

**HAND SANITIZER- alcohol gel**  
**On The Spot 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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**Hand Sanitizer**

**Active Ingredient(s)**

Ethyl Alcohol 75% v/v. Purpose: Antiseptic

**Purpose**

Antiseptic

**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**

- on 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**

Carbomer, Triethanolamine, Water (Aqua)

## Package Label - Principal Display Panel



500 mL NDC: 77490-075-05

### HAND SANITIZER

alcohol gel

#### Product Information

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:77490-075(NDC:74658-001)
<b>Route of Administration</b>	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
CARBOMER HOMO POLYMER TYPE B (ALLYL PENTAERYTHRITOL CROSSLINKED) (UNII: HHT01ZNK31)	0.4 mL in 100 mL
TROLAMINE (UNII: 9O3K93S3TK)	0.09 mL in 100 mL
WATER (UNII: 059QF0KO0R)	24.51 mL in 100 mL

#### Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:77490-075-05	500 mL in 1 BOTTLE; Type 0: Not a Combination Product	04/15/2020	

#### Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date

OTC monograph not final	part333A	04/15/2020	
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**Labeler** - On The Spot Products, LLC (117497833)

**Registrant** - On The Spot Products, LLC (117497833)

<b>Establishment</b>			
<b>Name</b>	<b>Address</b>	<b>ID/FEI</b>	<b>Business Operations</b>
On The Spot Products, LLC		117497833	relabel(77490-075)

Revised: 5/2020

On The Spot Products, LLC