# GREEN DOOR DISTILLING COMPANY HAND SANITIZER- alcohol anti septic 80% topical solution spray

# **Green Door Distilling Company 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.

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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

#### **Package Label - Principal Display Panel**

118 mL NDC: 77054-114-04



#### GREEN DOOR DISTILLING COMPANY HAND SANITIZER

alcohol anti septic 80% topical solution spray

#### **Product Information**

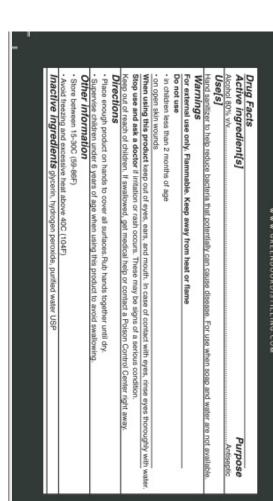
	Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:77054-118
ı	Route of Administration	TOPICAL		

ctive Ingredient/Active Moiety		
Ingredient Name	Basis of Strength	Strength
ALCOHOL (UNII: 3K9958 V90M) (ALCOHOL - UNII:3K9958 V90M)	ALCOHOL	94.4 mL in 118 mL

Inactive Ingredients		
Ingredient Name	Strength	
HYDRO GEN PERO XIDE (UNII: BBX060AN9V)	5.5 mL in 118 mL	
GLYCERIN (UNII: PDC6A3C0OX)	1.8 mL in 118 mL	
WATER (UNII: 059QF0KO0R)	16.3 mL in 118 mL	

Product Characteristics		
Color	Score	
Shape	Size	
Flavor	Imprint Code	
Contains		

Packaging			
# Item Code	Package Description	Marketing Start Date	Marketing End Date
NDC:77054-118- 04	118 mL in 1 BOTTLE, SPRAY; Type 0: Not a Combination Product	05/04/2020	





# **Marketing Information**

Marketing CategoryApplication Number or Monograph CitationMarketing Start DateMarketing End DateOTC monograph not finalpart333A05/04/2020

# Labeler - Green Door Distilling Company LLC (066326840)

### Registrant - Tyler Glasser (066326840)

Establishment				
Name	Address	ID/FEI	Business Operations	
Green Door Distilling Company LLC		066326840	manufacture(77054-118)	

Revised: 5/2020