

**HAND SANITIZER- alcohol gel**  
**ITECH 361 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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**ITECH -Iron Lab (alcohol 70% 1L)**

**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**

purified water USP, glycerin, carbomer, triethanolamine.

# Package Label - Principal Display Panel

1000 mL NDC: 74871-201-01

## Label Specifications

Product: Hand Sanitizer gel (33.8oz / 1Lt)

Label Size: 761 mm (h) x 152 mm(w)

Label Finish: Glossy

Background Color: Transparent

Artwork Bleed:

Printing:

--- Background Artwork Bleed  
— Label



**HAND SANITIZER**

alcohol gel

### Product Information

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:74871-201
<b>Route of Administration</b>	TOPICAL		

### Active Ingredient/Active Moiety

<b>Ingredient Name</b>	<b>Basis of Strength</b>	<b>Strength</b>
ALCOHOL (UNII: 3K9958V90M) (ALCOHOL - UNII:3K9958V90M)	ALCOHOL	70 mL in 100 mL

### Inactive Ingredients

<b>Ingredient Name</b>	<b>Strength</b>
CARBOMER 940 (UNII: 4Q93RCW27E)	0.4 g in 100 mL
GLYCERIN (UNII: PDC6A3C0OX)	1 mL in 100 mL
TROLAMINE (UNII: 9O3K93S3TK)	0.35 g in 100 mL
WATER (UNII: 059QF0KO0R)	

### Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:74871-201-01	1000 mL in 1 CONTAINER; 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** - ITECH 361 LLC (859157377)

### Establishment

Name	Address	ID/FEI	Business Operations
ITECH 361 LLC		859157377	label(74871-201)

Revised: 6/2020

ITECH361 LLC