

CONTAMINX- alcohol liquid

Spotlight Medical Inc.

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. 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 (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)

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.

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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


Package Label - Principal Display Panel

59 mL NDC: 79384-101-01

DRUG FACTS	
Active Ingredient: 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 of flame	
Do not use <ul style="list-style-type: none">• on 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: <ul style="list-style-type: none">• 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: <ul style="list-style-type: none">• Store between 15-30C (59-86F)• Avoid freezing and excessive heat above 40C (104)	
Inactive ingredients: glycerin, hydrogen peroxide, purified water USP	

MADE IN THE USA

88 mL NDC: 79384-101-02



ALCOHOL ANTISEPTIC 80%

Sanitizing Liquid

3oz (88ml)

DRUG FACTS

Active Ingredient: Alcohol 80% v/v	Purpose Antiseptic
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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 of flame

Do not use

- on 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 (104)

Inactive ingredients: glycerin, hydrogen peroxide, purified water USP



MADE IN THE USA

118 mL NDC: 79384-101-03



ALCOHOL ANTISEPTIC 80%

Sanitizing Liquid

4oz (118ml)

DRUG FACTS

Active Ingredient: Alcohol 80% v/v	Purpose Antiseptic
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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 of flame

Do not use

- on 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 (104)

Inactive ingredients: glycerin, hydrogen peroxide, purified water USP



MADE IN THE USA

236 mL NDC: 79384-101-04



ALCOHOL ANTISEPTIC 80%

Sanitizing Liquid

8oz (236ml)

DRUG FACTS

Active Ingredient:

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 of flame

Do not use

- on 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)
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Inactive ingredients: glycerin, hydrogen peroxide, purified water USP



**MADE IN
THE USA**

354 mL NDC: 79384-101-05



ALCOHOL ANTISEPTIC 80%

Sanitizing Liquid

12oz
(354 ml)

DRUG FACTS

Active Ingredient:
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 of flame

Do not use

- on 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 (104)

Inactive ingredients: glycerin, hydrogen peroxide, purified water USP





ALCOHOL ANTISEPTIC 80%

Sanitizing Liquid

16oz
(473 ml)

DRUG FACTS

Active Ingredient:
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 of flame

Do not use

- on 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 (104)

Inactive ingredients: glycerin, hydrogen peroxide, purified water USP





ALCOHOL ANTISEPTIC 80%

Sanitizing Liquid

64oz
(1892 ml)

DRUG FACTS

Active Ingredient:
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 of flame

Do not use

- on 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 (104)

Inactive ingredients: glycerin, hydrogen peroxide, purified water USP





ALCOHOL ANTISEPTIC 80%

Sanitizing Liquid **2.5 gal**
(9465 ml)

DRUG FACTS

Active Ingredient:
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 of flame

Do not use

- on 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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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 (104)

Inactive ingredients: glycerin, hydrogen peroxide, purified water USP

MADE IN THE USA 

18927 mL NDC: 79384-101-11



ALCOHOL ANTISEPTIC 80%

Sanitizing Liquid **5 gal**
(18927 ml)

DRUG FACTS

Active Ingredient:
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 of flame

Do not use

- on 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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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 (104)

Inactive ingredients: glycerin, hydrogen peroxide, purified water USP

MADE IN THE USA 

CONTAMINX

alcohol liquid

Product Information

Product Type

HUMAN OTC DRUG

Item Code (Source)

NDC:79384-101

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:79384-101-01	59 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	08/07/2020	
2	NDC:79384-101-02	88 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	08/07/2020	
3	NDC:79384-101-03	118 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	08/07/2020	
4	NDC:79384-101-04	236 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	08/07/2020	
5	NDC:79384-101-05	354 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	08/07/2020	
6	NDC:79384-101-06	473 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	08/07/2020	
7	NDC:79384-101-08	1892 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	08/07/2020	
8	NDC:79384-101-10	9465 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	08/07/2020	
9	NDC:79384-101-11	18927 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	08/07/2020	
Marketing Information				
Marketing Category		Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final		part333A	08/07/2020	

Labeler - Spotlight Medical Inc. (027833050)

Registrant - Spotlight Medical Inc. (027833050)

Establishment

Name	Address	ID/FEI	Business Operations
Spotlight Medical Inc.		027833050	manufacture(79384-101)