

SHSNH6-4621- ethyl alcohol gel
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.

SHSNH6-4621 ETHYL ALCOHOL 80 % Antiseptic Gel Topical Solution HAND SANITIZER with Vitamin E

Drug Facts

Active ingredients(s)

Ethyl Alcohol 80% 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

- 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 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 deionized water, polyethylene glycol, AMP-acrylates vinyl isodecanoate crosspolymer, glycerin, fragrance, tocopheryl acetate (vitamin E acetate)

Antiseptic Gel
Topical Solution
With Vitamin E

Packaging



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ethyl alcohol gel

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:73870-562
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
ALCOHOL (UNII: 3K9958V90M) (ALCOHOL - UNII:3K9958V90M)	ALCOHOL	80 L in 100 L

Inactive Ingredients

Ingredient Name	Strength
WATER (UNII: 059QF0KO0R)	
POLYETHYLENE GLYCOL, UNSPECIFIED (UNII: 3WJQ0SDW1A)	
AMINOMETHYLPROPANOL (UNII: LU49E6626Q)	
ACRYLATES/VINYL ISODECANOATE CROSSPOLYMER (10000 MPAS NEUTRALIZED AT 0.5%) (UNII: 2N8MDB79NA)	
GLYCERIN (UNII: PDC6A3C0OX)	
.ALPHA.-TOCOPHEROL ACETATE (UNII: 9E8X80D2L0)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:73870-562-33	1249 L in 1 CONTAINER; Type 0: Not a Combination Product	10/05/2020	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part333A	10/05/2020	

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

Name	Address	ID/FEI	Business Operations
Shotwell Hydrogenics, LLC		108985732	manufacture(73870-562)

Revised: 10/2020

Shotwell Hydrogenics, LLC