

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) AMP Neutralizer

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, aminomethyl propanol, 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, aminomethyl propanol, fragrance

Package Label - Principal Display Panel



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.

NET CONTENT 11 fl. oz. (325ml)

Drug Facts

Active Ingredient	Purpose
Alcohol 70% v/v	Antiseptic

Use[s]
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CONSOLIDATED CHEMICALS, LLC
3191 W Tharpe St, Tallahassee, FL 32303 USA
Ph: 850.575.0921 Fax: 850.270.6899
consolidatedchemicals.com

MADE IN THE USA

FRESHHANDS™
INSTANT HAND SANITIZER GEL

Contains Aloe, Vitamin E & Glycerin

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.

NET CONTENT 1 Gal (3.8L)

Drug Facts

Active Ingredient
Alcohol 70% v/v Antiseptic

Purpose
Antiseptic

Use[s]
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1 Gal NDC: 75632-240-40

FRESHHANDS INSTANT HAND SANITIZER GEL

alcohol gel

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:75632-240
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
AMINOMETHYLPROPANOL (UNII: LU49E6626Q)	0.065 g in 100 g
.ALPHA.-TOCOPHEROL ACETATE (UNII: 9E8X80D2L0)	0.025 g in 100 g
GLYCERIN (UNII: PDC6A3C0OX)	2 g in 100 g
WATER (UNII: 059QF0KO0R)	
ALOE VERA LEAF (UNII: ZY81Z83H0X)	0.1 g in 100 g
BUTYL ACRYLATE/METHYL METHACRYLATE/METHACRYLIC ACID COPOLYMER (18000 MW) (UNII: JZ1374NL9E)	2.75 g in 100 g

HYPROMELLOSES (UNII: 3NXW29V3WO)

0.375 g
in 100 g

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:75632-240-40	3328 g in 1 JUG; Type 0: Not a Combination Product	08/25/2020	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part333A	08/25/2020	

Labeler - Consolidated Chemicals, LLC (117478303)

Registrant - Consolidated Chemicals, LLC (117478303)

Establishment

Name	Address	ID/FEI	Business Operations
Consolidated Chemicals, LLC		117478303	manufacture(75632-240)

Revised: 12/2022

Consolidated Chemicals, LLC