

KLINARE HAND SANITIZER- alcohol gel

Química Blantex, S.A. de C.V.

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.

Klinare NDC 78342-003

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, Carbomer, Alkyl Lactate, Propylene Glycol, Fragrance, Aminomethyl Propanol,

Chamomilla Recutita Extract, Tocopheryl Acetate, Limonene

Package Label - Principal Display Panel

500 mL NDC: 78342-003-01



Net. 16.9 fl oz (500 mL)

Drug Facts

| Active Ingredient | Purpose |
|----------------------------|----------------|
| Ethyl alcohol 70% v/v..... | Antiseptic |

Use (s) Hand sanitizer to help reduce bacteria that potentially can cause disease.

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• on open skin wounds

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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.

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 15-30°C (59-86°F) • Avoid freezing and excessive heat above 40°C (104°F) • May discolor certain fabrics or surfaces

Inactive ingredients: Purified Water USP, Carbomer, Alkyl Lactate, Propylene Glycol, Fragrance, Aminomethyl Propanol, *Chamomilla recutita extract*, Tocopheryl Acetate, Limonene.

QUESTIONS: 800-517-2247

klinare

MADE IN MEXICO

DISTRIBUTED BY:

RediBag USA
135 Fulton Ave
New Hyde Park
NY 11040



KLINARE HAND SANITIZER

alcohol gel

Product Information

| | | | |
|--------------------------------|----------------|---------------------------|---------------|
| Product Type | HUMAN OTC DRUG | Item Code (Source) | NDC:78342-003 |
| Route of Administration | TOPICAL | | |

Active Ingredient/Active Moiety

| Ingredient Name | Basis of Strength | Strength |
|--|-------------------|-----------------|
| ALCOHOL (UNII: 3K9958V90M) (ALCOHOL - UNII:3K9958V90M) | ALCOHOL | 70 mL in 100 mL |

Inactive Ingredients

| Ingredient Name | Strength |
|--|--------------------|
| AMINOMETHYLPROPANOL (UNII: LU49E6626Q) | 0.1 mL in 100 mL |
| CARBOMER HOMO POLYMER, UNSPECIFIED TYPE (UNII: 0A5MM307FC) | 0.5 mL in 100 mL |
| C12-15 ALKYL LACTATE (UNII: GC844VRD7E) | 0.5 mL in 100 mL |
| WATER (UNII: 059QF0KO0R) | 28.44 mL in 100 mL |
| PROPYLENE GLYCOL (UNII: 6DC9Q167V3) | 0.2 mL in 100 mL |
| FRAGRANCE LEMON ORC2001060 (UNII: K1725A7G95) | 0.2 mL in 100 mL |
| MATRICARIA CHAMOMILLA WHOLE (UNII: G0R4UBI2ZZ) | 0.05 mL in 100 mL |
| ALPHA-TOCOPHEROL ACETATE (UNII: 9E8X80D2L0) | 0.01 mL in 100 mL |
| LIMONENE, (+)- (UNII: GFD7C86Q1W) | 0.001 mL in 100 mL |

Packaging

| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
|---|------------------|---|----------------------|--------------------|
| 1 | NDC:78342-003-01 | 500 mL in 1 BOTTLE; Type 0: Not a Combination Product | 07/31/2020 | |

Marketing Information

| Marketing Category | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date |
|-------------------------|--|----------------------|--------------------|
| OTC monograph not final | part333A | 07/31/2020 | |

Labeler - Química Blantex, S.A. de C.V. (810400366)

Establishment

| Name | Address | ID/FEI | Business Operations |
|-------------------------------|---------|-----------|---|
| Química Blantex, S.A. de C.V. | | 810400366 | manufacture(78342-003) , label(78342-003) |

Revised: 7/2020

Química Blantex, S.A. de C.V.