

**PURE HONEST HAND SANITIZER GEL- alcohol gel**  
**Primoris International 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.*

-----  
**[2021 renewal] PURE HONEST HAND SANITIZER GEL 500 mL**  
**79925-500-01**

**ACTIVE INGREDIENT**

Alcohol 70% w/w

**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

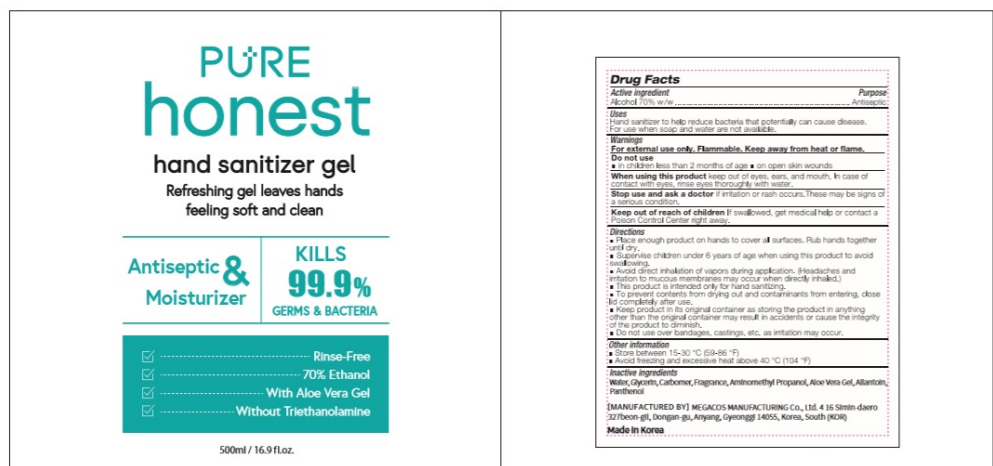
- Place enough product on hands to cover all surfaces. Rub hands together until dry.
- Supervise children under 6 years of age when using this product to avoid swallowing.
- Avoid direct inhalation of vapors during application. (Headaches and irritation to mucous membranes may occur when directly inhaled.)
- This product is intended only for hand sanitizing.
- To prevent contents from drying out and contaminants from entering, close lid completely after use.
- Keep product in its original container as storing the product in anything other than the original container may result in accidents or cause the integrity of the product to diminish.
- Do not use over bandages, castings, etc. as irritation may occur.

## OTHER INFORMATION

- Store between 15-30 °C (59-86 °F)
- Avoid freezing and excessive heat above 40 °C (104 °F)

## INACTIVE INGREDIENTS

Water, Glycerin, Carbomer, Fragrance, Aminomethyl Propanol, Aloe Vera Gel, Allantoin, Panthenol



Drug Facts	Purpose
<b>Active ingredients</b> Alcohol 70% w/w	Antiseptic
<b>Uses</b> Hand sanitizer to help reduce bacteria that potentially can cause disease. For use when soap and water are not available.	
<b>Warnings</b> For external use only. Flammable. Keep away from heat or flame.	
<b>Do not use</b> • In children less than 2 months of age • on open skin wounds	
<b>When using this product</b> keep out of eyes, ears, and mouth. In case of contact with eyes, rinse eyes thoroughly with water.	
<b>Stop use and ask a doctor</b> if irritation or rash occurs. These may be signs of a allergic condition.	
<b>Keep out of reach of children</b> If swallowed, get medical help or contact a Poison Control Center right away.	
<b>Directions</b> • 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. • Avoid direct inhalation of vapors during application. (Headaches and irritation to mucous membranes may occur when directly inhaled.) • This product is intended only for hand sanitizing. • To prevent contents from drying out and contaminants from entering, close lid completely after use. • Keep product in its original container as storing the product in anything other than the original container may result in accidents or cause the integrity of the product to diminish. • Do not use over bandages, castings, etc. as irritation may occur.	
<b>Other information</b> • Store between 15-30 °C (59-86 °F) • Avoid freezing and excessive heat above 40 °C (104 °F)	
<b>Inactive ingredients</b> Water, Glycerin, Carbomer, Fragrance, Aminomethyl Propanol, Aloe Vera Gel, Allantoin, Panthenol	
(MANUFACTURED BY) MEGACOS MANUFACTURING CO., LTD. 4-16 Simitto-dae-ro 307/beon-gil, Dongan-gu, Anyang, Gyeonggi 14055, Korea, South (KOR)	
Made in Korea	

**PURE HONEST HAND SANITIZER GEL**

alcohol gel

### Product Information

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:79925-500
<b>Route of Administration</b>	TOPICAL		

### Active Ingredient/Active Moiety

<b>Ingredient Name</b>	<b>Basis of Strength</b>	<b>Strength</b>
ALCOHOL (UNII: 3K9958V90M) (ALCOHOL - UNII:3K9958V90M)	ALCOHOL	350 mL in 500 mL

### Inactive Ingredients

<b>Ingredient Name</b>	<b>Strength</b>
ALOE VERA LEAF (UNII: ZY81Z83H0X)	
PANTHENOL (UNII: WW9CM0067Z)	
CARBOMER HOMOPOLYMER, UNSPECIFIED TYPE (UNII: 0A5MM307FC)	
AMINOMETHYLPROPANOL (UNII: LU49E6626Q)	
ALLANTOIN (UNII: 344S277G0Z)	
WATER (UNII: 059QF0KO0R)	
GLYCERIN (UNII: PDC6A3C0OX)	

### Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:79925-500-01	500 mL in 1 BOTTLE, PUMP; Type 0: Not a Combination Product	08/03/2020	

### Marketing Information

<b>Marketing Category</b>	<b>Application Number or Monograph Citation</b>	<b>Marketing Start Date</b>	<b>Marketing End Date</b>
OTC monograph not final	part333A	08/03/2020	

**Labeler** - Primoris International Co., Ltd. (694921686)

### Establishment

<b>Name</b>	<b>Address</b>	<b>ID/FEI</b>	<b>Business Operations</b>
MEGACOS MANUFACTURING Co., Ltd		694745986	manufacture(79925-500)