

## **ALCOHOL ANTISEPTIC- alcohol solution**

**Seaway Pharma 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.*

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### **Ethylalcohol 70% Hand sanitizer solution**

#### **Active Ingredient(s)**

Alcohol 70% v/v..... Purpose: Antiseptic

#### **Purpose**

Antiseptic

#### **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**

- 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 (104F)

#### **Inactive ingredients**

aloe vera gel, amino methyl propanol, carbomer, FD&C blue #1, FD&C yellow #10, fragrance, purified water, vitamin E

•may contain one or more of these ingredients if the product is a colored gel.

**Package Label - Principal Display Panel**

8 fl oz (237 mL) NDC: 73414-057-08

<b>Drug Facts</b>	<p>KILLS 99.9% GERMS</p>  <p>by SkinStitch</p> <h1>Hand Sanitizer</h1>  <p>Lemon Scent</p> <h2>Topical Liquid</h2> <p>70% Alcohol Antiseptic</p> <p>Hand Sanitizer • Non-sterile Solution</p> <p>8 fl oz (237 mL)</p>	<b>Drug Facts</b> (continued)
<b>Active Ingredient Purpose</b> Alcohol 70% v/v.....Antiseptic		<b>Directions</b>
<b>Uses</b> To help reduce bacteria that potentially can cause disease. For use when soap and water are not available.		■ 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.
<b>Warnings</b> For external use only. <b>Flammable. Keep away from heat or flame</b>		<b>Other Information</b>
<b>Do not use</b> ■ on children less than 2 months of age ■ on open skin wounds		■ Store between 15-30C (59-86F) ■ Avoid freezing and excessive heat above 40C (104F)
<b>When using this product</b> keep out of eyes, ears and mouth. In case of contact with eyes, rinse eyes thoroughly with water.	<b>Inactive Ingredients</b> FD&C blue #1*, fragrance, glycerin, hydrogen peroxide, purified water *may contain this ingredient if the product is a colored solution.	
<b>Stop use and ask a doctor</b> if irritation or rash occurs. These may be signs of a serious condition.	Distributed by  SkinStitch LLC  Massena, NY 13662 www.SkinDfense.com	
<b>Keep out of reach of children.</b> If swallowed, get medical help or contact a Poison Control Center right away.	 8 90965 00031 9	
	Lot # Exp.	

16 fl oz (473 mL) NDC: 73414-057-13

**Drug Facts**

**Active Ingredient Purpose**  
Alcohol 70% v/v...Antiseptic

**Uses**

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**

- 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. ▶

KILLS 99.9% GERMS



**Hand**   
**Sanitizer**



Lemon Scent

**Topical  
Liquid**

70% Alcohol  
Antiseptic

**Hand Sanitizer • Non-sterile Solution**  
**16 fl oz (473 mL)**

**Drug Facts** (continued)

**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**

FD&C blue #1\*, fragrance, glycerin, hydrogen peroxide, purified water,  
\*may contain this ingredient if the product is a colored solution.



Distributed by  
**USA SkinStitch LLC**  
Massena, NY 13662  
www.SkinDfense.com



32 fl oz (946 mL) NDC: 73414-057-14

**Drug Facts**

**Active Ingredient Purpose**  
Alcohol 70% v/v ... Antiseptic

**Uses**

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**

- 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. ▶

KILLS 99.9% GERMS

SkinDfense  
by SkinStitch

Hand Sanitizer



Lemon Scent

Topical Liquid

70% Alcohol Antiseptic

Hand Sanitizer • Non-sterile Solution

32 fl oz (946 mL)

**Drug Facts** (continued)

**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**

FD&C blue #1\*, fragrance, glycerin, hydrogen peroxide, purified water, \*may contain this ingredient if the product is a colored solution.



Distributed by

SkinStitch LLC



Massena, NY 13662  
www.SkinDfense.com



1 Gallon (3.78 L) NDC: 73414-057-91

KILLS 99.9% GERMS



**SkinDfense**  
by SkinStitch

# Hand Sanitizer

Topical Liquid

Lemon Scent      70% Alcohol Antiseptic

Hand Sanitizer • Non-sterile Solution  
1 Gallon (3.78 L)

**Drug Facts**

<b>Active Ingredient</b>	<b>Purpose</b>
Alcohol 70% v/v	Antiseptic
<b>Uses</b> To help reduce bacteria that potentially can cause disease. For use when soap and water are not available.	
<b>Warnings</b> For external use only. Flammable. Keep away from heat or flame	
<b>Do not use</b> <ul style="list-style-type: none"> <li>■ on children less than 2 months of age</li> <li>■ on open skin wounds</li> </ul>	
<b>When using this product</b> keep out of eyes, ears and mouth. In case of contact with eyes, rinse eyes thoroughly with water.	
<b>Stop use and ask a doctor</b> if irritation or rash occurs. These may be signs of a serious condition.	
<b>Keep out of reach of children.</b> If swallowed, get medical help or contact a Poison Control Center right away.	
<b>Directions</b> <ul style="list-style-type: none"> <li>■ Place enough product on hands to cover all surfaces. Rub hands together until dry.</li> <li>■ Supervise children under 6 years of age when using this product to avoid swallowing.</li> </ul>	
<b>Other Information</b> <ul style="list-style-type: none"> <li>■ Store between 15-30C (59-86F)</li> <li>■ Avoid freezing and excessive heat above 40C (104F)</li> </ul>	
<b>Inactive Ingredients</b> FD&C blue #1*, fragrance, glycerin, hydrogen peroxide, purified water, *may contain this ingredient if the product is a colored solution.	

Distributed by





Massena, NY 13662 • www.SkinDfense.com



8 90965 00038 8

**ALCOHOL ANTISEPTIC**

alcohol solution

**Product Information**

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:73414-057
<b>Route of Administration</b>	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
HYDROGEN PEROXIDE (UNII: BBX060AN9V)	
GLYCERIN (UNII: PDC6A3C0OX)	
FD&C BLUE NO. 1 (UNII: HBR47K3TBD)	
WATER (UNII: 059QF0K00R)	

**Product Characteristics**

<b>Color</b>		<b>Score</b>	
<b>Shape</b>		<b>Size</b>	

<b>Flavor</b>	LEMON	<b>Imprint Code</b>		
<b>Contains</b>				
<b>Packaging</b>				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:73414-057-01	59 mL in 1 BOTTLE; Type 0: Not a Combination Product	07/01/2020	
2	NDC:73414-057-04	118 mL in 1 BOTTLE; Type 0: Not a Combination Product	07/01/2020	
3	NDC:73414-057-06	177 mL in 1 BOTTLE; Type 0: Not a Combination Product	07/01/2020	
4	NDC:73414-057-08	177 mL in 1 BOTTLE; Type 0: Not a Combination Product	07/01/2020	
5	NDC:73414-057-13	473 mL in 1 BOTTLE; Type 0: Not a Combination Product	07/01/2020	
6	NDC:73414-057-14	946 mL in 1 BOTTLE; Type 0: Not a Combination Product	07/01/2020	
7	NDC:73414-057-91	3780 mL in 1 BOTTLE; Type 0: Not a Combination Product	07/01/2020	
<b>Marketing Information</b>				
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date	
OTC monograph not final	part333A	07/01/2020		

**Labeler** - Seaway Pharma Inc. (117218785)

**Registrant** - Seaway Pharma Inc. (117218785)

### Establishment

Name	Address	ID/FEI	Business Operations
Seaway Pharma Inc.		117218785	manufacture(73414-057)

Revised: 7/2020

Seaway Pharma Inc.