CRAZE NATURALS- alcohol gel CMM Capital, 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.

Craze Naturals Hand Sanitizer 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

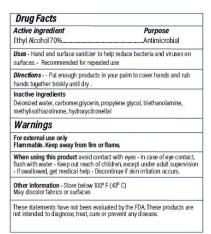
- Store between 15-30C (59-86F)
- Avoid freezing and excessive heat above 40C (104F)

Inactive ingredients

glycerin, hydrogen peroxide, purified water USP

Package Label - Principal Display Panel





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SANITIZER *70% ALCOHOL*

KILLS 99.99% OF ILLNESS CAUSING GERMS

Anti-fungal, Anti-bacterial, Anti-Microbial



20z (60 mL)







SANITIZER 70% ALCOHOL

> **KILLS 99.99% OF ILLNESS CAUSING GERMS**

Anti-fungal, Anti-bacterial, Anti-Microbial

GEL

160z (473 mL)





Drug Facts

Active ingredient

Ethyl Alcohol 70%

Purpose

Uses - Hand and surface sanitizer to help reduce bacteria and viruses on

surfaces. Recommended for repeated use

Directions - - Put enough products in your paim to cover hands and rub hands together briskly until dry

Inactive Ingredients
Deionized water, carbomer,glycerin, propylene glycol, triethanolamine, methylisalhiazolinone, hydroxycitronellal

Warnings

For external use only Flammable. Keep away from fire or flame.

When using this product avoid contact with eyes - In case of eye contact, flush with water - Keep out reach of children, except under adult supervision - If swallowed, get medical help - Discontinue if skin irritation occurs.

Other Information - Store below 100° F (43° C) May discolor fabrics or surfaces

These statements have not been evaluated by the FDA. These products are not intended to diagnose, treat, cure or prevent any disease.

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Drug Facts

Active ingredient

Purpose

Ethyl Alcohol 70%....

..Antimicrobial

Uses · Hand and surface sanitizer to help reduce bacteria and viruses on surfaces. · Recommended for repeated use

Directions - - Put enough products in your palm to cover hands and rub hands together briskly until dry.

Inactive Ingredients

Deionized water, carbomer,glycerin, propylene glycol, triethanolamine, methylisolhiazolinone, hydroxycitronellal

Warnings

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70% ALCOHOL

KILLS 99.99% OF ILLNESS CAUSING GERMS

Anti-fungal, Anti-bacterial, Anti-Microbial



80z (236 mL)







SANITIZER **70% ALCOHOL**

KILLS 99.99% OF ILLNESS CAUSING GERMS

Anti-fungal, Anti-bacterial, Anti-Microbial



1 Gallon (128 fl oz)





| Drug | Facts |
|------|-------|
| | |

Active ingredien Ethyl Alcohol 70%

Purpose .Antimicrobial

Uses - Hand and surface sanitizer to help reduce bacteria and viruses on surfaces. - Recommended for repeated use

Directions - - Put enough products in your palm to cover hands and rub

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Drug Facts

Active ingredient

Purpose

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SANITIZER 70% ALCOHOL

KILLS 99.99% OF ILLNESS CAUSING GERMS

Anti-fungal, Anti-bacterial, Anti-Microbial



320z (946 mL)





Drug Facts

Active ingredient

Purpose

Ethyl Alcohol 70%... .Antimicrobial

Uses - Hand and surface sanitizer to help reduce bacteria and viruses on surfaces. · Recommended for repeated use

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Inactive Ingredients

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0 mL NDC: 00000-000-00

CRAZE NATURALS

alcohol gel

| Product | Inform | nation |
|----------------|--------|--------|
| FIVUUCL | THUULH | ıauvıı |

Route of Administration

| Product Type | HUMAN OTC DRUG | Item Code (Source) | NDC:79661-002 |
|--------------|----------------|--------------------|---------------|
| | | | |

TOPICAL

Active Ingredient/Active Moiety

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

| Inactive 1 | Ing redients |
|------------|--------------|
|------------|--------------|

| inactive ingredients | | | |
|--|-------------------|--|--|
| Ingredient Name | Strength | | |
| GLYCERIN (UNII: PDC6A3C0OX) | 1.45 mL in 100 mL | | |
| HYPROMELLOSE 2208 (100 MPA.S) (UNII: B1QE5P712K) | 9 mL in 100 mL | | |

| WATER (UNII: 059QF0KO0R) | |
|---|----------------|
| HYDROXYPROPYL CELLULOSE, UNSPECIFIED (UNII: 9 XZ8 H6 N6 OH) | 9 mL in 100 mL |

| Packaging | | | | |
|-----------|---------------------------------|--|-------------------------|-----------------------|
| # | # Item Code Package Description | | Marketing Start Date | Marketing End Date |
| 1 | NDC:79661-002- 02 | 60 mL in 1 BOTTLE, DISPENSING; Type 0: Not a Combination Product | 03/30/2020 | |
| 2 | NDC:79661-002- 04 | 120 mL in 1 BOTTLE, DISPENSING; Type 0: Not a Combination Product | 03/30/2020 | |
| 3 | NDC:79661-002- 08 | 236 mL in 1 BOTTLE, DISPENSING; Type 0: Not a Combination Product | 03/30/2020 | |
| 4 | NDC:79661-002- 16 | 473 mL in 1 BOTTLE, DISPENSING; Type 0: Not a Combination Product | 03/30/2020 | |
| 5 | NDC:79661-002- 32 | 946 mL in 1 BOTTLE, DISPENSING; Type 0: Not a Combination Product | 03/30/2020 | |
| 6 | NDC:79661-002- 01 | 3785 mL in 1 BOTTLE, DISPENSING; 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 - CMM Capital, LLC (005409676)

| Establishment | | | | |
|------------------|---------|-----------|---------------------|--|
| Name | Address | ID/FEI | Business Operations | |
| CMM Capital, LLC | | 005409676 | label(79661-002) | |

Revised: 8/2020 CMM Capital, LLC