

HAND SANITIZER- ethyl alcohol gel
SentryPPE, 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.

Active Ingredient
Ethyl Alcohol 62% v/v

Purpose
Antiseptic

Uses:

Hand sanitizer to help reduce bacteria that potentially can cause disease.

For use when soap and water 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 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 way.

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°(59-86°)

Avoid freezing and excessive heat above 40°(104°)

May discolor certain fabrics or surfaces.


Inactive Ingredients

Water, Aloe Barbadensis Leaf Juice, Maltodextrin, Glycerin, Propylene Glycol, Acrylates/C10-30 Alkyl Acrylate Crosspolymer, Triethanoamine, Fragrance, Tocopheryl Acetate.



sentry PPE

HAND SANITIZER



62% Ethyl Alcohol

Sanitizing Gel

Moisturizing

16.9 fl oz / 500 ml

104mm

Drug Facts


Active Ingredients:	Purpose
Ethyl Alcohol 62% w/v	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 excessive heat above 40°C (104°F) • May discolor certain fabrics or surfaces	
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Distributed by:
SentryPPE, Inc.
8 The Green, Suite 10596
Dover, DE 19901 USA

Made in China

Batch Code: HAB001

Hand Sanitizer 500mL - PE17001



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HAND SANITIZER			
ethyl alcohol gel			
Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:78398-169
Route of Administration	TOPICAL		
Active Ingredient/Active Moiety			
Ingredient Name	Basis of Strength	Strength	
ALCOHOL (UNII: 3K9958V90M) (ALCOHOL - UNII:3K9958V90M)	ALCOHOL	62 mL in 100 mL	
Inactive Ingredients			
Ingredient Name	Strength		
MALTODEXTRIN (UNII: 7CVR7L4A2D)			
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)			
WATER (UNII: 059QF0KO0R)			
ALOE VERA LEAF (UNII: ZY81Z83H0X)			
GLYCERIN (UNII: PDC6A3C0OX)			

CARBOMER INTERPOLYMER TYPE A (55000 CPS) (UNII: 59TL3WG5CO)	
TROLAMINE (UNII: 9O3K93S3TK)	
.ALPHA.-TOCOPHEROL ACETATE (UNII: 9E8X80D2L0)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:78398-169-01	500 mL in 1 BOTTLE, PUMP; Type 0: Not a Combination Product	05/29/2020	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part333E	05/29/2020	

Labeler - SentryPPE, Inc. (117289386)

Revised: 5/2020

SentryPPE, Inc.