

HAND SANITIZER- dr montys germ buster liquid

HAND SANITIZER- isopropyl alcohol liquid

Montezuma Winery 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.

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. Isopropyl Alcohol (75%, 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)

Isopropyl Alcohol 75% v/v. Purpose: Antiseptic

Drug Facts**Active ingredient[s]**

Isopropyl alcohol 75% v/v.....Antiseptic

Purpose**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, purified water USP

Dr. Monty's Ultimate Germ Buster
Formula approved by World Health Organization.

For external use only.

Produced & Bottled by:

Montezuma Winery & Hidden Marsh Distillery

Seneca Falls, NY

375mL

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& Hidden Marsh Distillery

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Monty's

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BUSTER



Gettin' ribbet germs!

Isopropyl Alcohol Antiseptic 75% | Topical Solution
Hand Sanitizer Non-Sterile Solution | 375mL

Alcohol 80% v/v. Purpose: Antiseptic

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Alcohol Antiseptic 80% | Topical Solution
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Antiseptic, Hand Sanitizer

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- Avoid freezing and excessive heat above 40C (104F)

Inactive ingredients glycerin, hydrogen peroxide, purified water USP

Dr. Monty's Ultimate Germ Buster
Formula approved by World Health Organization.

For external use only.

Produced & Bottled by:

Montezuma Winery & Hidden Marsh Distillery

Seneca Falls, NY

750mL

Stay healthy & happy!

Montezuma Winery
& Hidden Marsh Distillery

Dr.
Monty's

ULTIMATE
GERM
BUSTER



Gettin' ribbet germs!

Alcohol Antiseptic 80% | Topical Solution
Hand Sanitizer Non-Sterile Solution | 750mL

Inactive ingredients

glycerin, hydrogen peroxide, purified water USP

Drug Facts**Active ingredient[s]**

Isopropyl alcohol 75% v/v.....Antiseptic

Purpose**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, purified water USP

Dr. Monty's Ultimate Germ Buster
Formula approved by World Health Organization.

For external use only.

Produced & Bottled by:

Montezuma Winery & Hidden Marsh Distillery

Seneca Falls, NY

375mL

Stay healthy & happy!

Drug Facts

Active ingredient[s]

Alcohol 80% v/v.....

Purpose

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, purified water USP

Dr. Monty's Ultimate Germ Buster
Formula approved by World Health Organization.

For external use only.

Produced & Bottled by:

Montezuma Winery & Hidden Marsh Distillery

Seneca Falls, NY

750mL

Stay healthy & happy!

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& Hidden Marsh Distillery

Dr.
Monty's

ULTIMATE
GERM
BUSTER



Gettin' ribbet germs!

Alcohol Antiseptic 80% | Topical Solution
Hand Sanitizer Non-Sterile Solution | 750mL

Package Label - Principal Display Panel

375 ml NDC: 74357-0001-1

Drug Facts**Active ingredient[s]**

Isopropyl alcohol 75% v/v.....Antiseptic

Purpose**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, purified water USP

Dr. Monty's Ultimate Germ Buster
Formula approved by World Health Organization.

For external use only.

Produced & Bottled by:

Montezuma Winery & Hidden Marsh Distillery

Seneca Falls, NY

375mL

Stay healthy & happy!

Montezuma Winery
& Hidden Marsh Distillery

Dr.
Monty's

ULTIMATE
GERM
BUSTER



Gettin' ribbet germs!

Isopropyl Alcohol Antiseptic 75% | Topical Solution
Hand Sanitizer Non-Sterile Solution | 375mL

750 ml NDC: 74357-0002-2

Drug Facts

Active ingredient[s]

Alcohol 80% v/v.....

Purpose

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, purified water USP

Dr. Monty's Ultimate Germ Buster
Formula approved by World Health Organization.

For external use only.

Produced & Bottled by:

Montezuma Winery & Hidden Marsh Distillery

Seneca Falls, NY

750mL

Stay healthy & happy!

Montezuma Winery
& Hidden Marsh Distillery

Dr.
Monty's

ULTIMATE
GERM
BUSTER



Gettin' ribbet germs!

Alcohol Antiseptic 80% | Topical Solution
Hand Sanitizer Non-Sterile Solution | 750mL

HAND SANITIZER

dr montys germ buster liquid

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:74357-0002
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
ALCOHOL (UNII: 3K9958V90M) (ALCOHOL - UNII:3K9958V90M)	ALCOHOL	80 mL in 100 mL

Inactive Ingredients

Ingredient Name	Strength
GLYCERIN (UNII: PDC6A3C0OX)	1.45 mL in 100 mL
HYDROGEN PEROXIDE (UNII: BBX060AN9V)	0.125 mL in 100 mL
WATER (UNII: 059QF0KO0R)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:74357-0002-1	750 mL in 1 BOTTLE, GLASS; Type 0: Not a Combination Product	03/30/2020	
2	NDC:74357-0002-2	750 mL in 1 BOTTLE, GLASS; Type 0: Not a Combination Product	04/18/2020	

Marketing Information

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

HAND SANITIZER

isopropyl alcohol liquid

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:74357-0001
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
ISOPROPYL ALCOHOL (UNII: ND2M416302) (ISOPROPYL ALCOHOL - UNII:ND2M416302)	ISOPROPYL ALCOHOL	75 mL in 100 mL

Inactive Ingredients

Ingredient Name	Strength
GLYCERIN (UNII: PDC6A3C0OX)	1.45 mL in 100 mL
HYDROGEN PEROXIDE (UNII: BBX060AN9V)	0.125 mL in 100 mL
WATER (UNII: 059QF0KO0R)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
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1	NDC:74357-0001-1	750 mL in 1 BOTTLE, GLASS; Type 0: Not a Combination Product	03/30/2020	
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Marketing Information

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

Labeler - Montezuma Winery LLC (145480229)

Establishment

Name	Address	ID/FEI	Business Operations
Montezuma Winery LLC		145480229	manufacture(74357-0001, 74357-0002)

Revised: 4/2020

Montezuma Winery LLC