

HAND SANITIZER- alcohol liquid freedom chemical corporation

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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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

glycerin, hydrogen peroxide, purified water USP

Guardian Hand Sanitizer 1 gallon



HAND SANITIZER

1 GL (128 oz)

Drug Facts

Active ingredient

80% Ethyl Alcohol

Purpose

Antiseptic

Uses Hand sanitizer to help reduce bacteria on the skin

Warnings

Flammable. Keep away from fire or flame.

For external use only.

When using this product do not use in eyes. In case of contact with eyes, rinse with water.

Stop use and ask doctor if irritation and redness persist

Keep out of reach of children

If swallowed, get medical help promptly

Inactive Ingredients

Glycerine, Hydrogen Peroxide, Distilled Water

Manufactured By
Freedom Chemical Corporation
19685 Descartes, Foothill Ranch, CA 92610
Questions Call: 949.988.0488
www.GuardianSanitizer.com



MANUFACTURED IN USA



3785.41 mL NDC: 76548-001-01

Guardian Hand Sanitizer 1 gallon back

3785.41 mL NDC: 76548-001-01 Guardian Hand Sanitizer 1 gallon Front

HAND SANITIZER

alcohol liquid

Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:76548-001
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety		
Ingredient Name	Basis of Strength	Strength
ALCOHOL (UNII: 3K9958V90M) (ALCOHOL - UNII:3K9958V90M)	ALCOHOL	80 mL in 1000 mL

Inactive Ingredients	
Ingredient Name	Strength
GLYCERIN (UNII: PDC6A3C0OX)	1.45 mL in 1000 mL
HYDROGEN PEROXIDE (UNII: BBX060AN9V)	0.125 mL in 1000 mL
WATER (UNII: 059QF0K00R)	18.425 mL in 1000 mL

Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:76548-001-01	3785.41 mL in 1 BOTTLE; Type 9: Other Type of Part 3 Combination Product (e.g., Drug/Device/Biological Product)	04/08/2020	

Marketing Information			
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part333A	04/08/2020	

Labeler - freedom chemical corporation (015700913)

Registrant - freedom chemical corporation (015700913)

Establishment			
Name	Address	ID/FEI	Business Operations
freedom chemical corporation		015700913	manufacture(76548-001)

Revised: 4/2020

freedom chemical corporation