

PPE361 HAND SANITIZER WITH ALOE VERA AND VITAMIN E- ethyl 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.

ITECH361 PPE361 HAND SANITIZER WITH ALOE VERA AND VITAMIN E 60 mL

DRUG FACTS

ACTIVE INGREDIENT

Ethyl Alcohol 75%

PURPOSE

Antiseptic

USES

Hand sanitizer to help reduce bacteria that potentially can cause disease.

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)

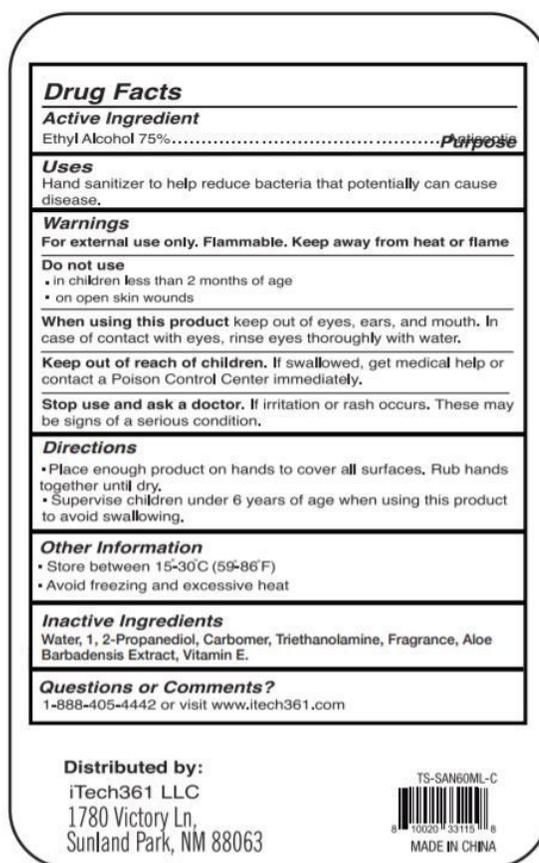
INACTIVE INGREDIENTS

Water (Aqua), 1,2-Propanediol, Carbomer, Triethanolamine, Fragrance, Aloe Barbadensis Extract, Vitamin E.

QUESTIONS OR COMMENTS?

1-888-405-4442 or visit www.itech361.com.

PPE361 HAND SANITIZER WITH ALOE VERA AND VITAMIN E 60 mL (NDC 74871-063-00)



PPE361 HAND SANITIZER WITH ALOE VERA AND VITAMIN E

ethyl alcohol gel

Product Information

| | | | |
|--------------------------------|----------------|---------------------------|---------------|
| Product Type | HUMAN OTC DRUG | Item Code (Source) | NDC:74871-063 |
| Route of Administration | 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 |
|---|----------|
| TROLAMINE (UNII: 9O3K93S3TK) | |
| ALOE VERA LEAF (UNII: ZY81Z83H0X) | |
| POLYACRYLIC ACID (8000 MW) (UNII: 73861X4K5F) | |
| WATER (UNII: 059QF0KO0R) | |
| FRAGRANCE LAVENDER & CHIA F-153480 (UNII: SXS9CO2TZK) | |
| TOCOPHEROL (UNII: R0ZB2556P8) | |
| PROPANEDIOL (UNII: 5965N8W85T) | |

Packaging

| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
|---|------------------|---|----------------------|--------------------|
| 1 | NDC:74871-063-00 | 60 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product | 09/25/2020 | |

Marketing Information

| Marketing Category | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date |
|-------------------------|--|----------------------|--------------------|
| OTC monograph not final | part333A | 09/25/2020 | |

Labeler - ITECH 361 LLC (859157377)**Registrant** - ITECH 361 LLC (859157377)**Establishment**

| Name | Address | ID/FEI | Business Operations |
|---------------------------------------|---------|-----------|------------------------|
| GUANGZHOU GOTDYA FINE CHEMICAL CO LTD | | 551470189 | manufacture(74871-063) |

Establishment

| Name | Address | ID/FEI | Business Operations |
|---------------|---------|-----------|---------------------|
| ITECH 361 LLC | | 859157377 | pack(74871-063) |

Revised: 9/2020

ITECH361 LLC