

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.

Rude Cosmetics Gel Hand Sanitizer Cherry Blossom 90ml

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: 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

Water(aqua), Isopropyl Alcohol, Propylene Glycol, Glycerin, Peg-6 (and) AMP-Acrylates/Vinyl Isodecanoate Crosspolymer, Aloe Barbadensis Leaf Juice, Tocopheryl Acetate, Aluminum Hydroxide, Bis(Glycidoxyphenyl)Propane/Bisaminomethylnorbornane Copolymer, CI 45380, CI45410, Fragrance.

Package Label - Principal Display Panel

90 mL NDC: 74044-0040-3

GERM KILLER

HAND SANITIZER GEL

Cherry Blossom

Désinfectant pour les mains / Desinfectante para manos

70% Ethyl Alcohol

CDC recommends 60%+
No water or soap needed

Adios Germs

Rude

MADE IN USA

90 ml / 3 fl. oz.

Drug Facts

Active Ingredient Purpose
Ethyl Alcohol 70% Antimicrobial

Uses

- Disinfect hands and common household surfaces.

Warnings

Flammable. Keep away from fire or flame.
For external use only
When using this product do not use in or near the eyes. In case of contact, rinse eyes thoroughly with water.
Stop use and ask a doctor if irritation or rash appears and lasts.
Keep out of reach of children. If swallowed, get medical help or contact a Poison Control Center right away.

Directions

- Use two spritz on one hand and rub hands together till dry.
- No rinsing required • No towels needed

Other information

- Do not store above 110°F (43°C)
- May discolor certain fabrics or surfaces

Inactive ingredients

Water(aqua), Isopropyl Alcohol, Propylene Glycol, Glycerin, Peg-6 (and) AMP-Acrylates/Vinyl Isodecanoate Crosspolymer, Aloe Barbadensis Leaf Juice, Tocopheryl Acetate, Aluminum Hydroxide, Bis(Glycidoxyphenyl)Propane/Bisaminomethylnorbornane Copolymer, CI 45380, CI 45410, Fragrance.

MADE IN USA

2-060

MADE IN U.S.A.
NDC# 74044-0040-3 LOT#: JB20-001 EXP: 05/2022

crucifyfree

ALABAMA ARIZONA CALIFORNIA COLORADO CONNECTICUT DELAWARE FLORIDA GEORGIA ILLINOIS INDIANA IOWA KANSAS KENTUCKY LOUISIANA MARYLAND MASSACHUSETTS MICHIGAN MINNESOTA MISSISSIPPI MISSOURI MONTANA NEBRASKA NEVADA NEW JERSEY NEW YORK NORTH CAROLINA NORTH DAKOTA OHIO OKLAHOMA OREGON PENNSYLVANIA RHODE ISLAND SOUTH CAROLINA SOUTH DAKOTA TEXAS UTAH VERMONT VIRGINIA WASHINGTON WISCONSIN WYOMING

RUDE COSMETICS INC. L.A. CA 90071, U.S.A.
P.N.R CONSULTANCY LTD. F18 5FT, U.K.
P.N.R CONSULTANCY LTD. 152, OFFICE 9,
SGN9030, MALTA,
MADE IN U.S.A.

SANITIZER GEL 90 ML 21009

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HAND SANITIZER

alcohol gel

Product Information

Product Type

HUMAN OTC DRUG

Item Code (Source)

NDC:74044-0040

Route of Administration	TOPICAL
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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
GLYCERIN (UNII: PDC6A3C0OX)	0.48 mL in 100 mL
ALOE (UNII: V5VD430YW9)	0.13 mL in 100 mL
WATER (UNII: 059QF0K00R)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:74044-0040-3	90 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	05/05/2020	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part333A	05/05/2020	

Labeler - Jon Davler, Inc. (097710185)

Establishment

Name	Address	ID/FEI	Business Operations
Jon Davler, Inc.		097710185	manufacture(74044-0040)

Revised: 5/2020

Jon Davler, Inc.