

HAND SANITIZER- alcohol gel

Ripshot Enterprises Corp

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) (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 (4% v/v).
- c. Hydrogen peroxide (0.1251% v/v).
- d. Sterile distilled water or boiled cold water.
- e. Polyquaternium-10 (1%v/v) for its anti-static and moisturizing properties

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

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, Polyquaternium-10

Ripshot Hand Sanitizer Formula

59.1471mL NDC: 78586-435-02

RECOMMENDED FORMULA 70%

Drug Facts

Active Ingredient(s)	Purpose
Alcohol 70% v/v	Antiseptic

Use(s) 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.

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Other information

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

inactive ingredients glycerin, hydrogen peroxide, polyquaternium-10

Ripshot™

HAND SANITIZER FORMULA

DENATURED ALCOHOL

MADE IN CANADA **ALCOHOL BASED 70%**

2oz

**ETHANOL (ETHYL ALCOHOL)
70% AS DETERMINED BY
DIGITAL DENSITY METER.**

**FOR USE IN PRODUCTION OF
HAND SANITIZERS
(ANTISEPTIC HANDRUBS) ONLY.
NOT POTABLE**

MANUFACTURED WITH LOVE

BY: **Ripshot™** BOTTLING CO.
ONTARIO, CANADA
403-816-7468
INFO@RIPSHOT.CO
DUNS: 241994209
NDC:

6 28110 81297 1

OR

Drug Facts	
Active ingredient[s]	Purpose
Alcohol 70% v/v	Antiseptic
Use[s] 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	
<ul style="list-style-type: none"> • 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.	
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• Supervise children under 6 years of age when using this product to avoid swallowing.	
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 glycerin, hydrogen peroxide, polyquatonium-10, purified water USP	
Questions? 1-855-368-1585 (M-F 8:30am-4:30pm EST).	

PPEGlobalHealth®

Hand Sanitizer Gel

Non-sterile Solution



Alcohol Antiseptic 70%
Topical Solution

2 FL OZ (59 mL)

Distributed by: PPE Global Health
1022 E Lancaster Ave, Bryn Mawr, Pa 19010 USA
PPEGlobalHealth.com Made in Canada LOT:



118.294mL NDC: 78586-435-04

Drug Facts

Active ingredient(s)	Purpose
Alcohol 70% v/v	Antiseptic

Use(s): 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.

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, polyquat-ernium-10



Ripshot™

HAND
SANITIZER
FORMULA

DENATURED ALCOHOL



4oz

ETHANOL (ETHYL ALCOHOL)
70% AS DETERMINED BY
DIGITAL DENSITY METER.

FOR USE IN PRODUCTION OF
HAND SANITIZERS
(ANTISEPTIC HANDRUBS) ONLY.
NOT POTABLE



BY: *Ripshot* BOTTLING CO.
ONTARIO, CANADA
403-816-7468
INFO@RIPSHOT.CO
DUNS: 241994209
NDC:



OR

PPE Global Health[®] Hand Sanitizer Gel

Non-sterile Solution



Alcohol Antiseptic 70%
Topical Solution

4 FL OZ (118 mL)

Drug Facts

Active ingredient[s]	Purpose
Alcohol 70% v/v	Antiseptic

Use[s] 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.

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Keep out of reach of children. If swallowed, get medical help or contact a Poison Control Center right 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 15-30°C (59-86°F)
- Avoid freezing and excessive heat above 40°C (104°F)

Inactive ingredients glycerin, hydrogen peroxide, polyquaterrium-10, purified water USP

Questions? 1-855-368-1585 (M-F 8:30am-4:30pm EST).

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1022 E Lancaster Ave, Bryn Mawr, Pa 19010 USA
PPEGlobalHealth.com
Made in Canada



236.588mL NDC: 78586-435-08

Drug Facts

Active ingredient(s)	Purpose
Alcohol 70% v/v	Antiseptic

Use(s): 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.

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, polyquat-ernium-10



Ripshot™

HAND
SANITIZER
FORMULA

DENATURED ALCOHOL



8oz

ETHANOL (ETHYL ALCOHOL)
70% AS DETERMINED BY
DIGITAL DENSITY METER.

FOR USE IN PRODUCTION OF
HAND SANITIZERS
(ANTISEPTIC HANDRUBS) ONLY.
NOT POTABLE



BY: *Ripshot* BOTTLING CO.
ONTARIO, CANADA
403-816-7468
INFO@RIPSHOT.CO
DUNS: 241994209
NDC:



473.176mL NDC: 78586-435-16

Drug Facts

Active ingredient(s)	Purpose
Alcohol 70% v/v	Antiseptic

Use(s): 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.

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Keep out of reach of children. If swallowed, get medical help or contact a Poison Control Center right 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, polyquat-ernium-10



Ripshot™

HAND
SANITIZER
FORMULA

DENATURED ALCOHOL



16oz

ETHANOL (ETHYL ALCOHOL)
70% AS DETERMINED BY
DIGITAL DENSITY METER.

FOR USE IN PRODUCTION OF
HAND SANITIZERS
(ANTISEPTIC HANDRUBS) ONLY.
NOT POTABLE



BY: *Ripshot* BOTTLING CO.
ONTARIO, CANADA
403-816-7468
INFO@RIPSHOT.CO
DUNS: 241994209
NDC:



OR

PPE Global Health[®]

Hand Sanitizer Gel

Non-sterile Solution

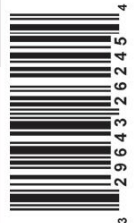


Alcohol Antiseptic 70%
Topical Solution

16 FL OZ (473 mL)

Drug Facts	
Active ingredient[s]	Purpose
Alcohol 70% v/v.....	Antiseptic
Use[s] 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 <ul style="list-style-type: none">• 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.	
Directions • Place enough product on hands to cover all surfaces. Rub hands together until dry. <ul style="list-style-type: none">• Supervise children under 6 years of age when using this product to avoid swallowing.	
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 glycerin, hydrogen peroxide, polyquaterrium-10, purified water USP	
Questions? 1-855-368-1585 (M-F 8:30am-4:30pm EST)	

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1022 E Lancaster Ave, Bryn Mawr, Pa 19010 USA
PPEGlobalHealth.com
Made in Canada
LOT:



946.353mL NDC: 78586-435-32

Drug Facts

Active ingredient(s)	Purpose
Alcohol 70% v/v	Antiseptic

Use(s): 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

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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, polyquat-ernium-10



Ripshot™

HAND
SANITIZER
FORMULA

DENATURED ALCOHOL



32oz

ETHANOL (ETHYL ALCOHOL)
70% AS DETERMINED BY
DIGITAL DENSITY METER.

FOR USE IN PRODUCTION OF
HAND SANITIZERS
(ANTISEPTIC HANDRUBS) ONLY.
NOT POTABLE



BY: *Ripshot* BOTTLING CO.
ONTARIO, CANADA
403-816-7468
INFO@RIPSHOT.CO
DUNS: 241994209
NDC:



OR

PPEGlobalHealth[®]

Hand Sanitizer Gel

Non-sterile Solution



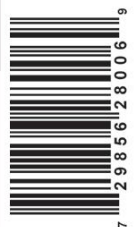
Alcohol Antiseptic 70%
Topical Solution

32 FL OZ (946 mL)

3785.41mL NDC: 78586-435-40

Drug Facts	
Active ingredient[s]	Purpose
Alcohol 70% v/v	Antiseptic
Use[s] 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 <ul style="list-style-type: none">• 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.	
Directions • Place enough product on hands to cover all surfaces. Rub hands together until dry. <ul style="list-style-type: none">• Supervise children under 6 years of age when using this product to avoid swallowing.	
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 glycerin, hydrogen peroxide, polyquaternium-10, purified water USP	
Questions? 1-855-368-1585 (M-F 8:30am-4:30pm EST).	

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PPEGlobalHealth.com
Made in Canada
LOT:



PPEGlobalHealth[®]

Hand Sanitizer Gel

Non-sterile Solution

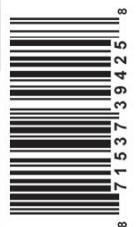


Alcohol Antiseptic 70%
Topical Solution

128 FL OZ (3785 mL)

Drug Facts	
Active ingredient[s]	Purpose
Alcohol 70% v/v	Antiseptic
Use[s] 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 <ul style="list-style-type: none">• in children less than 2 months of age• on open skin wounds	
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Inactive ingredients glycerin, hydrogen peroxide, polyquaternium-10, purified water USP	
Questions? 1-855-368-1585 (M-F 8:30am-4:30pm EST).	

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PPEGlobalHealth.com
Made in Canada
LOT:



HAND SANITIZER

alcohol gel

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:78586-435
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
POLYQUATERNIUM-10 (125 MPA.S AT 2 %) (UNII: L45WU8S981)	1 mL in 100 mL
DENATONIUM BENZOATE (UNII: 4YK5Z54AT2)	0.00049 mL in 100 mL
GLYCERIN (UNII: PDC6A3C0OX)	4 mL in 100 mL
HYDROGEN PEROXIDE (UNII: BBX060AN9V)	0.125 mL in 100 mL
WATER (UNII: 059QF0K00R)	24.8744 mL in 100 mL

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:78586-435-02	59.1471 mL in 1 BOTTLE, DISPENSING; Type 0: Not a Combination Product	07/30/2020	
2	NDC:78586-435-04	118.294 mL in 1 BOTTLE, DISPENSING; Type 0: Not a Combination Product	07/30/2020	
3	NDC:78586-435-08	236.588 mL in 1 BOTTLE, DISPENSING; Type 0: Not a Combination Product	07/30/2020	
4	NDC:78586-435-16	473.176 mL in 1 BOTTLE, DISPENSING; Type 0: Not a Combination Product	07/30/2020	
5	NDC:78586-435-32	946.353 mL in 1 BOTTLE, DISPENSING; Type 0: Not a Combination Product	07/30/2020	
6	NDC:78586-435-40	3780 mL in 1 BOTTLE, DISPENSING; Type 0: Not a Combination Product	08/19/2020	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part333A	03/30/2020	

Labeler - Ripshot Enterprises Corp (241994209)

Registrant - Ripshot Enterprises Corp (241994209)

Establishment			
Name	Address	ID/FEI	Business Operations
Ripshot Enterprises Corp		241994209	manufacture(78586-435)

Revised: 8/2020

Ripshot Enterprises Corp