

**HAND SANITIZER- alcohol liquid**  
**KLM Promo Products, LLC**

*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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**klm hand sanitizer**

This is a hand sanitizer manufactured according to the Temporary Policy for Preparation of Certain Alcohol-Based Hand Sanitizer Products During the Public Health Emergency (CoViD-19); Guidance for Industry.

The hand sanitizer is manufactured using only the following United States Pharmacopoeia (USP) grade ingredients in the preparation of the product (percentage in final product formulation) consistent with World Health Organization (WHO) recommendations:

- a. Alcohol (ethanol) (USP or Food Chemical Codex (FCC) grade) (80%, volume/volume (v/v)) in an aqueous solution denatured according to Alcohol and Tobacco Tax and Trade Bureau regulations in 27 CFR part 20.
- b. Glycerol (1.45% v/v).
- c. Hydrogen peroxide (0.125% v/v).
- d. Sterile distilled water or boiled cold water.

The firm does not add other active or inactive ingredients. Different or additional ingredients may impact the quality and potency of the product.

**Active Ingredient(s)**

Ethyl Alcohol 62%. Purpose: Antiseptic

**Purpose**

Antiseptic, Hand Sanitizer

**Use**

Decrease bacteria and germs on the hands when water, soap, and towel are not available recommended for repeated use

**Warnings**

For external use only. Flammable. Keep away from heat or flame

**Do not use**

Do not use in ears and mouth

When using this product avoid contact with eyes. In case of contact flush eyes with water.

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

Children under 6, use only under adult supervision. Not recommended for infants.

**Directions**

- pump as needed on to your palms and thoroughly spread on both hands
- rub into skin until dry

**Other information**

- store at 20°(68°-77°)
- may discolor fabrics

**Inactive ingredients**

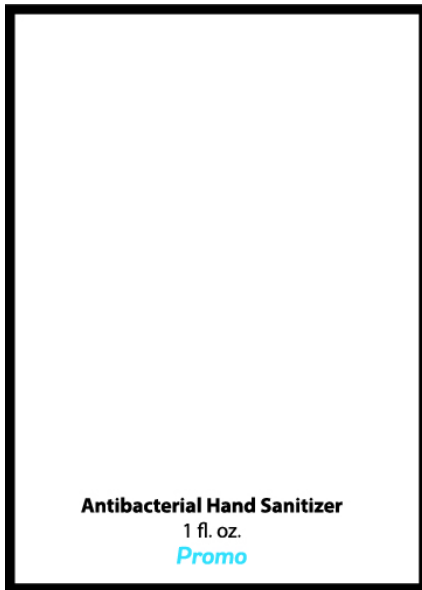
Purified Water, Triethanolamine, Glycerin, Disodium EDTA, carbomer

**Package Label - Principal Display Panel**

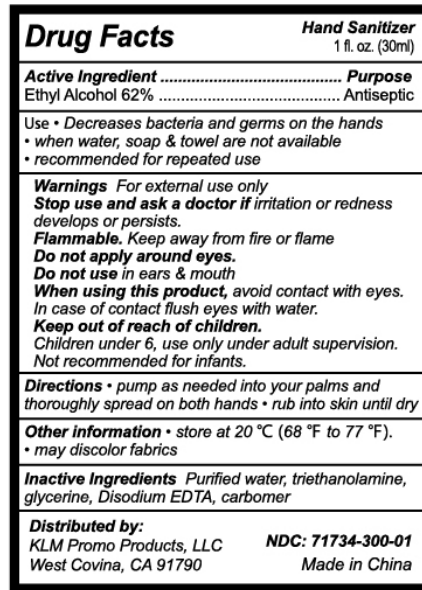
30 mL NDC: 77165-300-01

antibacterial hand sanitizer

1 fl.oz. (30ml)



front



back

42 mm

30 mm

HAND SANITIZER			
alcohol liquid			
Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:77165-300
Route of Administration	TOPICAL		

**Active Ingredient/Active Moiety**

Ingredient Name	Basis of Strength	Strength
ALCOHOL (UNII: 3K9958V90M) (ALCOHOL - UNII:3K9958V90M)	ALCOHOL	62 mL in 100 mL

**Inactive Ingredients**

Ingredient Name	Strength
CARBOMER COPOLYMER TYPE C (ALLYL PENTAERYTHRITOL CROSSLINKED) (UNII: 1N11AG4X4L)	
GLYCERIN (UNII: PDC6A3C00X)	
WATER (UNII: 059QF0K00R)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
EDETATE DISODIUM (UNII: 7FLD91C86K)	
TROLAMINE (UNII: 9O3K93S3TK)	

**Packaging**

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:77165-300-01	30 mL in 1 BOTTLE; Type 0: Not a Combination Product	03/30/2020	
2	NDC:77165-300-02	60 mL in 1 BOTTLE; Type 0: Not a Combination Product	03/30/2020	

**Marketing Information**

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part333A	03/30/2020	

**Labeler** - KLM Promo Products, LLC (017087764)**Registrant** - JIANGMEN SHUIZIRUN SANITARY ARTICLES CO., LTD. (544530534)

Revised: 5/2020

KLM Promo Products, LLC