box with sections for Active Ingredients, Uses, Warnings, Do not use, Directions, Other information, and Inactive Ingredients. At the bottom right, there is a barcode with the number 8 13732 01459 3 and the company name CONTROLTEK with contact information.

DRUG FACTS

ACTIVE INGREDIENTS:
Ethyl alcohol 70% v/v antiseptic

Uses:
Hand sanitizer to help reduce bacteria that potentially can cause disease. For use when soap and water are unavailable.

Warnings:
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Other information:

- Store between 15°-30° C (59°-86° F)
- Avoid freezing and excessive heat above 40° C (104° F)

Inactive Ingredients:
acrylate polymer, aminoethyl propanol, fragrance, glycerin, hydrogen peroxide, polyethylene glycol, purified water USP.

CONTROLTEK
1536 N. Main St., Mt. Pleasant, TN 38474
ph: 888.808.6970 | controltekusa.com
NDC: 75682-734-01

8 13732 01459 3

3785.41mL NDC: 75862-734-01



ShieldTEK™

Advanced

HAND SANITIZER

70% Alcohol Based Antiseptic Gel

Kills 99.9% of Bacteria

Non-sterile Topical Solution

32 fl oz (946 ml)

DRUG FACTS

ACTIVE INGREDIENTS:

Ethyl alcohol 70% v/v antiseptic

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Hand sanitizer to help reduce bacteria that potentially can cause disease. For use when soap and water are unavailable.

Warnings:

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NDC: 75682-734-32



946mL NDC: 75682-734-32

ShieldTEK™

Advanced
HAND SANITIZER
70% Alcohol Based Antiseptic Gel
Kills 99.9% of Bacteria

Non-sterile Topical Solution
8 fl oz (236 ml)

DRUG FACTS

ACTIVE INGREDIENTS:
Ethyl alcohol 70% v/v antiseptic

Uses:
Hand sanitizer to help reduce bacteria that potentially can cause disease. For use when soap and water are unavailable.

Warnings:
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Do not use

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CONTROLTEK
 1536 N. Main St., Mt. Pleasant, TN 38474
 ph: 888.808.6970 | controltekusa.com
NDC: 75682-734-08

236 mL NDC: 75682-734-08

SHIELDTEK HAND SANITIZER

alcohol gel

Product Information

| | | | |
|--------------------------------|----------------|---------------------------|---------------|
| Product Type | HUMAN OTC DRUG | Item Code (Source) | NDC:75682-734 |
| 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 |
|-------------------------------------|-------------------|
| LINALOOL, (+/-)- (UNII: D81QY6I88E) | |
| RAPIDGEL EZ1 (UNII: 33JH4A7R2K) | |
| LIMONENE, (+/-)- (UNII: 9MC3I34447) | |
| GERANIOL (UNII: L837108USY) | |
| GLYCERIN (UNII: PDC6A3C0OX) | 1.45 mL in 100 mL |

| | |
|---|--------------------|
| HYDROGEN PEROXIDE (UNII: BBX060AN9V) | 0.125 mL in 100 mL |
| WATER (UNII: 059QF0K00R) | |

Packaging

| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
|---|------------------|--|----------------------|--------------------|
| 1 | NDC:75682-734-08 | 236 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product | 03/30/2020 | |
| 2 | NDC:75682-734-32 | 946 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product | 03/30/2020 | |
| 3 | NDC:75682-734-01 | 3785.41 mL in 1 JUG; 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 - Froggy's Fog LLC (144348161)

Registrant - Froggy's Fog LLC (144348161)

Establishment

| Name | Address | ID/FEI | Business Operations |
|------------------|---------|-----------|------------------------|
| Froggy's Fog LLC | | 144348161 | manufacture(75682-734) |

Revised: 1/2021

Froggy's Fog LLC