

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.

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

- May discolor fabrics or surfaces. Avoid excessive heat. Store below 105F (40C).

Inactive ingredients

Water (Aqua), Tert-Butyl Alcohol, Denatonium Benzoate, Carbomer, Triethanolamine.

Package Label - Principal Display Panel



HAND SANITIZER			
alcohol gel			
Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:77490-075(NDC:74658-001)
Route of Administration	TOPICAL		
Active Ingredient/Active Moiety			
	Ingredient Name	Basis of Strength	Strength
	ALCOHOL (UNII: 3K9958 V90M) (ALCOHOL - UNII:3K9958 V90M)	ALCOHOL	75 mL in 100 mL
Inactive Ingredients			

Ingredient Name	Strength
DENATONIUM BENZOATE (UNII: 4YK5Z54AT2)	0.0004 mL in 100 mL
CARBOMER HOMO POLYMER TYPE B (ALLYL PENTAERYTHRITOL CROSSLINKED) (UNII: HHT01ZNK31)	0.3 mL in 100 mL
TROLAMINE (UNII: 9O3K93S3TK)	0.09 mL in 100 mL
WATER (UNII: 059QF0K00R)	24.52 mL in 100 mL
TERT-BUTYL ALCOHOL (UNII: MD83SFE959)	0.093 mL in 100 mL

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:77490-075-50	5000 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	

Labeler - On The Spot Products, LLC (117497833)

Registrant - On The Spot Products, LLC (117497833)

Establishment

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

Revised: 11/2020

On The Spot Products, LLC