

**PURE CARE HAND SANITIZER- alcohol gel**  
**KINGKEY MBC LIFE TECHNOLOGY GROUP 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.*

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**Active Ingredient**

Alcohol 75% 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 59-86<sup>0</sup>F (15-30<sup>0</sup>C)
- Avoid freezing and excessive heat above 104<sup>0</sup>F (40<sup>0</sup>C)

**Inactive ingredients**

**Package Label - Principal Display Panel**



<b>Drug Facts</b>	
<b>Active ingredient[s]</b>	<b>Purpose</b>
Alcohol 75% v/v	Antiseptic
<b>Use[s]</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 month 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 sign of a serious 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.	
<b>Other information</b> • Store between 59-86°F(15-30°C) • Avoid freezing and excessive heat above 104°F(40°C)	
<b>Inactive ingredients</b> Aminomethylpropanol,Carbomer,Glycerin,Purified water USP	

Distributed by:  
Gourmet Home Product, LLC, New York, NY 10016  
Made in China  
NDC:



**PURE CARE HAND SANITIZER**

alcohol gel

Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:73928-004
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety		
Ingredient Name	Basis of Strength	Strength
ALCOHOL (UNII: 3K9958V90M) (ALCOHOL - UNII:3K9958V90M)	ALCOHOL	75 mL in 100 mL

Inactive Ingredients	
Ingredient Name	Strength
WATER (UNII: 059QF0K00R)	
GLYCERIN (UNII: PDC6A3C00X)	

CARBOMER HOMO POLYMER TYPE C (ALLYL PENTAERYTHRITOL CROSSLINKED) (UNII: 4Q93RCW27E)

AMINOMETHYLPROPANOL (UNII: LU49E6626Q)

### Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:73928-004-01	59 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	05/26/2020	
2	NDC:73928-004-02	148 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	05/26/2020	
3	NDC:73928-004-03	236 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	05/26/2020	
4	NDC:73928-004-04	500 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	05/26/2020	
5	NDC:73928-004-05	946 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	05/26/2020	
6	NDC:73928-004-06	3785 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	05/26/2020	

### Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part333A	05/26/2020	

**Labeler** - KINGKEY MBC LIFE TECHNOLOGY GROUP CO., LTD (545349263)

### Establishment

Name	Address	ID/FEI	Business Operations
KINGKEY MBC LIFE TECHNOLOGY GROUP CO., LTD		545349263	manufacture(73928-004)

Revised: 5/2020

KINGKEY MBC LIFE TECHNOLOGY GROUP CO., LTD