

DR.JMEELAB HAND SANITIZER- alcohol gel
JMPBIO co., Ltd.

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.

ACTIVE INGREDIENT

Active ingredients: ALCOHOL 70.0%

INACTIVE INGREDIENT

Inactive ingredients:

Water, Glycerin, Butylene Glycol, Carbomer, Triethanolamine, Rosmarinus Officinalis (Rosemary) Leaf Extract, Paeonia Suffruticosa Bark Extract, Aloe Barbadosensis Leaf Extract, Calendula Officinalis Flower Extract

PURPOSE

Purpose: SANITIZER

WARNINGS

Warnings:

1.Do not use the product on the following areas:

Around the eyes and ears, in the mouth, large body parts and damaged skin(Irritation may occur)

2.If you experience any of the following symptoms, discontinue use of the product immediately and consult a physician or pharmacist.

1) Hypersensitivity symptoms, e.g. rash, erythema, itchiness, and edema

2)Skin irritation symptoms

3.Other precautions

1) For external use only (do not swallow).

2) Avoid contact with eyes. If contact occurs, wash with clean water and consult a doctor or pharmacist.

3)Be careful not to inhale vapors in cases of extended or prolonged use. (Repeating inhaling of large amounts of ethanol vapor may cause irritation of the mucous membranes and headaches).

(Limited to ethanol-containing products)

4) If used repeatedly in the same area, care should be provided as the skin may become rough due to excessive oil removal.

5) Do not use sealed bandages, cast bandages, or packs as they may cause irritation.

6) Do not use this drug on the anal or vagina areas, or with hot packs, as it may cause irritation or chemical burns.

7) Use only for the intended purposes.

4.Precautions for storage

1) Keep away from direct sunlight and do not expose the product to heating devices or flame.

2) Keep out of reach of children and go to the hospital immediately if swallowed.

3) After use, close the lid completely to prevent the product from drying or foreign objects from getting inside the container.

4) Storing the product in a different container may cause accidents or deterioration of quality.

Therefore, keep the product in its original container.

Dust or foreign substances may get on the product while using it.

KEEP OUT OF REACH OF CHILDREN

Keep out of reach of children and go to the hospital immediately if swallowed.

Uses

Uses:

- instant hand antiseptic to reduce bacteria that potentially
- Hand Sanitizer to help reduce bacteria on the ski that could cause disease
- Recommended for repeated use

Directions

Directions:

Take an appropriate amount on your hands and rub thoroughly to dry.

Children under 6 years of age should be supervised when using this product

PACKAGE LABEL.PRINCIPAL DISPLAY PANEL

| | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
|--|--|-------------------|--|---------------------------|----------------|---------------|-----------|-------------|--|--|--|---|--|-------------------------------|--|-----------------|--|---|--|--|--|--|--|--|--|-------------------|--|--|--|-----------------------------|--|---|--|--|--|-----------------------------|--|
|   ETHANOL 70% KILLS 99.99% OF GERMS <input checked="" type="checkbox"/> No Wash Type <input checked="" type="checkbox"/> Made in Korea <input checked="" type="checkbox"/> Professional 500mL / 17.64 FL OZ | <table border="1"><tr><td colspan="2">Drug Facts</td></tr><tr><td><i>Active Ingredients</i></td><td><i>Purpose</i></td></tr><tr><td>ALCOHOL 70.0%</td><td>SANITIZER</td></tr><tr><td colspan="2">Uses</td></tr><tr><td colspan="2">●Instant hand satiseptic to reduce bacteria that potentially</td></tr><tr><td colspan="2">●Hand Sanitizer to help reduce bacteria on the ski that could cause disease</td></tr><tr><td colspan="2">●Recommended for repeated use</td></tr><tr><td colspan="2">Warnings</td></tr><tr><td colspan="2">1.Do not use the product on the following areas: Around the eyes, ears, in the mouth, large body parts and damaged skin(Irritation may occur)</td></tr><tr><td colspan="2">2.If you experience any of the following symptoms, discontinue use of the product immediately and consult a physician or pharmacist.</td></tr><tr><td colspan="2">3. 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DR.JMEELAB HAND SANITIZER

alcohol gel

Product Information

| | | | |
|-------------------------|----------------|--------------------|---------------|
| Product Type | HUMAN OTC DRUG | Item Code (Source) | NDC:72144-040 |
| Route of Administration | TOPICAL | | |

Active Ingredient/Active Moiety

| Ingredient Name | Basis of Strength | Strength |
|--|-------------------|-----------------|
| ALCOHOL (UNII: 3K9958V90M) (ALCOHOL - UNII:3K9958V90M) | ALCOHOL | 350 g in 500 mL |

Inactive Ingredients

| Ingredient Name | Strength |
|--|----------|
| Water (UNII: 059QF0KO0R) | |
| Glycerin (UNII: PDC6A3C0OX) | |
| Butylene Glycol (UNII: 3XUS85K0RA) | |
| CARBOMER HOMO POLYMER, UNSPECIFIED TYPE (UNII: 0A5MM307FC) | |
| TROLAMINE (UNII: 9O3K93S3TK) | |
| ROSEMARY (UNII: IJ67X351P9) | |
| PAEONIA X SUFRUTICOSA ROOT BARK (UNII: BUG255FE7X) | |
| ALOE VERA LEAF (UNII: ZY81Z83H0X) | |
| CALENDULA OFFICINALIS FLOWER (UNII: P0M7O4Y7YD) | |

Packaging

| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
|---|------------------|---|----------------------|--------------------|
| 1 | NDC:72144-040-01 | 500 mL in 1 BOTTLE, PUMP; Type 0: Not a Combination Product | 04/01/2020 | |

Marketing Information

| Marketing Category | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date |
|-------------------------|--|----------------------|--------------------|
| OTC monograph not final | part333E | 04/01/2020 | |

Labeler - JMPBIO co., Ltd. (688415479)

Registrant - JMPBIO co., Ltd. (688415479)

Establishment

| Name | Address | ID/FEI | Business Operations |
|---------------------|---------|-----------|------------------------|
| AT Bio Pharm Co Ltd | | 695742996 | manufacture(72144-040) |

