PREMIER PURE PROTECTION- ethyl alcohol gel
RPP PRODUCTS, 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 72% v/v

Purpose

Antimicrobial

Uses

hand sanitizer to help reduce bacteria on the skin

Warnings

Flammable, keep away from fire or flame

For external use only

When using this product do not use in or near the eyes

In case of contact rinse thoroughly with water

When using this product

do not use in or near the eyes. In case of contact, rinse eyes thoroughly with water

Stop use and ask doctor if

irritation or rash appears and lasts

Keep out of reach of children.

If swallowed, get medical help right away or contact a Poison Control Center immediately.

Directions

- Put enough product in your palm to cover hands and rub hands together briskly until dry.
- children under 6 years of age should be supervised when using this PREMIER PURE

Other information

- Store below 110^0 F (43^0C)
- May discolor certain fabrics or surfaces
- This product does not contain any chemicals known to the State of California to cause cancer, birth defects, or any other reproductive harm

Inactive ingredients

Water, Glycerin, Ethanolamine, Carbomer, Propylene Glycol, Fragrance, Citric Acid

Product Label

PREMIER PURE PROTECTION

ethyl alcohol gel

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:73945-004
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety		
Ingredient Name	**Basis of Strength**	**Strength**
ALCOHOL (UNII: 3K9958V90M) (ALCOHOL - UNII:3K9958V90M)	ALCOHOL	72 mL in 100 mL

Inactive Ingredients	
Ingredient Name	**Strength**
WATER (UNII: 059QF0KO0R)	
GLYCERIN (UNII: PDC6A3C0OX)	
MONOETHANOLAMINE (UNII: 5KV86114PT)	
CARBOMER HOMOPOLYMER TYPE C (ALLYL PENTAERYTHRITOL CROSSLINKED) (UNII: 4Q93RCW27E)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
CITRIC ACID MONOHYDRATE (UNII: 2968PHW8QP)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:73945-004-01	59 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	04/10/2020	
2	NDC:73945-004-02	88.72 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	04/10/2020	
3	NDC:73945-004-03	118.3 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	04/10/2020	
4	NDC:73945-004-04	236.59 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	04/10/2020	
5	NDC:73945-004-05	295.74 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	04/10/2020	
6	NDC:73945-004-06	354.88 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	04/10/2020	
7	NDC:73945-004-07	443.17 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	04/10/2020	
8	NDC:73945-004-08	946 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	04/10/2020	
9	NDC:73945-004-09	1890 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	04/10/2020	
10	NDC:73945-004-10	2000 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	04/10/2020	
11	NDC:73945-004-11	2800 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	04/10/2020	
12	NDC:73945-004-12	3780 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	04/10/2020	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC MONOGRAPH NOT FINAL	part333A	04/10/2020	

Labeler - RPP PRODUCTS, INC. (623623852)

Establishment

Name	Address	ID/FEI	Business Operations
RPP PRODUCTS, INC.		623623852	manufacture(73945-004)

Revised: 5/2020 RPP PRODUCTS, INC.