

**HAND SANITIZER- alcohol gel**  
**Vola Global 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(s)**

Alcohol 70% v/v. Purpose: Antiseptic

**Purpose**

Antiseptic, Hand Sanitizer

**Use**

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.

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

### Inactive ingredients

glycerin, aminomethylpropanol, carbomer, purified water USP





**DIRECTIONS FOR USE:** Apply a blanket of alcohol-based hand gel and cover all surfaces of the hands that needs until dry.  
**ACTIVE INGREDIENT:** Ethanol CAS 64-17-5, 70g per 100g  
**EC/EN/IN/ISO/EN14466 APPROVED**  
**WARNING:** Flammable liquid and vapor. Causes serious eye irritation. Keep out of reach of children. Keep away from heat, hot surfaces, sparks, open flames and other ignition sources. No smoking. If in fire, use water cautiously with water. For medical attention, remove contact lenses, if present and easy to do. Continue rinsing. If eye irritation persists, get medical advice/attention. Dispose of contents container in accordance with national regulations. For broader safety, always read the label and product information before use.

Produced by L&L MacHouse GmbH, Paderborn, 33094, Germany



ITEM NO. 08C180



MADE IN UK  
because clean matters.™



KILLS 99.99% OF GERMS AND VIRUSES



HAND SANITISER GEL

- 70% alcohol formula
- Antibacterial action
- WATER ACTION
- ENZYMES
- SPICES
- ESSENTIAL OILS

500ml e3





## HAND SANITIZER

alcohol gel

### Product Information

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:81251-761
<b>Route of Administration</b>	TOPICAL, CUTANEOUS		

### 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
<b>AMINOMETHYLPROPANOL (PERFLUORO-C6-C12 ETHYL)PHOSPHATE</b> (UNII: QCD5R22RNT)	0.04 mL in 100 mL
<b>CARBOMER INTERPOLYMER TYPE A (ALLYL SUCROSE CROSSLINKED)</b> (UNII: 59TL3WG5CO)	6 mL in 100 mL
<b>GLYCERIN</b> (UNII: PDC6A3C0OX)	1 mL in 100 mL
<b>WATER</b> (UNII: 059QF0KO0R)	22.96 mL in 100 mL

### Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:81251-761-50	500 mL in 1 BOTTLE, PUMP; Type 0: Not a Combination Product	03/30/2020	
2	NDC:81251-761-25	250 mL in 1 BOTTLE, PUMP; Type 0: Not a Combination Product	03/30/2020	
3	NDC:81251-761-55	5000 mL in 1 BOTTLE; Type 0: Not a Combination Product	03/30/2020	
4	NDC:81251-761-10	100 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** - Vola Global Ltd (226091388)

**Registrant** - Vola Global Ltd (226091388)

### Establishment

Name	Address	ID/FEI	Business Operations
Vola Global Ltd		226091388	manufacture(81251-761)

Revised: 1/2021

Vola Global Ltd