

SHSNH6-4500- 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.

SHSNH6-4500 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 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 carbomer, glycerin, triethanolamine, deionized water

Packaging

SHSNH6-4500
ETHYL ALCOHOL 70%
Antiseptic
Topical Solution

HAND SANITIZER
 Non-Sterile Solution

Tote
 1249 Liters

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SHSNH6-4500
 ethyl alcohol solution

Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:73870-505
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
ALCOHOL (UNII: 3K9958V90M) (ALCOHOL - UNII:3K9958V90M)	ALCOHOL	70 L in 100 L

Inactive Ingredients

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

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:73870-505-33	1249 L in 1 CONTAINER; Type 0: Not a Combination Product	04/09/2020	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part333A	04/09/2020	

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

Name	Address	ID/FEI	Business Operations
Shotwell Hydrogenics, LLC		108985732	manufacture(73870-505)

Revised: 4/2020

Shotwell Hydrogenics, LLC