

DIRE 70% GEL HAND SANITIZER - W- alcohol gel

Applichem, 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.

Active Ingredient(s)

Alcohol 80% 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

- on 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.

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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), Glycerin, Hydrogen Peroxide, Alkyl Acrylate Crosspolymer, Triethanolamine, Aloe, Lauryl Alcohol, Myristyl Alcohol, Fragrance (Parfum), PEG Dimethicone

Package Label - Principal Display Panel

HAND SANITIZER
NON-STERILE SOLUTION
ALCOHOL ANTISEPTIC 70%
TOPICAL SOLUTION


7 19283 82082 2

DIRE

GEL HAND SANITIZER
KILLS 99.99% OF GERMS

 LEMON & ALOE VERA

1 GALLON/3 78L - 70% ALCOHOL
MADE IN THE USA

Drug Facts

Active ingredient(s) Medicinal ingredient: Ethyl alcohol 70% v/v	Purpose Antiseptic
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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.	
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3780 mL NDC: 74751-008-01

DIRE 70% GEL HAND SANITIZER - W				
alcohol gel				
Product Information				
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:74751-008	
Route of Administration	TOPICAL			
Active Ingredient/Active Moiety				
Ingredient Name		Basis of Strength	Strength	
ALCOHOL (UNII: 3K9958V90M) (ALCOHOL - UNII:3K9958V90M)		ALCOHOL	70.6646 mL in 100 mL	
Inactive Ingredients				
Ingredient Name			Strength	
MYRISTYL LACTATE (UNII: 1D822OC34X)			0.3895 mL in 100 mL	
ALOE VERA LEAF (UNII: ZY81Z83H0X)			0.0012 mL in 100 mL	
TROLAMINE (UNII: 9O3K93S3TK)			0.5177 mL in 100 mL	
WEST INDIAN LEMONGRASS OIL (UNII: 5BIA40E9ED)			0.0924 mL in 100 mL	
METHACRYLIC ACID - ETHYL ACRYLATE COPOLYMER (4500 MPA.S) (UNII: T967IEU43C)			0.2087 mL in 100 mL	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)			0.1284 mL in 100 mL	
GLYCERIN (UNII: PDC6A3C0OX)			0.2805 mL in 100 mL	
WATER (UNII: 059QF0KO0R)				
PEG-10 DIMETHICONE (600 CST) (UNII: 8PR7V1SVM0)			0.0215 mL in 100 mL	
Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:74751-008-01	3780 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	10/01/2020	
2	NDC:74751-008-	236 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination	10/01/2020	

4	08	Product	10/01/2020	
3	NDC:74751-008-16	473 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	10/01/2020	
4	NDC:74751-008-32	946 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	10/01/2020	
Marketing Information				
Marketing Category		Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final		part333A	10/01/2020	

Labeler - Applichem, Inc (039829528)