

DEFENSE ANTISEPTIC HAND SANITIZER- ethyl alcohol gel
Lusty Libation Ltd.

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.

Defense Antiseptic Hand Sanitizer Gel

Drug Facts

Active ingredient

Ethyl alcohol 70%

Purpose

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

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?

You may also report serious side effects to this phone number.

Mon-Fri 9:00 AM - 5:00 PM

HOLISTIC LIVING

NPN: 80099248

Manufactured by: Lusty Libation Inc. 620 Supertest Rd., Unit 5, Toronto, ON, Canada M3J 2M5

Product of Canada.

www.holisticlivingltd.com

Packaging

Package 60 mL



Package 118 mL



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

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 620 Supertest Rd., Unit 5, Toronto, ON, Canada M3J 2M5

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



Hand Sanitizer Gel

NPN: 80099248

70% ALCOHOL

4 fl oz (118 mL)

■ 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.

Package 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, fragrance, glycerin, hydrogen peroxide, hydroxyethyl cellulose, water

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HOLISTIC LIVING

def+nse

Antiseptic Hand Sanitizer Gel

NPN: 80099248

70% ALCOHOL

8 fl oz (237 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.

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

Package 500 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, fragrance, glycerin, hydrogen peroxide, hydroxyethyl cellulose, water

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HOLISTIC LIVING

def+nse

Antiseptic Hand Sanitizer Gel

NPN: 80099248

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

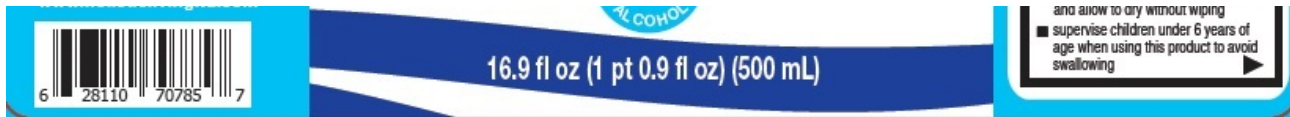
Stop use and ask a doctor if

- 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



Packaging

Package 1L



Drug Facts	
Active ingredient	Purpose
Ethyl alcohol 70%	Antiseptic
Uses	
<ul style="list-style-type: none"> 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	
<ul style="list-style-type: none"> in children less than 2 months of age on open skin wounds 	
When using this product	
<ul style="list-style-type: none"> do not get into eyes. In case of contact, rinse eyes thoroughly with water. 	
Stop use and ask a doctor if	
<ul style="list-style-type: none"> 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	
<ul style="list-style-type: none"> 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
<ul style="list-style-type: none"> 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
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Package 4 L



Drug Facts	
Active ingredient	Purpose
Ethyl alcohol 70%	Antiseptic
Uses	
<ul style="list-style-type: none"> 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	
<ul style="list-style-type: none"> in children less than 2 months of age on open skin wounds 	
When using this product	
<ul style="list-style-type: none"> do not get into eyes. In case of contact, rinse eyes thoroughly with water. 	
Stop use and ask a doctor if	
<ul style="list-style-type: none"> 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	
<ul style="list-style-type: none"> 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
<ul style="list-style-type: none"> 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
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DEFNSE ANTISEPTIC HAND SANITIZER

ethyl alcohol gel

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:77846-888
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
ALCOHOL (UNII: 3K9958V90M) (ALCOHOL - UNII:3K9958V90M)	ALCOHOL	70 mL in 100 mL

Inactive Ingredients

Ingredient Name	Strength
DENATONIUM BENZOATE (UNII: 4YK5Z54AT2)	
GLYCERIN (UNII: PDC6A3C0OX)	
HYDROGEN PEROXIDE (UNII: BBX060AN9V)	
HYDROXYETHYL CELLULOSE, UNSPECIFIED (UNII: T4V6TWG28D)	
WATER (UNII: 059QF0KO0R)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:77846-888-02	60 mL in 1 BOTTLE; Type 0: Not a Combination Product	07/26/2020	
2	NDC:77846-888-04	118 mL in 1 BOTTLE; Type 0: Not a Combination Product	07/26/2020	
3	NDC:77846-888-08	237 mL in 1 BOTTLE; Type 0: Not a Combination Product	07/26/2020	
4	NDC:77846-888-16	500 mL in 1 BOTTLE; Type 0: Not a Combination Product	07/26/2020	
5	NDC:77846-888-10	1000 mL in 1 BOTTLE; Type 0: Not a Combination Product	07/26/2020	
6	NDC:77846-888-40	4000 mL in 1 BOTTLE; Type 0: Not a Combination Product	07/26/2020	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part333A	07/26/2020	

Labeler - Lusty Libation Ltd. (203992437)

Establishment

Name	Address	ID/FEI	Business Operations
Lusty Libation Ltd.		203992437	manufacture(77846-888)

