ALCOHOL ANTISEPTIC- alcohol gel
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.

Ethylalcohol 70% Hand sanitizer gel

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

- 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

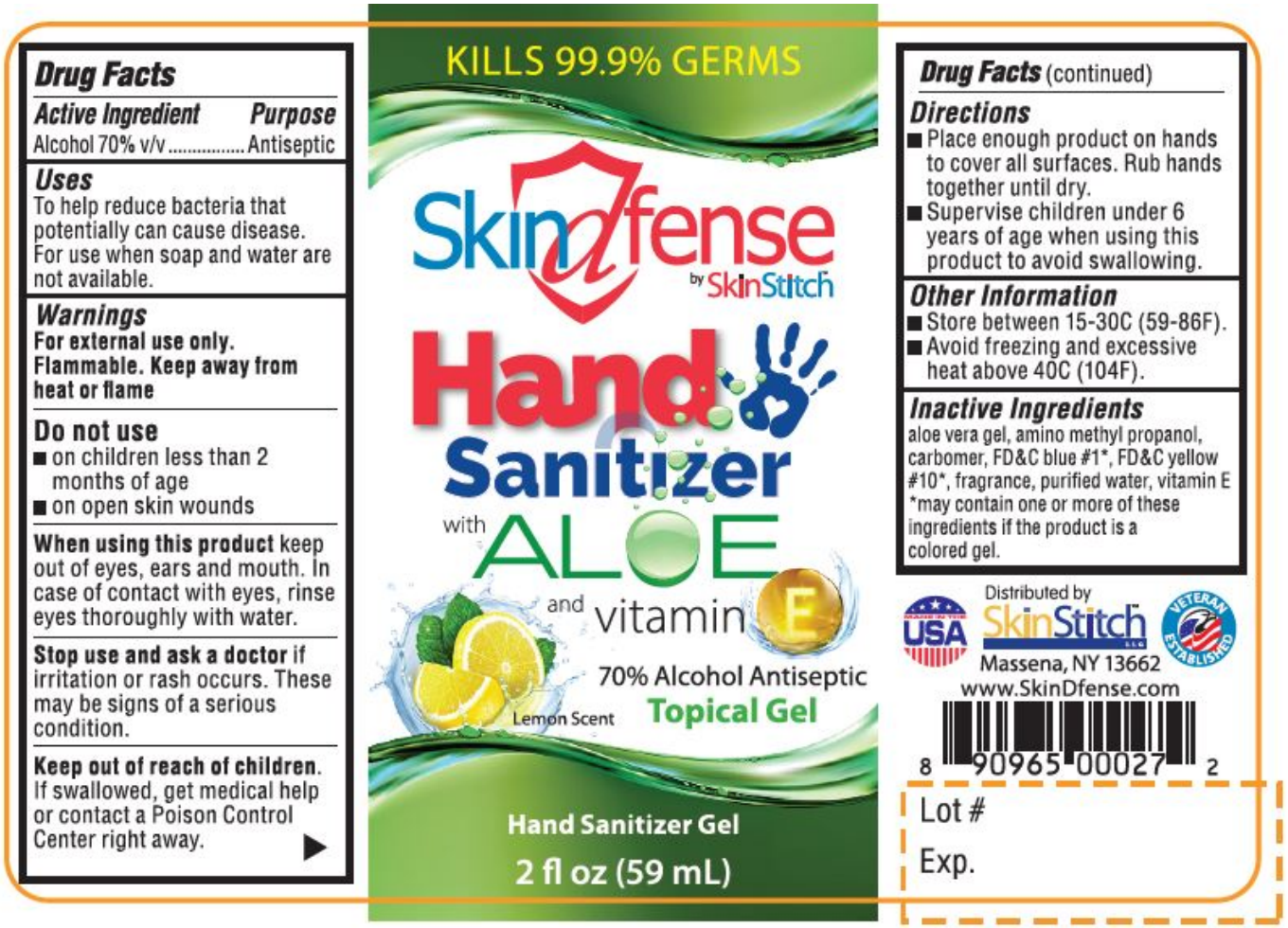
- Store between 15-30C (59-86F)
- Avoid freezing and excessive heat above 40C (104F)

Inactive ingredients

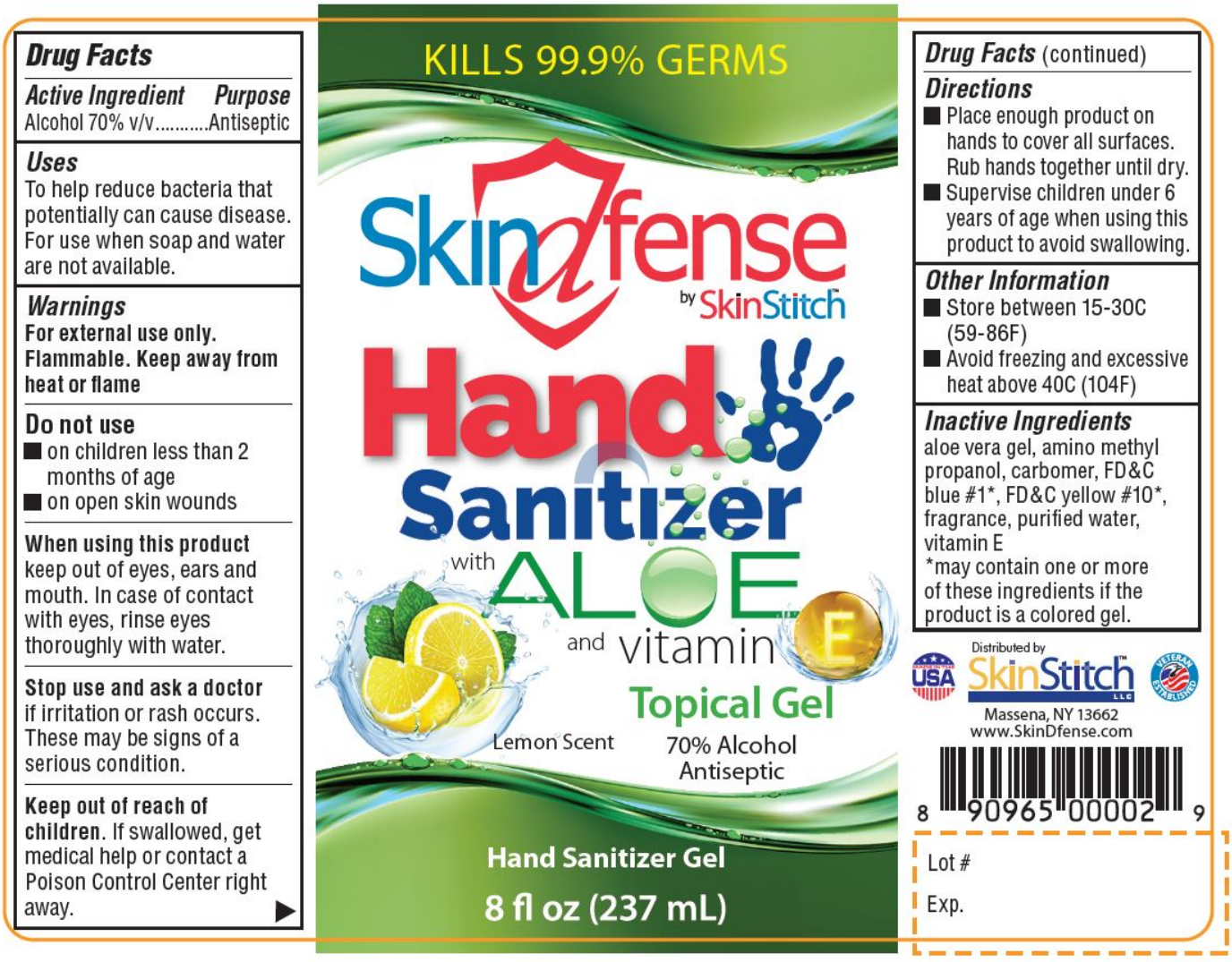
aloe vera gel, amino methyl propanol, carbomer, FD&C blue #1·, FD&C yellow #10·, fragrance, purified water, vitamin E
•may contain one or more of these ingredients if the product is a colored gel.

Package Label - Principal Display Panel

2 fl oz (59 mL) NDC: 73414-058-01



8 fl oz (237 mL) NDC: 73414-058-08



16 fl oz (473 mL) NDC: 73414-058-13

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

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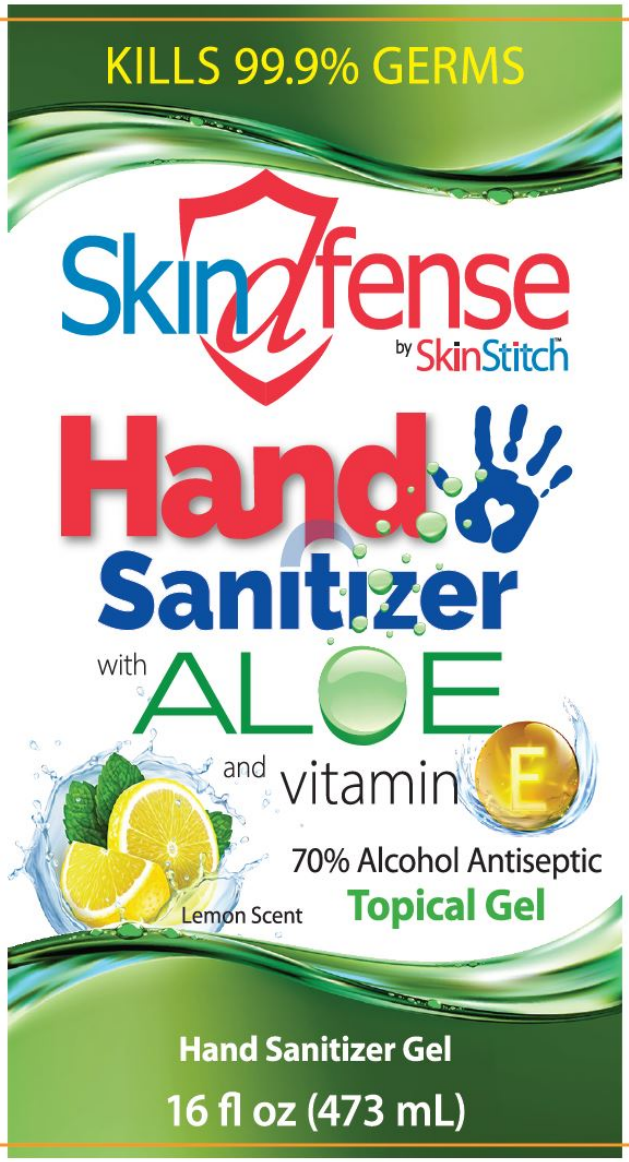

Drug Facts (continued)

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
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.

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

8 90965 00012 8

32 fl oz (946 mL) NDC: 73414-058-14

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.

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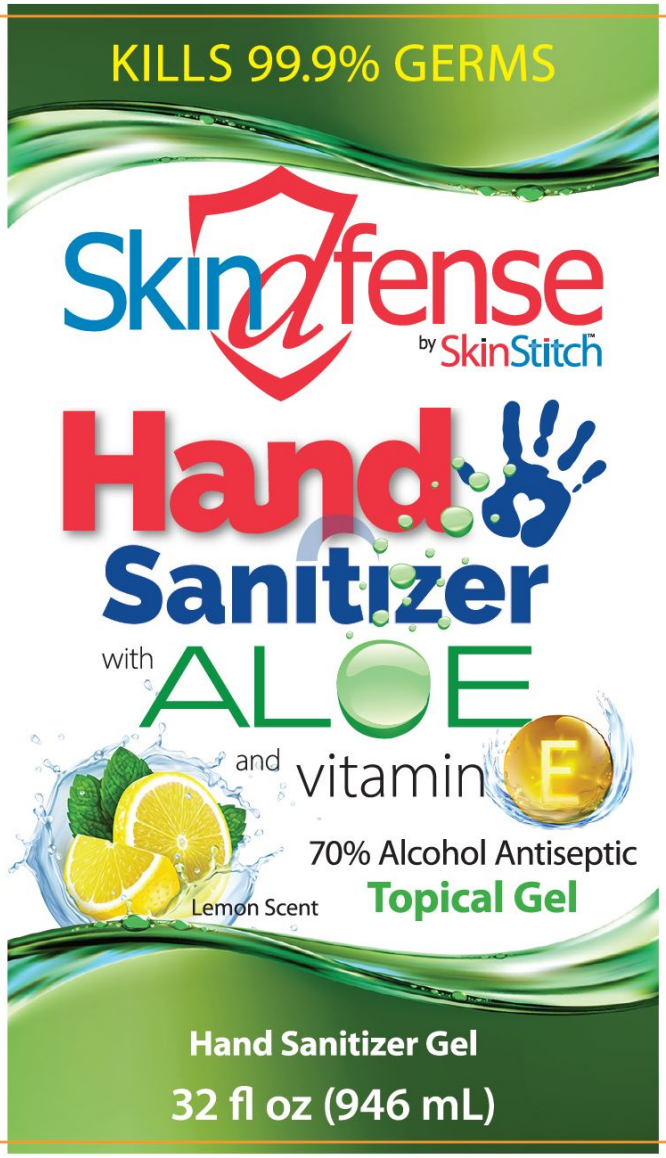


Drug Facts (continued)

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.

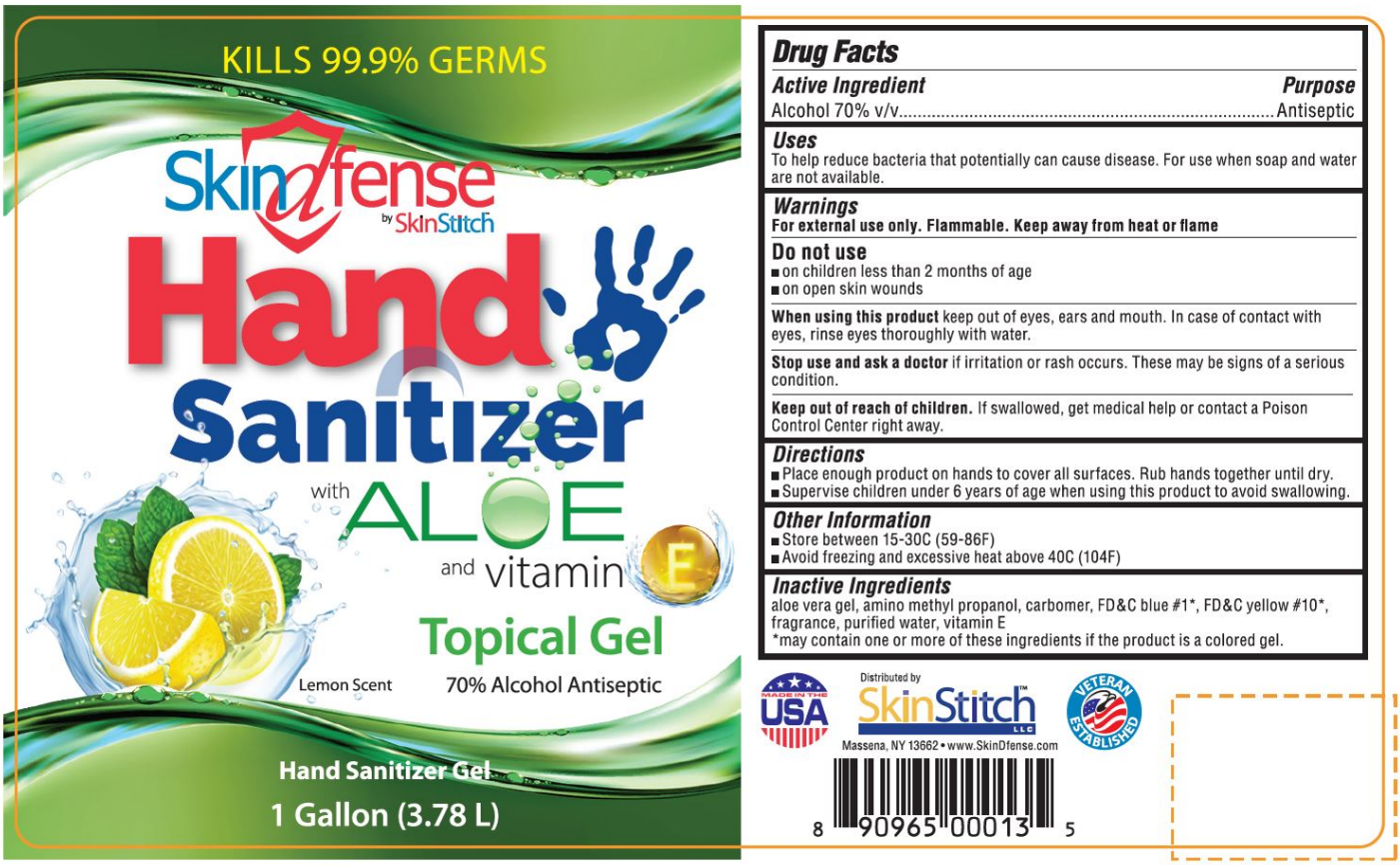
Other Information
- Store between 15-30C (59-86F).
- Avoid freezing and excessive heat above 40C (104F).

Inactive Ingredients
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.

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

8 90965 00029 6

1 Gallon (3.78 L) NDC: 73414-058-91



ALCOHOL ANTISEPTIC

alcohol gel

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:73414-058
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**
ALOE VERA LEAF (UNII: ZY81Z83H0X)	
AMINOMETHYLPROPANOL (UNII: LU49E6626Q)	
CARBOMER 1342 (UNII: 809Y72KV36)	
FD&C BLUE NO. 1 (UNII: H3R47K3TBD)	
D&C YELLOW NO. 10 (UNII: 35SW5USQ3G)	
WATER (UNII: 059QF0KO0R)	
.ALPHA.-TOCOPHEROL (UNII: H4N855PNZ1)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:73414-058-01	59 mL in 1 BOTTLE; Type 0: Not a Combination Product	07/01/2020	
2	NDC:73414-058-04	118 mL in 1 BOTTLE; Type 0: Not a Combination Product	07/01/2020	
3	NDC:73414-058-06	177 mL in 1 BOTTLE; Type 0: Not a Combination Product	07/01/2020	
4	NDC:73414-058-08	237 mL in 1 BOTTLE; Type 0: Not a Combination Product	07/01/2020	
5	NDC:73414-058-13	473 mL in 1 BOTTLE; Type 0: Not a Combination Product	07/01/2020	
6	NDC:73414-058-14	946 mL in 1 BOTTLE; Type 0: Not a Combination Product	07/01/2020	
7	NDC:73414-058-91	3780 mL in 1 BOTTLE; Type 0: Not a Combination Product	07/01/2020	

Marketing Information

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(73414-058)

Revised: 7/2020 Seaway Pharma Inc.