

FRESHANDS INSTANT HAND SANITIZER GEL- alcohol gel

Consolidated Chemicals, 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% Alcohol Gel Sanitizer (Acrylate & HPMC)

70% Alcohol Gel Sanitizer

This hand sanitizer is an over the counter drug product manufactured with active and inactive ingredients provided below:

Active Ingredient: Ethyl Alcohol 70% v/v

Inactive Ingredients: water, acrylate copolymer, glycerin, hydroxypropyl methylcellulose, aloe barbadensis, tocopheryl acetate, triethanolamine, fragrance

Manufacturing of this hand sanitizer is consistent with 21 CFR Part 310.

Active Ingredient(s)

Alcohol 70% 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

water, acrylate copolymer, glycerin, hydroxypropyl methylcellulose, aloe barbadensis, tocopheryl acetate, triethanolamine, fragrance

Package Label - Principal Display Panel

FresHands™ Instant Hand Sanitizer Gel

70% Alcohol


*Contains Aloe, Vitamin E
& Glycerin*

Dye Free

Kills 99.9% of most common
germs that may cause illness.

DANGER: FLAMMABLE
KEEP OUT OF REACH OF CHILDREN.
KEEP AWAY FROM FIRE OR FLAME.
FOR EXTERNAL USE ONLY.
See other cautions on opposite panel
of label.

4 fl. oz. (118 ml)

| Drug Facts | |
|---|------------------------------|
| Active Ingredient 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 <ul style="list-style-type: none">• 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. | |
| Directions <ul style="list-style-type: none">• 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 <ul style="list-style-type: none">• Store between 15-30C (59-86F)• Avoid freezing and excessive heat above 40C (104F) | |
| Inactive ingredients water, acrylate copolymer, glycerin, hydroxypropyl methylcellulose, aloe barbadensis, tocopheryl acetate, triethanolamine, fragrance | |
|  Consolidated Chemicals, LLC , 3191 West Tharpe St., Tallahassee FL 32303 Ph: (850) 575-0321 | |

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8 fl. oz. (236 ml)

Drug Facts

| Active Ingredient | Purpose |
|-----------------------|------------|
| Alcohol 70% v/v | Antiseptic |

Use[s]
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11 fl. oz. (325 ml)

| Drug Facts | |
|--|------------------------------|
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| Warnings For external use only. Flammable. Keep away from heat or flame. | |
| Do not use <ul style="list-style-type: none"> • 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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1 Gal (3.8 L)

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3800 mL NDC: 75632-230-40

FRESHHANDS INSTANT HAND SANITIZER GEL

alcohol gel

Product Information

| | | | |
|--------------------------------|----------------|---------------------------|---------------|
| Product Type | HUMAN OTC DRUG | Item Code (Source) | NDC:75632-230 |
| Route of Administration | TOPICAL | | |

Active Ingredient/Active Moiety

| Ingredient Name | Basis of Strength | Strength |
|---|-------------------|---------------|
| ALCOHOL (UNII: 3K9958V90M) (ALCOHOL - UNII:3K9958V90M) | ALCOHOL | 65 g in 100 g |

Inactive Ingredients

| Ingredient Name | Strength |
|--|------------------|
| .ALPHA.-TOCOPHEROL ACETATE (UNII: 9E8X80D2L0) | 0.025 g in 100 g |
| TROLAMINE (UNII: 9O3K93S3TK) | 0.2 g in 100 g |
| BUTYL ACRYLATE/METHYL METHACRYLATE/METHACRYLIC ACID COPOLYMER (18000 MW) (UNII: JZ1374NL9E) | 2.75 g in 100 g |
| ALOE VERA LEAF (UNII: ZY81Z83H0X) | 0.1 g in 100 g |
| GLYCERIN (UNII: PDC6A3C0OX) | 2 g in 100 g |
| HYPROMELLOSES (UNII: 3NXW29V3WO) | 0.375 g in 100 g |

WATER (UNII: 059QF0KO0R)

Packaging

| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
|---|------------------|---|----------------------|--------------------|
| 1 | NDC:75632-230-40 | 3328 g in 1 JUG; Type 0: Not a Combination Product | 07/10/2020 | |
| 2 | NDC:75632-230-11 | 286 g in 1 BOTTLE, PUMP; Type 0: Not a Combination Product | 07/10/2020 | |
| 3 | NDC:75632-230-08 | 208 g in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product | 07/10/2020 | |
| 4 | NDC:75632-230-04 | 104 g in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product | 07/10/2020 | |

Marketing Information

| Marketing Category | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date |
|-------------------------|--|----------------------|--------------------|
| OTC monograph not final | part333A | 07/10/2020 | |

Labeler - Consolidated Chemicals, LLC (117478303)

Registrant - Consolidated Chemicals, LLC (117478303)

Establishment

| Name | Address | ID/FEI | Business Operations |
|-----------------------------|---------|-----------|------------------------|
| Consolidated Chemicals, LLC | | 117478303 | manufacture(75632-230) |

Revised: 12/2022

Consolidated Chemicals, LLC