

ALCOHOL BASED HAND SANITIZER- ethyl alcohol solution
Seattle Sanitizer 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.

☐ **SEATTLE SANITIZER**

Drug Facts

Active ingredient(s)

Ethyl Alcohol 85% 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

- 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 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)
- *Denatured Alcohol, Ethyl Alcohol 85% as determined by hydrometer.*

Inactive ingredients glycerin, hydrogen peroxide, purified water USP

HIGHEST POTENCY 85% ETHANOL

HAND SANITIZER FOR FASTER MORE COMPLETE SANITIZING OF HANDS AND OTHER SURFACES

Highly effective while easy on your skin

FDA APPROVED FORMULA

non sterile solution

MADE IN THE USA

MANUFACTURED BY SKYBOUND SPIRITS

IN SEATTLE WASHINGTON

945 ELLIOT AVE WEST

SEATTLE, WA 98119

WWW.SEATTLESANITIZER.COM

Packaging

<p style="text-align: center;">SEATTLE SANITIZER</p> <p style="text-align: center;">MADE IN THE USA HIGHEST POTENCY 85% ETHANOL</p> <hr/> <p style="text-align: center;">HAND SANITIZER FOR FASTER MORE COMPLETE SANITIZING OF HANDS AND OTHER SURFACES</p> <p style="text-align: center;">Highly effective while easy on your skin FDA APPROVED FORMULA</p> <p style="text-align: center;">non sterile solution 2 fl oz 59.14 ml</p> <p>MANUFACTURED BY SKYBOUND SPIRITS IN SEATTLE WASHINGTON 945 ELLIOT AVE WEST SEATTLE, WA 98119 WWW.SEATTLESANITIZER.COM</p>  <p>7 12198 14835 7</p>	<table border="1"><tr><td colspan="2">Drug Facts</td></tr><tr><td>Active ingredient(s)</td><td>Purpose</td></tr><tr><td>Ethyl Alcohol 85% v/v.....</td><td>Antiseptic</td></tr><tr><td colspan="2">Use(s)</td></tr><tr><td colspan="2">Hand sanitizer to help reduce bacteria that can potentially cause disease. For use when soap and water are not available.</td></tr><tr><td colspan="2">Warnings</td></tr><tr><td colspan="2">For external use only. Flammable. Keep away from heat or flame.</td></tr><tr><td colspan="2">Do not use</td></tr><tr><td colspan="2">• on children less than 2 months of age • on open skin wounds</td></tr><tr><td colspan="2">When using this product keep out of eyes, ears and mouth. In case of contact with eyes, rinse thoroughly with water.</td></tr><tr><td colspan="2">Stop use and ask a doctor if irritation or rash occurs. These may be signs of a serious condition.</td></tr><tr><td colspan="2">Keep out of reach of children. If swallowed, get medical help or contact a Poison Control Center right away.</td></tr><tr><td colspan="2">Directions</td></tr><tr><td colspan="2">• 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.</td></tr><tr><td colspan="2">Other information</td></tr><tr><td colspan="2">• Store between 15-30C (59-86F) • Avoid freezing and excessive heat above 40C (104F)</td></tr><tr><td colspan="2">Inactive ingredients</td></tr><tr><td colspan="2">• Glycerin, hydrogen peroxide, purified water USP</td></tr></table>	Drug Facts		Active ingredient(s)	Purpose	Ethyl Alcohol 85% v/v.....	Antiseptic	Use(s)		Hand sanitizer to help reduce bacteria that can potentially 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 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	
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HAND SANITIZER FOR FASTER
MORE COMPLETE SANITIZING
OF HANDS AND OTHER SURFACES



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Highly effective
while easy on your skin
FDA APPROVED FORMULA

non sterile solution

4 fl oz 118.29 ml

Drug Facts	
Active ingredient(s) Ethyl Alcohol 85% v/v...	Purpose Antiseptic
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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 15-30°C (59-86°F) • Avoid freezing and use within 60 days of 4°C (40°F) • Denatured Alcohol 85% by Alcohol 85% is denatured ethyl alcohol	
Inactive Ingredients • Glycerin, hydrogen peroxide, purified water USP	

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HAND SANITIZER FOR FASTER
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FDA APPROVED FORMULA

non sterile solution
8 fl oz 236.5 ml

Drug Facts	
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non sterile solution
16 fl oz 473.17 ml

Drug Facts	
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non sterile solution
64 fl oz 1.89 liter

Drug Facts	
Active ingredient(s)	Purpose
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Hand sanitizer to help reduce bacteria that potentially can cause disease. For use when soap and water are not available.	
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FDA APPROVED FORMULA

non sterile solution
128 fl oz 3.78 liters

Drug Facts	
Active ingredient(s)	Purpose
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ALCOHOL BASED HAND SANITIZER

ethyl alcohol solution

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:78539-001
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name		Basis of Strength	Strength	
ALCOHOL (UNII: 3K9958V90M) (ALCOHOL - UNII:3K9958V90M)		ALCOHOL	85 mL in 100 mL	
Inactive Ingredients				
Ingredient Name		Strength		
GLYCERIN (UNII: PDC6A3C0OX)				
HYDROGEN PEROXIDE (UNII: BBX060AN9V)				
WATER (UNII: 059QF0K00R)				
Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:78539-001-02	59.14 mL in 1 BOTTLE; Type 0: Not a Combination Product	03/30/2020	
2	NDC:78539-001-04	118.29 mL in 1 BOTTLE; Type 0: Not a Combination Product	03/30/2020	
3	NDC:78539-001-08	236.5 mL in 1 BOTTLE; Type 0: Not a Combination Product	03/30/2020	
4	NDC:78539-001-16	473.17 mL in 1 BOTTLE; Type 0: Not a Combination Product	03/30/2020	
5	NDC:78539-001-32	1890 mL in 1 BOTTLE; Type 0: Not a Combination Product	03/30/2020	
6	NDC:78539-001-64	3780 mL in 1 BOTTLE; Type 0: Not a Combination Product	03/30/2020	
Marketing Information				
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date	
OTC monograph not final	part333A	03/30/2020		

Labeler - Seattle Sanitizer LLC (130478322)

Establishment

Name	Address	ID/FEI	Business Operations
Seattle Sanitizer LLC		130478322	manufacture(78539-001)

Revised: 7/2020

Seattle Sanitizer LLC