

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.

RIN ASOBI Hand Sanitizer Gel 101

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 75% 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), Propylene Glycol, Glycerin, Peg-6 (and) AMP-Acrylates/Vinyl Isodecanoate Crosspolymer, Aloe Barbadensis Leaf Juice, Tocopheryl Acetate.

Package Label - Principal Display Panel

○ ○ ○ Profits will be donated
○ ○ ○ LET'S BEAT COVID-19 TOGETHER!

SAVE THE WORLD
Hand Sanitizer
OPERATION TOMODACHI

Kills 99.99% Alcohol 75% 2FL OZ (59ml)

Drug Facts

Active Ingredient	Purpose
Ethyl alcohol 75%	Antimicrobial

Uses

- Hand sanitizer to help reduce bacteria on skin that could cause disease
- Recommended for repeated use

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

- Place enough product in your palm to thoroughly cover your hands
- Rub hands together briskly until 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, Propylene Glycol, Glycerin, Peg-6 (and)AMP-Acrylates/Vinyl Isodecanoate Crosspolymer, Aloe Barbadensis Leaf Juice, Tocopheryl Acetate.

Manufactured in a FDA registered facility.
 Distributed by YS Media Agency Inc.
 20675 S Western Ave, Torrance CA 90501, USA

NDC 74044-0101-2
 LOT NUMBER XXXXX
 EXP: XX/XX/XXXX

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60 mL NDC: 74044-0101-2

HAND SANITIZER			
alcohol gel			
Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:740 44-0 10 1
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
ALCOHOL (UNII: 3K9958V90M) (ALCOHOL - UNII:3K9958V90M)	ALCOHOL	75 mL in 100 mL

Inactive Ingredients

Ingredient Name	Strength
ALOE (UNII: V5VD430YW9)	0.13 mL in 100 mL
GLYCERIN (UNII: PDC6A3C0OX)	0.71 mL in 100 mL
WATER (UNII: 059QF0K00R)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:74044-0101-2	60 mL in 1 BOTTLE, PLASTIC; 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 - Jon Davler, Inc. (097710185)**Establishment**

Name	Address	ID/FEI	Business Operations
Jon Davler, Inc.		097710185	manufacture(74044-0101)

Revised: 4/2020

Jon Davler, Inc.