CORNELLS- alcohol liquid Premier Cosmetics

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

Isopropyl alcohol 70% v/v.

Purpose

Antiseptic

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

- 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 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.

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 $15-30^{\circ}$ C (59- 86° F). Avoid freezing and excessive heat above 40° C (104° F).

Inactive ingredients

Aqua, Glycerin, Propylene Glycol, Isopropyl Myristate, Benzalkonium Chloride, Fragrance, Tocopheryl Acetate, Aloe barbadensis Leaf Extract.

Package Label - Principal Display Panel

Label 100 mL

AY PROTECTE



ISOPROPYL ALCOHOL70% KILLS 99.9% OF GERMS



100ml e 3.38 fl.oz

TAY PROTECTEL

INSTANT HAND



ISOPROPYL ALCOHOL 70%

Drug Facts
Active Ingredient(s) Purpose
Isopropyl alcohol 70% y/v
Use(s)
Hand sanitizer to help reduce bacteria that potentially can cause disease. For use when soap and water are not
avalable.
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 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.
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)
Inactive ingredients
Aqua, Glycerin, Propylene Glycol, Isopropyl Myrtstate, Benzalkonium Chloride, Fragrance, Tocopheryl Acetate,
Nine Ranhaderick Leaf Petrant



by PUI 0 9001: 2015 and ISO 22716: 200: Portified Company



CORNELLS

alcohol liquid

Product Information

HUMAN OTC DRUG Product Type Item Code (Source) NDC:78117-004

Route of Administration TOPICAL

Active Ingredient/Active Moiety

Basis of Strength Ingredient Name Strength ISOPROPYL ALCOHOL (UNII: ND2M416302) (ISOPROPYL ALCOHOL -ISOPROPYL 70 mL UNII:ND2M416302) ALCOHOL in 100 mL

Inactive Ingredients Ingredient Name Strength WATER (UNII: 059QF0KO0R) GLYCERIN (UNII: PDC6A3C0OX) PROPYLENE GLYCOL (UNII: 6DC9Q167V3) ISOPROPYL MYRISTATE (UNII: 0 RE8 K4LNJS) **BENZALKO NIUM CHLO RIDE** (UNII: F5UM2KM3W7) .ALPHA.-TO COPHEROL ACETATE (UNII: 9E8X80D2L0) ALOE VERA LEAF (UNII: ZY81Z83H0X)

Packaging							
#	Item Code	Package Description	Marketing Start Date	Marketing End Date			
1	NDC:78117-004-01	100 mL in 1 CAN; Type 0: Not a Combination Product	06/01/2020				

Marketing Information								
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date					
OTC monograph not final	part333A	06/01/2020						

Labeler - Premier Cosmetics (557941540)

Establishment								
Name	Address	ID/FEI	Business Operations					
Premier Cosmetics		557941540	manufacture (78 117-0 0 4)					

Revised: 6/2020 Premier Cosmetics