FAMILIE HAND SANITIZER- isopropyl alcohol gel DOJB PARTNERSHIP 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.

This is a hand sanitizer manufactured according to the Temporary Policy for Preparation of Certain Alcohol-Based Hand Sanitizer Products During the Public Health Emergency (CoViD-19); Guidance for Industry.

The hand sanitizer is manufactured using only the following United States Pharmacopoeia (USP) grade ingredients in the preparation of the product (percentage in final product formulation) consistent with World Health Organization (WHO) recommendations:

- a. Isopropyl Alcohol (75%, v/v) in an aqueous solution denatured according to Alcohol and Tobacco Tax and Trade Bureau regulations in 27 CFR part 20.
- b. Glycerol (1.45% v/v).
- c. Hydrogen peroxide (0.125% v/v).
- d. Sterile distilled water or boiled cold water.

The firm does not add other active or inactive ingredients. Different or additional ingredients may impact the quality and potency of the product.

Active Ingredient(s)

Isopropyl Alcohol 75% 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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Keep out of reach of children. If swallowed, get medical help or contact a Poison Control Center right away.

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, hydrogen peroxide, purified water USP

Package Label - Principal Display Panel

500ml NDC: 78734





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| Drug Facts Active Ingredient Directions: Put a thumbnail size amount in the seas of age should be supervised when used to infants. Information: * Do not store above fait tecommended for infants. Intertion the seas of age should be supervised when used to infants. Intertion the seas of age should be supervised when used to infants. Intertion the seas of age should be supervised when used to infants. Intertion the seas of age should be supervised when used to infants. Intertion the seas of age should be supervised when used to infants. Intertion the seas of age should be supervised when used to infants. Intertion the sease of children. Intertion of the sease of children. Intertion of the date in all sease of the sea | nhand shand | |

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FAMILIE HAND SANITIZER

isopropyl alcohol gel

| | ation | | | | | | |
|--|--|---------------------------------|---------------------|------------------|-------------------|----------------------------|--|
| Product Type | | HUMAN OTC DRUG | Item Code (Sour | Code (Source) | | NDC:78734-284 | |
| Route of Administr | ation | TOPICAL | | | | | |
| | | | | | | | |
| Active Ingredie | nt/Active Moi | ety | | | | | |
| Ingredient Name | | | | | ength | Strength | |
| ISOPROPYL ALCOHOL (UNII: ND2M416302) (ISOPROPYL ALCOHOL - UNII:ND2M416302) | | | | | | mL 100 mL | |
| | | | | | | | |
| Inactive Ingredi | ents | | | | | | |
| Ingredient Name | | | | | Strength | | |
| GLYCERIN (UNII: PDC6A3C0OX) | | | | | 1.45 mL in 100 mL | | |
| GLYCERIN (UNII: PD | CUAJCUUAJ | | | 1.45 IIIL III 10 | | | |
| GLYCERIN (UNII: PD HYDROGEN PEROX | | 0 AN9 V) | | 0.125 mL in 10 | | | |
| | IDE (UNII: BBX06 | 50 AN9 V) | | | | | |
| HYDRO GEN PERO X | IDE (UNII: BBX06 | 50 AN9 V) | | | | | |
| HYDRO GEN PERO X | IDE (UNII: BBX06 | 50 AN9 V) | | | | | |
| HYDROGEN PEROX WATER (UNII: 059QF | IDE (UNII: BBX06 | 50 AN9 V) | | | | | |
| HYDROGEN PEROX WATER (UNII: 059QF Packaging | IDE (UNII: BBX06 F0KO0R) | 0 AN9 V) Package Description | Marketi | | 00 mL | ng End Date | |
| HYDROGEN PEROX WATER (UNII: 059QF Packaging # Item Code | IDE (UNII: BBX06 F0KO0R) | | | 0.125 mL in 14 | 00 mL | ng End Date | |
| HYDROGEN PEROX WATER (UNII: 059QF Packaging # Item Code | IDE (UNII: BBX06 F0KO0R) | Package Description | | 0.125 mL in 14 | 00 mL | ng End Date | |
| HYDROGEN PEROX WATER (UNII: 059QF Packaging # Item Code | IDE (UNII: BBX06 F0KO0R) | Package Description | | 0.125 mL in 14 | 00 mL | ng End Date | |
| HYDROGEN PEROX WATER (UNII: 059QF Packaging # Item Code 1 NDC:78734-284-01 | IDE (UNII: BBX06 F0KO0R) 500 mL in 1 BO | Package Description | | 0.125 mL in 14 | 00 mL | ng End Date | |
| HYDROGEN PEROX WATER (UNII: 059QF Packaging # Item Code | IDE (UNII: BBX06 F0KO0R) 500 mL in 1 BO formation | Package Description | on Product 06/09/20 | 0.125 mL in 14 | 00 mL | ng End Date ng End Date | |

Labeler - DOJB PART NERSHIP LLC (117541463)

Establishment

| Name | Address | ID/FEI | Business Operations |
|------------------------------------|---------|-----------|----------------------------|
| Shenzhen Lantern Science Co., ltd. | | 421222423 | manufacture(78734-284) |

Revised: 6/2020

DOJB PART NERSHIP LLC