

HAND SANITIZER- hand sanitizer aerosol, foam IBUUMERANG 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.

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.

Stop use and ask a doctor if irritation or rash occurs. These may be signs of a serious condition.

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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

3.78 L NDC: 82011-310-01

skintech: by ZENCE

properties

SkinTech Antimicrobial foam is capable of protecting you and your loved ones skin for 4 continuous hours while gently moisturizing your skin.

benefits

SkinTech has been proven to maintain effectiveness through hand-washings! A single application will keep your hands protected for 4 hours and acts as a bio-chemical glove to protect your hands. Kills a wide spectrum of bacteria, viruses and fungi on contact without needing to reapply.

SkinTech is alcohol-free, non-irritating, colorless, non-toxic, and safe for kids, pets, and the environment.

directions

Wash your hands prior to applying for maximum protection. Apply 1ml on your hands, which is about 2 pumps. Rub your hands together on top as well as the palms and let dry allowing the invisible chemical glove to form.

izence.com

LOT:

EXP DATE:



skintech
by ZENCE

SKINCARE

ANTISEPTIC
FOAM

PROTECTS THE
SKIN FOR 4 HOURS



clean



moisturize



protect

1 gallon (3.78 liters)

Drug Facts

Active ingredient Purpose
Benzalkonium chloride 0.13% ...Antiseptic

Use

■ for hand washing to decrease bacteria on the skin

Warnings

For external use only.

Do not use in the eyes

Stop use and ask a doctor if

■ irritation and redness develop. If condition persists for more than 72 hours consult a doctor.

Keep out of reach of children. If swallowed, get medical help or contact a Poison Control Center right away.

Directions

wet hands thoroughly with product and allow to dry without wiping

Other information

avoid use in case of hypersensitivity to benzalkonium chloride

Inactive ingredients

Citric Acid, Hydroxyethylcellulose, Lanolin Ethoxylated, Povidone, Propylene Glycol, Water

Questions or Comments?

support@izence.com

It is not medicine - only for external use.



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HAND SANITIZER

hand sanitizer aerosol, foam

Product Information

| | | | |
|--------------------------------|----------------|---------------------------|---------------|
| Product Type | HUMAN OTC DRUG | Item Code (Source) | NDC:82011-310 |
| Route of Administration | TOPICAL | | |

Active Ingredient/Active Moiety

| Ingredient Name | Basis of Strength | Strength |
|---|-----------------------|------------------|
| BENZALKONIUM CHLORIDE (UNII: F5UM2KM3W7) (BENZALKONIUM - UNII: 7N6JUD5X6Y) | BENZALKONIUM CHLORIDE | 0.13 kg in 100 L |

Inactive Ingredients

| Ingredient Name | Strength |
|---|------------------|
| CITRIC ACID MONOHYDRATE (UNII: 2968PHW8QP) | 0.125 L in 100 L |
| POVIDONE (UNII: FZ989GH94E) | 0.05 L in 100 L |
| WATER (UNII: 059QF0KO0R) | |
| HYDROXYETHYL CELLULOSE, UNSPECIFIED (UNII: T4V6TWG28D) | 0.1 L in 100 L |
| LANOLIN (UNII: 7EV65EAW6H) | 0.05 L in 100 L |

PROPYLENE GLYCOL (UNII: 6DC9Q167V3)

1.45 L in 100 L

Packaging

| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
|---|------------------|---|----------------------|--------------------|
| 1 | NDC:82011-310-01 | 3.78 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 - IBUUMERANG LLC (117662391)

Establishment

| Name | Address | ID/FEI | Business Operations |
|----------------|---------|-----------|------------------------|
| IBUUMERANG LLC | | 117662391 | manufacture(82011-310) |

Revised: 6/2021

IBUUMERANG LLC