

## **HAND SANITIZER- alcohol spray**

**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 SPRAY Hand Sanitizer 100ml Peppermint/Lemon**

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, Aloe Barbadensis Leaf Juice, Tocopheryl Acetate, Citrus Medica Limonum (Lemon) Peel Oil, Mentha Piperita (Peppermint) Oil.

### Package Label - Principal Display Panel

100 mL NDC:74044-0041-3

**GERM KILLER**

**Peppermint + Lemon**

**HAND and SURFACE SANITIZER SPRAY**

Spray Désinfectant / Spray Desinfectante

**70% Ethyl Alcohol**

CDC recommends 60%+ Disinfects hands & common household surfaces

**Adios Germs**

**Rude**

**MADE IN USA**

100 mL / 3.4 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 spritzes 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, Aloe Barbadensis Leaf Juice, Tocopheryl Acetate, Citrus Medica Limonum (Lemon) Peel Oil, Mentha Piperita (Peppermint) Oil.

**MADE IN USA**

2-060

**Rude**

RUDE COSMETICS INC. LA, CA 90017, U.S.A.  
 P. N. R. CONSULTANCY LTD, FY8 5FT, UK.  
 SGN9030, MALTA.  
 MADE IN U.S.A.  
 NDC# 74044-0041-3 LOT#: JD20-001 EXP: 05/2022

**SANITIZER SPRAY 100 ML 21010**

8 50018 21010 2

## HAND SANITIZER

alcohol spray

### Product Information

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:74044-0041
<b>Route of Administration</b>	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
WATER (UNII: 059QF0KO0R)	
ALOE (UNII: V5VD430YW9)	0.13 mL in 100 mL

**Packaging**

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:74044-0041-3	100 mL in 1 BOTTLE, SPRAY; 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(74044-0041)

Revised: 5/2020

Jon Davler, Inc.