

SANITIZER CREAM- sanitizer cream cream
Clima Cool Express, 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.

Use

Hand Sanitizer to help reduce bacteria that potentially can cause disease. For use when soap and water are not available.

Purpose

Antiseptic, Cream Sanitizer

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)

Benzalkonium Chloride 0.05% v/v. Purpose: Antiseptic

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 USP, fragrance

Package Label - Principal Display Panel

Cream Sanitizer

960 mL (32.46 fl. oz.)

| | |
|---|------------------------------|
| Drug Facts | |
| Active ingredient. Benzalkonium Chloride 0.05%v/v..... | Purpose Antiseptic |
| Use[s] Cream 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 <ul style="list-style-type: none">• 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. | |
| Directions <ul style="list-style-type: none">• 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 <ul style="list-style-type: none">• Store between 15-30C (59-86F)• Avoid freezing and excessive heat above 40C (104F) | |
| Inactive ingredients fragrance, purified water USP | |

Questions? Call 52-33-1145-1204
Clima Cool Express, S.A de C.V
Jesus Garcia No. 781, Guadalajara, Jalisco, Mexico, 44200
Made in México

NET CONTENTS
960 mL
(32.46 fl. oz.)

960g NDC 80306-001-03

SANITIZER CREAM

sanitizer cream cream

Product Information

| | | | |
|--------------------------------|----------------|---------------------------|---------------|
| Product Type | HUMAN OTC DRUG | Item Code (Source) | NDC:80306-001 |
| Route of Administration | TOPICAL | | |

Active Ingredient/Active Moiety

| Ingredient Name | Basis of Strength | Strength |
|---|--------------------------|-----------------|
| BENZALKONIUM CHLORIDE (UNII: F5UM2KM3W7) (BENZALKONIUM - UNII:7N6JUD5X6Y) | BENZALKONIUM CHLORIDE | 0.5 g in 100 g |

Inactive Ingredients

| Ingredient Name | Strength |
|---|------------------|
| FRAGRANCE CLEAN ORC0600327 (UNII: 329LCV5BTF) | 0.005 g in 100 g |
| WATER (UNII: 059QF0KO0R) | |

Packaging

| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
|---|------------------|--|-----------------------------|---------------------------|
| 1 | NDC:80306-001-01 | 250 g in 1 BOTTLE; Type 0: Not a Combination Product | 03/30/2020 | |
| 2 | NDC:80306-001-02 | 500 g in 1 BOTTLE; Type 0: Not a Combination Product | 03/30/2020 | |
| 3 | NDC:80306-001-03 | 960 g in 1 BOTTLE; Type 0: Not a Combination Product | 03/30/2020 | |
| 4 | NDC:80306-001-04 | 3790 g in 1 BOTTLE; Type 0: Not a Combination Product | 03/30/2020 | |
| 5 | NDC:80306-001-05 | 20000 g in 1 BOTTLE; 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 - Clima Cool Express, S.A de C.V. (951582482)

Registrant - Clima Cool Express, S.A. de C.V. (951582482)

Establishment

| Name | Address | ID/FEI | Business Operations |
|----------------------------------|----------------|---------------|----------------------------|
| Clima Cool Express, S.A. de C.V. | | 951582482 | manufacture(80306-001) |

Revised: 8/2020

Clima Cool Express, S.A de C.V.