

HANDS ANTISEPTIC HAND SANITIZER GEL- 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

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) (70%, 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 (0.86% v/v).
- c. Hydrogen peroxide (0.1081% v/v).
- d. Sterile distilled water or boiled cold water.
- e. Hydroxyethyl cellulose

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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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, hydroxyethyl cellulose

Package Label - Principal Display Panel

2oz NDC: 78586-555-02

Drug Facts (continued)

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

Other information

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

Inactive ingredients denatonium benzoate, 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 by: Lusty Libation Inc.
620 Superst Rd., Unit 5, Toronto, ON, Canada M3J 2M5

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

HOLISTIC LIVING

HANDS

Antiseptic Hand Sanitizer Gel

70% ALCOHOL

NDC: 000-00000-00

2 fl oz (60 mL)

Drug Facts

Active ingredient	Purpose
Ethyl alcohol 70%	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.

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4oz NDC: 78586-555-04

Drug Facts (continued)

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

Other information

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

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

Questions? +1-800-656-8326
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NDC: 00-00000-00
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620 Supertest Rd., Unit 5, Toronto, ON, Canada M3J 2M5

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**Antiseptic
Hand Sanitizer Gel**

70%

ALCOHOL

4 fl oz (118 mL)

Drug Facts

Active ingredient	Purpose
Ethyl alcohol 70%	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.

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8oz NDC: 78586-555-08

8 fl oz (237 mL)

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, glycerin, hydrogen peroxide, hydroxyethyl cellulose, water


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**Antiseptic
Hand Sanitizer Gel**

70%

ALCOHOL

Drug Facts

Active ingredient	Purpose
Ethyl alcohol 70%	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

NDC: 000-00000-00

16oz NDC: 78586-555-16

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, glycerin, hydrogen peroxide, hydroxyethyl cellulose, water

Questions? +1-800-656-8326
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Mon-Fri 9:00 AM - 5:00 PM

NDC: 00-00000-00

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HOLISTIC LIVING



Antiseptic Hand Sanitizer Gel



16 fl oz (500 mL)

Drug Facts

Active Ingredient	Purpose
Ethyl alcohol 70%	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/flammable
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

1L NDC: 78586-555-10



HOLISTIC LIVING



Antiseptic Hand Sanitizer Gel



NDC: 00-00000-00

34 fl oz (1 L)

Drug Facts

Active ingredient Purpose

Ethyl alcohol 70%.....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

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, glycerin, hydrogen peroxide, hydroxyethyl cellulose, water

Questions? +1-800-656-8326

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4L NDC: 78586-555-40



HOLISTIC LIVING



Antiseptic Hand Sanitizer Gel



NDC: 00-00000-00

135 fl oz (4 L)

Drug Facts

Active ingredient Purpose

Ethyl alcohol 70%.....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

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,
glycerin, hydrogen peroxide, hydroxyethyl cellulose,
water

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HANDS ANTISEPTIC HAND SANITIZER GEL

alcohol gel

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:78586-555
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
ALCOHOL (UNII: 3K9958V90M) (ALCOHOL - UNII:3K9958V90M)	ALCOHOL	71.35 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)	0.125 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:78586-555-02	59.1471 mL in 1 BOTTLE, DISPENSING; Type 0: Not a Combination Product	08/01/2020	
2	NDC:78586-555-04	118.294 mL in 1 BOTTLE, DISPENSING; Type 0: Not a Combination Product	08/01/2020	
3	NDC:78586-555-08	236.588 mL in 1 BOTTLE, DISPENSING; Type 0: Not a Combination Product	08/01/2020	
4	NDC:78586-555-16	473.176 mL in 1 BOTTLE, DISPENSING; Type 0: Not a Combination Product	08/01/2020	
5	NDC:78586-555-10	1000 mL in 1 BOTTLE, DISPENSING; Type 0: Not a Combination Product	08/01/2020	
6	NDC:78586-555-40	4000 mL in 1 BOTTLE, DISPENSING; Type 0: Not a Combination Product	08/01/2020	

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(78586-555)

Revised: 7/2020

Ripshot Enterprises