HAND SANITIZER- ethyl alcohol gel DERMARITE INDUSTRIES, LLC

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.

GELRITE 75

Active Ingredient(s)

Ethyl Alcohol 75% Purpose: Antiseptic

Purpose

Antiseptic, Hand Sanitizer

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.

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. 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 110F
- May discolor some fabrics or surfaces.
- Report adverse events to DermaRite Industries, PO box 7209, North Bergen, NJ 07047

Inactive ingredients

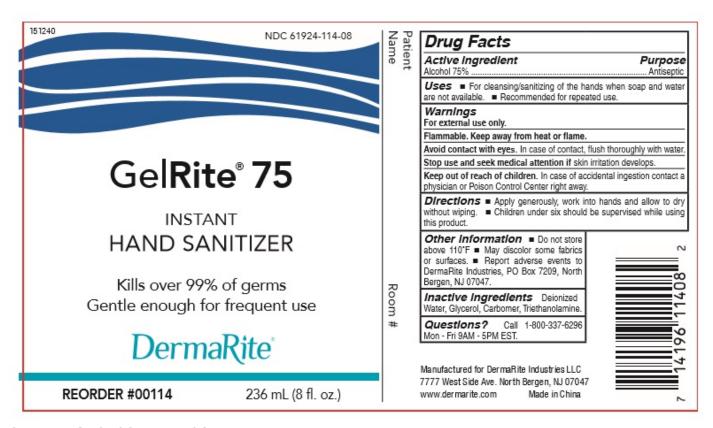
Deionized Water, glycerol, Carbomer, Triethanolamine

Ouestions?

Call 1-800-337-6296

Mon-Fri 9AM- 5PM EST.

Package Label - Principal Display Panel



8 oz NDC: 61924-114-08

HAND SANITIZER ethyl alcohol gel **Product Information** HUMAN OTC DRUG NDC:61924-114 **Product Type** Item Code (Source) **TOPICAL Route of Administration 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				
TROLAMINE (UNII: 903K93S3TK)					
GLYCERIN (UNII: PDC6A3C0OX)					
WATER (UNII: 059QF0KO0R)					
CARBOMER 934 (UNII: Z135WT9208)					

F	Packaging						
#	Item Code	Package Description	Marketing Start Date	Marketing End Date			
1	NDC:61924- 114-08	236 mL in 1 BOTTLE, DISPENSING; Type 0: Not a Combination Product	06/18/2020				
2	NDC:61924- 114-16	500 mL in 1 BOTTLE, DISPENSING; Type 0: Not a Combination Product	06/18/2020				
3	NDC:61924- 114-04	118 mL in 1 BOTTLE, PUMP; Type 0: Not a Combination Product	07/08/2020				

Marketing Information						
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date			
OTC monograph not final	part333A	06/18/2020				

Labeler - DERMARITE INDUSTRIES, LLC (883925562)

Revised: 1/2022 DERMARITE INDUSTRIES, LLC