SANIFY- alcohol gel
Ripshot Enterprises

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.

Hand Sanitizer

The hand sanitizer is manufactured using only the following ingredients in the preparation of the product (percentage in final product formulation).

a. Alcohol (ethanol) (71.35%, 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 (0.8648% v/v).
c. Hydrogen peroxide (0.1081% v/v).
d. Hydroxyethyl cellulose
e. Sterile distilled water or boiled cold water.

The alcohol utilized in this formulation is consistent with the recommendations outlined in the Temporary Policy for Preparation of Certain Alcohol-Based Hand Sanitizer Products During the Public Health Emergency (COVID-19) Guidance for Industry

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.

Stop use and ask a doctor if irritation or rash occurs. These may be signs of a serious condition.

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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

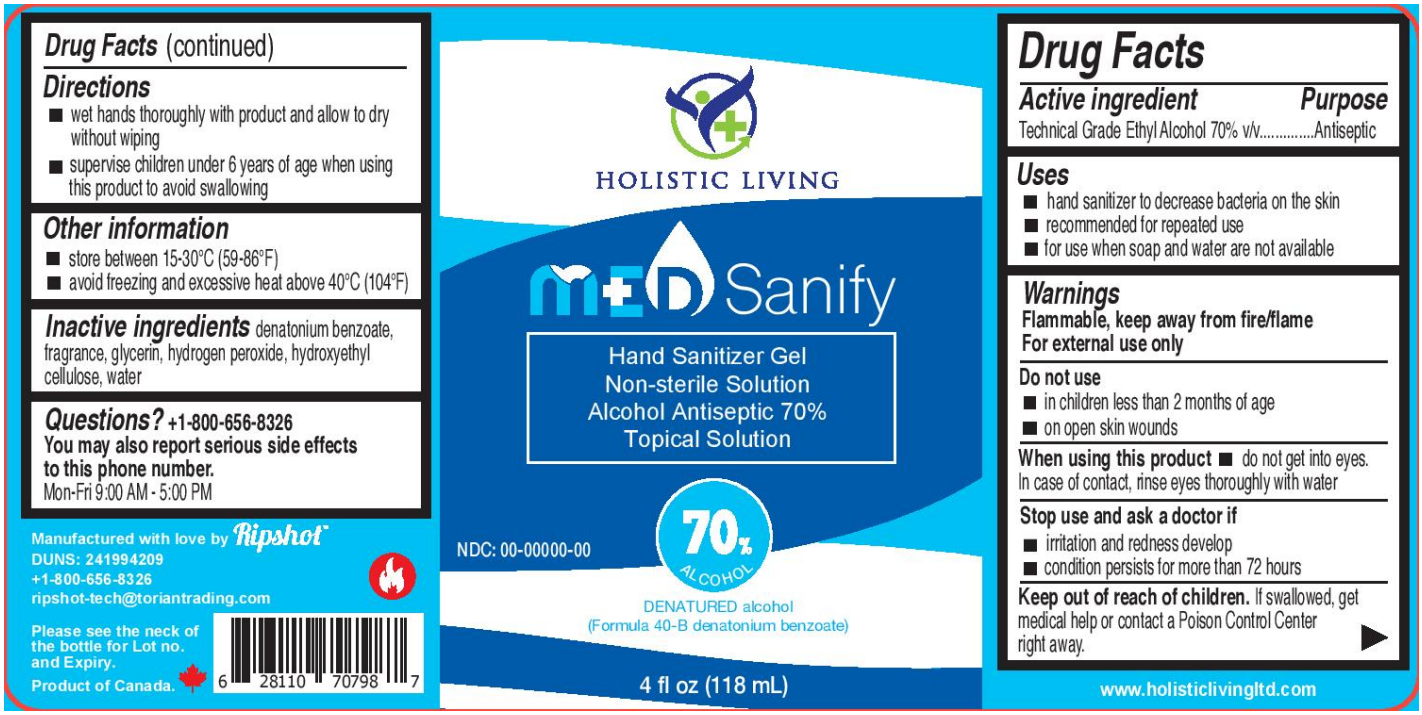
- Store between 15-30C (59-86F)
- Avoid freezing and excessive heat above 40C (104F)

Inactive ingredients

glycerin, hydrogen peroxide, purified water,Hydroxyethyl cellulose

Package Label - Principal Display Panel

118mL NDC: 78586-558-04



236mL NDC: 78586-558-08

500mL NDC: 78586-558-69

1000mL NDC:78586-558-10


HOLISTIC LIVING
MED Sanify
Hand Sanitizer Gel
Non-sterile Solution
Alcohol Antiseptic 70%
Topical Solution
NDC: 00000-000-00
70% ALCOHOL
DENATURED alcohol
(Formula 40-B denatonium benzoate)
33.81 fl oz (1 qt 1.81 fl oz) (1 L)

Drug Facts

Active ingredient **Purpose**

Technical Grade Ethyl Alcohol 70% v/v.....Antiseptic

Uses

- hand sanitizer to decrease bacteria on the skin
- recommended for repeated use
- for use when soap and water are not available

Warnings

Flammable, keep away from fire/flame
For external use only

Do not use

- in children less than 2 months of age
- on open skin wounds

When using this product ■ do not get into eyes. In case of contact, rinse eyes thoroughly with water.

Stop use and ask a doctor if

- irritation and redness develop
- condition persists for more than 72 hours

Keep out of reach of children. If swallowed, get medical help or contact a Poison Control Center right away.

Directions

- wet hands thoroughly with product and allow to dry without wiping
- supervise children under 6 years of age when using this product to avoid swallowing ▶

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Drug Facts (continued)

Other information

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

Inactive ingredients denatonium benzoate, fragrance, glycerin, hydrogen peroxide, hydroxyethyl cellulose, water

Questions? +1-800-656-8326
You may also report serious side effects to this phone number.
Mon-Fri 9:00 AM - 5:00 PM

Manufactured with love by Ripshot™
DUNS: 241994209
+1-800-656-8326
ripshot-tech@toriantrading.com

Please see the neck of the bottle for Lot no. and Expiry.

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Product of Canada.

SANIFY

alcohol gel

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:78586-558
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety		
Ingredient Name	**Basis of Strength**	**Strength**
ALCOHOL (UNII: 3K9958V90M) (ALCOHOL - UNII:3K9958V90M)	ALCOHOL	71.351 mL in 100 mL

Inactive Ingredients

Ingredient Name	Strength
HYDROXYETHYL CELLULOSE (100 MPA.S AT 2%) (UNII: R33S7TK2EP)	0.7027 mL in 100 mL
GLYCERIN (UNII: PDC6A3C0OX)	0.8648 mL in 100 mL
HYDROGEN PEROXIDE (UNII: BBX060AN9V)	0.1081 mL in 100 mL
WATER (UNII: 059QF0KO0R)	27.027 mL in 100 mL

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:78586-558-04	118.294 mL in 1 BOTTLE, DISPENSING; Type 0: Not a Combination Product	08/01/2020	
2	NDC:78586-558-08	236.588 mL in 1 BOTTLE, DISPENSING; Type 0: Not a Combination Product	08/01/2020	
3	NDC:78586-558-10	1000 mL in 1 BOTTLE, DISPENSING; Type 0: Not a Combination Product	08/01/2020	
4	NDC:78586-558-69	500 mL in 1 BOTTLE, DISPENSING; Type 0: Not a Combination Product	09/22/2020	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part333A	08/01/2020	

Labeler - Ripshot Enterprises (241994209)

Registrant - Ripshot Enterprises (241994209)

Establishment

Name	Address	ID/FEI	Business Operations
Lusty Libation Ltd.		203992437	manufacture(78586-558)

Revised: 9/2020 Ripshot Enterprises