GELRITE- hand sanitizer 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

Active Ingredient

Alcohol 65%

Purpose

Skin Protectant

Uses

- For handwashing to decrease bacteria on skin.
- Recommended for repeated use.

Warnings

For external use only.

Flammable. Keep away from heat and flame.

Avoid contact with eyes. In case of contact, flush thoroughly with water.

Stop use and ask a doctor if skin irritation develops.

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Directions

- Wet hands thoroughly with product and allow to dry without wiping.
- Children under six should be supervised while using this product.

Other Information

- Do not store above 105°F
- May discolor some fabrics or surfaces
- You may report a serious adverse event to DermaRite Industries, PO Box 7209, North Bergen, NJ 07047

Inactive ingredients

Water, Propylene Glycol, Carbomer, Polysorbate 20, Fragrance, t-Butanol,

Triethanolamine, Tocopherol Acetate, Sodium Isostearoyl Lactate, Denatonium Benzoate

Questions?

Call 1-800-337-6296 Mon-Fri 9AM-5PM EST.

Keep out of reach of children

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

GelRite Package Label Principal Display Panel

GELRITE
hand sanitizer gel

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:61924-106
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety		
Ingredient Name	**Basis of Strength**	**Strength**
ALCOHOL (UNII: 3K9958V90M) (ALCOHOL - UNII:3K9958V90M)	ALCOHOL	65 mL in 100 mL

Inactive Ingredients	
Ingredient Name	**Strength**
WATER (UNII: 059QF0KO0R)	
CARBOMER 940 (UNII: 4Q93RCW27E)	
DENATONIUM BENZOATE ANHYDROUS (UNII: M5BA6GAF1O)	
.ALPHA.-TOCOPHEROL ACETATE (UNII: 9E8X80D2L0)	
PROPYLENE GLYCOL 1,2-DISTEARATE (UNII: T65PN3O37H)	
BUTANOL (MIXED ISOMERS) (UNII: WB09NY83YA)	
2,4,5-T-TROLAMINE (UNII: 9007L1DAXM)	
SODIUM ISOSTEAROYL LACTYLATE (UNII: 8730J0D3EV)	

Packaging				
#	**Item Code**	**Package Description**	**Marketing Start Date**	**Marketing End Date**
1	NDC:61924-106-04	118 mL in 1 BOTTLE, DISPENSING; Type 0: Not a Combination Product	04/25/2006	
2	NDC:61924-106-16	473 mL in 1 BOTTLE, PUMP; Type 0: Not a Combination Product	04/25/2006	
3	NDC:61924-106-27	800 mL in 1 BAG; Type 0: Not a Combination Product	04/25/2006	
4	NDC:61924-106-34	1000 mL in 1 BAG; Type 0: Not a Combination Product	04/25/2006	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part333A	04/25/2006	

Labeler - DERMARITE INDUSTRIES, LLC (883925562)

Registrant - DERMARITE INDUSTRIES, LLC (883925562)

Establishment

Name	Address	ID/FEI	Business Operations
DERMARITE INDUSTRIES LLC		883925562	manufacture(61924-106)