

HAND SANITIZER- ethyl alcohol gel
Zhejiang RIFESHOW Cosmetics Co., Ltd.

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.

Zhejiang RIFESHOW Cosmetics Co., Ltd.
Hand Sanitizer
236ml 56084-028-01
500ml 56084-028-02

Active Ingredient(s)

Alcohol 75%

Purpose

Antiseptic

Use

- For cleansing/sanitizing of the hands when soap and water are not available.
- Recommended for repeated use.

Warnings

- For external use only.
- Flammable. Keep away from heat or flame.
- Avoid contact with eyes. In case of contact, flush thoroughly with water.

Stop use and seek medical attention if skin irritation develops.

Keep out of reach of children. In case of accidental ingestion contact a physician or Poison Control Center right away.

Directions

- Apply generously, work into hands and allow to dry without wiping.
- Children under six should be supervised while using this product.

Other information

- Do not store above 110°.
- May discolor some fabrics or surfaces.
- Report adverse events to DermaRite Industries, PO Box 7209, North Bergen, NJ 07047.

Inactive ingredients

Deionized Water, Glycerol, Carbomer, Triethanolamine.

Call 1-800-337-6296

Mon-Fri 9AM- 5PM EST.

Package Label - Principal Display Panel

236 mL NDC: 56084-028-01

151240
NDC 61924-114-08

GelRite® 75

INSTANT HAND SANITIZER

Kills over 99% of germs
Gentle enough for frequent use

REORDER #00114
236 mL (8 fl. oz.)

Patient Name _____ Room # _____	<p>Drug Facts</p> <p>Active Ingredient Purpose Alcohol 75% Antiseptic</p> <p>Uses ■ For cleansing/sanitizing of the hands when soap and water are not available. ■ Recommended for repeated use.</p> <p>Warnings For external use only. Flammable. Keep away from heat or flame. Avoid contact with eyes. In case of contact, flush thoroughly with water. Stop use and seek medical attention if skin irritation develops. Keep out of reach of children. In case of accidental ingestion contact a physician or Poison Control Center right away.</p> <p>Directions ■ Apply generously, work into hands and allow to dry without wiping. ■ Children under six should be supervised while using this product.</p> <p>Other Information ■ Do not store above 110°F ■ May discolor some fabrics or surfaces. ■ Report adverse events to DermaRite Industries, PO Box 7209, North Bergen, NJ 07047.</p> <p>Inactive Ingredients Deionized Water, Glycerol, Carbomer, Triethanolamine.</p> <p>Questions? Call 1-800-337-6296 Mon - Fri 9AM - 5PM EST.</p>	<p style="font-size: small; margin: 0;">14196 11408 2</p>
--	---	---

Manufactured for DermaRite Industries LLC
 7777 West Side Ave. North Bergen, NJ 07047
 www.dermarite.com Made in China

500 mL NDC: 56084-028-02

HAND SANITIZER

ethyl alcohol gel

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:56084-028
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
WATER (UNII: 059QF0KO0R)	
CARBOMER 934 (UNII: Z135WT9208)	
GLYCERIN (UNII: PDC6A3C0OX)	
TROLAMINE (UNII: 9O3K93S3TK)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:56084-028-01	236 mL in 1 BOTTLE, DISPENSING; Type 0: Not a Combination Product	11/13/2020	
2	NDC:56084-028-02	500 mL in 1 BOTTLE, DISPENSING; Type 0: Not a Combination Product	11/13/2020	

Marketing Information			
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part333A	11/13/2020	

Labeler - Zhejiang RIFESHOW Cosmetics Co., Ltd. (560843477)

Establishment

Name	Address	ID/FEI	Business Operations
Zhejiang RIFESHOW Cosmetics Co., Ltd.		560843477	manufacture(56084-028)

Establishment

Name	Address	ID/FEI	Business Operations
DERMARITE INDUSTRIES, LLC		883925562	label(56084-028)

Revised: 11/2020

Zhejiang RIFESHOW Cosmetics Co., Ltd.