

## **CLEAN HANDS SANITIZING GEL- alcohol gel**

### **Blue Cat**

*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.*

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### **Clean Hands Sanitizing Gel**

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. Alcohol (ethanol) (USP or Food Chemical Codex (FCC) grade) (80%, volume/volume (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)**

Alcohol 80% 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

glycerin, aloe vera, vitamin e acetate, fragrance, carbomer, purified water USP

### Package Label - Principal Display Panel

000 mL NDC: 78415-003-01

|   |  |  |
|---|--|--|
| <p><b>ACTIVE INGREDIENT</b><br/>Ethyl Alcohol &gt;70% v/v</p>   |   | <p><b>INSTANT HAND SANITIZING GEL</b> is &gt;70% v/v Ethyl Alcohol and carefully selected emollients such as Vitamin E &amp; Aloe Vera moisturizers.</p>               |
| <p><b>PURPOSE</b><br/>Antimicrobial</p>   |  | <p><b>HAZARD STATEMENTS</b><br/>May cause eye irritation. May be harmful if swallowed.</p>   |
| <p><b>USES</b><br/>To help keep hands clean. For repeated use.</p>  |  | <p><b>PRECAUTIONARY STATEMENTS</b><br/>Forms smooth, slippery surfaces on floors, posing an accident risk.</p>   |
| <p><b>WARNINGS</b><br/>For external use only. Flammable. Keep away from heat or flame. 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 appears or persists. Keep out of reach of children. If swallowed, get medical help or contact a Poison Control Center immediately.</p> |  | <p><b>STORAGE AND HANDLING</b><br/>Store in a dry and well-ventilated place. Store in a closed container. Keep cool. Use / follow appropriate industrial practice.</p> |
| <p><b>DIRECTIONS</b><br/>Wet hands thoroughly and briskly rub hands together for 20-30 seconds or until dry. Supervise children &lt;6 years of age when using to avoid swallowing.</p>  |  | <p><b>SPILL RESPONSE</b><br/>Wipe away or for larger spills, dike area in front / around spill and contain for appropriate disposal.</p>                               |
| <p><b>INACTIVE INGREDIENTS</b><br/>Purified Water, Glycerin-26, PEG-40 Hydrogenated Castor Oil, Carbomer, Vitamin E Acetate, Aloe Vera, Fragrance.</p>  | <p>Emergency Phone Number<br/>1-800-424-9300</p>  | <p>bcluxuryamenities.com<br/>lifeisbetterwithcleanhands.com<br/>Toll-free: 1-800-756-4442</p>  |
| <p>Emergency Phone Number<br/>1-800-424-9300</p>  |  |   |
|    |  |  |

## CLEAN HANDS SANITIZING GEL

alcohol gel

### Product Information

|                                |                |                           |               |
|--------------------------------|----------------|---------------------------|---------------|
| <b>Product Type</b>            | HUMAN OTC DRUG | <b>Item Code (Source)</b> | NDC:78415-003 |
| <b>Route of Administration</b> | TOPICAL        |                           |               |

**Active Ingredient/Active Moiety**

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

**Inactive Ingredients**

| Ingredient Name  | Strength         |
|--|------------------|
| ALOE VERA FLOWER (UNII: 575DY8C1ER)                        | 0.01 L in 100 L  |
| CARBOMER HOMO POLYMER, UNSPECIFIED TYPE (UNII: 0A5MM307FC) | 0.5 L in 100 L   |
| PEG-40 HYDROGENATED LANOLIN (UNII: 959P5CXE48)             | 0.3 L in 100 L   |
| GLYCERIN (UNII: PDC6A3C0OX)                                | 1.42 L in 100 L  |
| AMINOMETHYL PROPANEDIOL (UNII: CZ7BU4QZJZ)                 | 0.15 L in 100 L  |
| WATER (UNII: 059QF0K00R)                                   | 27.61 L in 100 L |
| .ALPHA.-TOCOPHEROL ACETATE, D- (UNII: A7E6112E4N)          | 0.01 L in 100 L  |

**Packaging**

| # | Item Code        | Package Description                                    | Marketing Start Date | Marketing End Date |
|---|------------------|--|----------------------|--------------------|
| 1 | NDC:78415-003-01 | 3.785 L 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** - Blue Cat (795910491)**Registrant** - Custom Blenders (057505117)**Establishment**

| Name            | Address | ID/FEI    | Business Operations    |
|-----------------|---------|-----------|------------------------|
| Custom Blenders |         | 057505117 | manufacture(78415-003) |

Revised: 6/2020

Blue Cat