

MODSOCLEAN HAND SANITIZER- benzalkonium chloride liquid

VitalPure 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.

Ben sanitizerza

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

Drug Facts

Active ingredients	Purpose
Benzalkonium Chloride 0.13%	Anti-microbial
Uses	
For hand sanitizing to eliminate microbial on skin	
Warnings	
For external use only. Do not use in eyes. In case of eye contact, flush thoroughly and seek medical assistance	
Stop use if redness or irritation occurs, or if condition persists for more than 72 hours seek medical attention	
Keep out of the reach of Children. If swallowed, seek medical help or contact a Poison Control Center immediately.	
Directions	
Dispense an adequate amount in palm to allow complete coverage of hands. Rub hands together thoroughly until dry. Supervise young children while using this product.	
Provides up to 4 hrs of ongoing anti-microbial protection	
Inactive Ingredients:	
Purified water, glycerin and citric acid	
Questions? inquiries@n2nango.com	
www.n2nango.com	
N2N Global LLC	
2013 W Overton Rd #182	
Edmond, OK 73033	

MADE IN USA

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MODSOCLEAN

Hand Sanitizer

Effective against most germs and viruses

Alcohol Free, Fragrance Free

2 oz

The formula for **MODSOCLEAN HAND SANITIZER** was created to destroy the most difficult viruses and bacteria, yet leave the least impact to our planet. Modsoclean Hand Sanitizer is safe for children, pets, sensitive areas and the environment, and is alcohol free. It works like nothing else.

Manufactured for N2N Global LLC
by VitalPure Labs
2104 B Memorial Blvd
Kerrville TX 78028

FDA
FDA-NDC Reg. # 77881-004-01

000 mL NDC: 00000-000-00

MODSOCLEAN HAND SANITIZER

benzalkonium chloride liquid

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:77881-004
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 mg in 100 mg	
Inactive Ingredients				
Ingredient Name		Strength		
GLYCERIN (UNII: PDC6A3C0OX)				
WATER (UNII: 059QF0K00R)				
Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:77881-004-01	60 mg in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	09/08/2020	
Marketing Information				
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date	
OTC monograph not final	part333A	09/07/2020		

Labeler - VitalPure LLC (073341428)

Registrant - VitalPure LLC (073341428)

Establishment

Name	Address	ID/FEI	Business Operations
VitalPure LLC		073341428	manufacture(77881-004)

Revised: 9/2020

VitalPure LLC