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 15-300059-8600

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/C1O-30 Alkyl Acrylate Crosspolymer, Triethanoamine, Fragrance, Tocopheryl Acetate.



HAND **SANITIZER**



8 fl oz / 236 ml

Drug Facts

Active Ingredients: Purpose Ethyl Alcohol 62% v/v_____

Uses: 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 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.

- . 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

Inactive Ingredients:

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

Distributed by: SentryPPE, Inc. 8 The Green, Suite 10596 Dover, DE 19901 USA

Made In China

Batch Code: HAB001



HAND SANITIZER

ethyl alcohol gel

Product Information

HUMAN OTC DRUG Product Type Item Code (Source) NDC:78398-008

TOPICAL **Route of Administration**

Active Ingredient/Active Moiety

Basis of Strength Ingredient Name Strength ALCOHOL (UNII: 3K9958V90M) (ALCOHOL - UNII:3K9958V90M) ALCOHOL 62 mL in 100 mL

Inactive Ingredients	
Ingredient Name	Strength
MALTO DEXTRIN (UNII: 7CVR7L4A2D)	
PROPYLENE GLYCOL (UNII: 6 DC9 Q167V3)	
WATER (UNII: 059QF0KO0R)	
ALOE VERA LEAF (UNII: ZY81Z83H0X)	

GLYCERIN (UNII: PDC6A3C0OX)	
CARBOMER INTERPOLYMER TYPE A (55000 CPS) (UNII: 59TL3WG5CO)	
TROLAMINE (UNII: 9O3K93S3TK)	
.ALPHATO COPHEROL ACETATE (UNII: 9E8X80D2L0)	

Packaging			
# Item Code	Package Description	Marketing Start Date	Marketing End Date
1 NDC:78398-008- 01	236 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.