

HAND SANITIZER- alcohol gel

Jon Davler, Inc.

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.

Value Queen Fragrance Free hand Sanitizing Gel 70% v/v 60ml

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)

Ethyl Alcohol 70% v/v. Purpose: Antimicrobial

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

Water (aqua), Propylene Glycol, Glycerin, Peg-6 (and) AMP-Acrylates/Vinyl Isodecanoate Crosspolymer, Aloe Barbadensis Leaf Juice, Tocopheryl Acetate.

Package Label - Principal Display Panel

60 mL NDC: 74044-0057-2

ESSENTIAL LUXURY

KILLS GERMS

METHANOL

Fragrance Free
HAND SANITIZING GEL
Essential Oils
Keep Hands Safe & Soft

VITAMIN E ALOE VERA **70% ALCOHOL** VEGAN CRUELTY FREE

MADE IN USA
2 fl. oz. (60 ml)

Drug Facts
Active Ingredient Ethyl Alcohol 70%..... **Purpose** Antimicrobial
Uses: • Hand sanitizer to help reduce bacteria on skin. • Recommended for repeated use.
Warnings
Flammable. Keep away from fire or flame.
For external use only: • Do not use product in or near the eyes. In case of contact, rinse eyes thoroughly with water • Stop use & ask a doctor if irritation or rash appears & lasts.
Keep out of reach of children. If swallowed, get medical help or contact a Poison Control Center right away.
Directions: • Place product in your palm to thoroughly cover your hands • Rub hands together briskly until dry • No rinsing required.
Other information
 • Do not store above 110°F (43°C)
 • May discolor certain fabrics or surfaces
Inactive ingredients: Water (aqua), Propylene Glycol, Glycerin, Peg-6 (and) AMP-Acrylates/Vinyl Isodecanoate Crosspolymer, Aloe Barbadensis Leaf Juice, Tocopheryl Acetate.

Manufactured in FDA registered facility.
Distributed by Value Queen LLC
Kennesaw, GA 30144, USA
crucityfree andvegan

#EL7703 FF GEL
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NDC# 74044-0057-2
LOT #08BJ EXP: 08/2022

HAND SANITIZER

alcohol gel

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:74044-0057
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

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

Inactive Ingredients

Ingredient Name	Strength
.ALPHA.-TOCOPHEROL ACETATE, DL- (UNII: WR1WPI7EW8)	0.094 mL in 100 mL
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	0.677 mL in 100 mL
GLYCERIN (UNII: PDC6A3C0OX)	0.451 mL in 100 mL
POLYETHYLENE GLYCOL 300 (UNII: 5655G9Y8AQ)	2.821 mL in 100 mL
WATER (UNII: 059QF0KO0R)	
ALOE (UNII: V5VD430YW9)	0.094 mL in 100 mL

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:74044-0057-2	60 mL in 1 BOTTLE, DISPENSING; Type 0: Not a Combination Product	08/19/2020	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part333A	08/19/2020	

Labeler - Jon Davler, Inc. (097710185)**Establishment**

Name	Address	ID/FEI	Business Operations
Jon Davler, Inc.		097710185	manufacture(74044-0057)

Revised: 8/2020

Jon Davler, Inc.