PREMIER- alcohol gel
Handock Cosmetics Co., Ltd.

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

ALCOHOL 70%

INACTIVE INGREDIENTS

Water, Propylene Glycol, Glycerin, Butylene Glycol, Triethanolamine, Carbomer

PURPOSE

Antiseptic

WARNINGS

Flammable. Keep away from flame and fire. For external use only.

When using this product
Keep out of eyes. In case of contact, rinse eyes thoroughly with water.

Stop use and ask a doctor if
irritation or redness develops and lasts.

Keep out of reach of children
If swallowed, get medical help or contact a Poison Control Center right away.

KEEP OUT OF REACH OF CHILDREN

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

Uses

Hand sanitizer to help reduce bacteria on the skin.
*Kills most common germs that may cause illness.

Directions

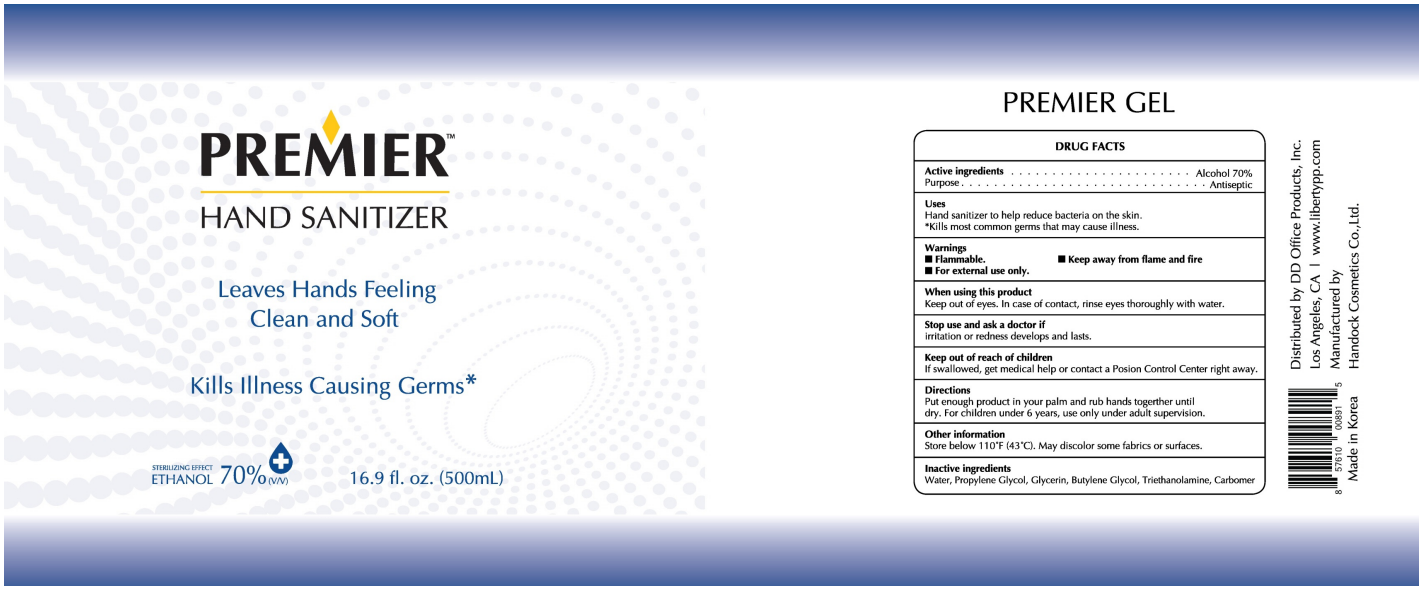
Put enough product in your palm and rub hands together until dry.
For children under 6 years, use only under adult supervision.

Other information

Other information:
Store below 110°F (43°C)
May discolor some fabrics or surfaces

PACKAGE LABEL - PREMIER GEL 250mL

PACKAGE LABEL - PREMIER GEL 500mL



PREMIER

alcohol gel

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:76369-8110
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
ALCOHOL (UNII: 3K9958V90M) (ALCOHOL - UNII:3K9958V90M)	ALCOHOL	70 mL in 100 mL

Inactive Ingredients

Ingredient Name	Strength
Water (UNII: 059QF0KO0R)	
Propylene Glycol (UNII: 6DC9Q167V3)	
Glycerin (UNII: PDC6A3C0OX)	
TROLAMINE (UNII: 9O3K93S3TK)	
CARBOMER HOMOPOLYMER, UNSPECIFIED TYPE (UNII: 0A5MM307FC)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:76369-8110-1	250 mL in 1 BOTTLE, PUMP; Type 0: Not a Combination Product	05/01/2020	
2	NDC:76369-8110-2	500 mL in 1 BOTTLE, PUMP; Type 0: Not a Combination Product	05/01/2020	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part333E	05/01/2020	

Labeler - Handock Cosmetics Co., Ltd. (688037204)

Registrant - Handock Cosmetics Co., Ltd. (688037204)

Establishment

Name	Address	ID/FEI	Business Operations
Handock Cosmetics Co., Ltd.		688037204	manufacture(76369-8110)

Revised: 5/2020 Handock Cosmetics Co., Ltd.