

**SHSNH6-4501- ethyl alcohol solution**  
**Shotwell Hydrogenics, 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.*

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**SNSNH6-4501 Antiseptic Topical Solution HAND SANITIZER Non-Sterile Solution**

***Drug Facts***

**☐Active ingredients(s)**

Ethyl Alcohol 70% 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 eyes thoroughly with water.

**☐Stop use and ask for a doctor** ☐if irritation 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 Centre 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***

deionized water, glycerin, carbomer, triethanolamine, fragrance

**Packaging**

SHSNH6-4501  
**ETHYL ALCOHOL 70%**  
**Antiseptic**  
**Topical Solution**  
  
**HAND SANITIZER**  
**Non-Sterile Solution**  
  
Tote  
1249 Liters

<b>Drug Facts</b>	
<b>Active ingredient(s)</b> Ethyl Alcohol 70% v/v.....	<b>Purpose</b> Antiseptic
<b>Use(s)</b> Hand sanitizer to help reduce bacteria that potentially can cause disease. For use when soap and water are not available	
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<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 for a doctor</b> if irritation 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>	
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<b>Inactive ingredients</b> deionized water, glycerin, carbomer, triethanolamine, fragrance	

<b>SHSNH6-4501</b>			
ethyl alcohol solution			
<b>Product Information</b>			
<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:73870-515
<b>Route of Administration</b>	TOPICAL		
<b>Active Ingredient/Active Moiety</b>			
	<b>Ingredient Name</b>	<b>Basis of Strength</b>	<b>Strength</b>

ALCOHOL (UNII: 3K9958V90M) (ALCOHOL - UNII:3K9958V90M)	ALCOHOL	70 L in 100 L
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### Inactive Ingredients

Ingredient Name	Strength
WATER (UNII: 059QF0KO0R)	
GLYCERIN (UNII: PDC6A3C0OX)	
CARBOMER HOMO POLYMER, UNSPECIFIED TYPE (UNII: 0A5MM307FC)	
TROLAMINE (UNII: 9O3K93S3TK)	

### Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:73870-515-33	1249 L in 1 CONTAINER; Type 0: Not a Combination Product	04/27/2020	

### Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part333A	04/27/2020	

**Labeler** - Shotwell Hydrogenics, LLC (108985732)

### Establishment

Name	Address	ID/FEI	Business Operations
Shotwell Hydrogenics, LLC		108985732	manufacture(73870-515)

Revised: 5/2020

Shotwell Hydrogenics, LLC