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.

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

Inactive ingredients

glycerin, hydrogen peroxide, purified water USP

Package Label - Principal Display Panel

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

5.07 fl oz (150ml)

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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150 mL NDC: 82011-210-02

HAND SANITIZER

hand sanitizer aerosol, foam

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:82011-210
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 g in 100 mL

Inactive Ingredients	
Ingredient Name	**Strength**
CITRIC ACID MONOHYDRATE (UNII: 2968PHW8QP)	0.125 mL in 100 mL
POVIDONE (UNII: FZ989GH94E)	0.05 mL in 100 mL
WATER (UNII: 059QF0KO0R)	
LANOLIN (UNII: 7EV65EAW6H)	0.05 mL in 100 mL
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	1.45 mL in 100 mL

HYDROXYETHYL CELLULOSE, UNSPECIFIED (UNII: T4V6TWG28D)	0.1 mL in 100 mL

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:82011-210-02	150 mL 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(82011-210)

Revised: 6/2021 IBUUMERANG LLC