

HAND SANITIZER- ethyl alcohol gel
KLEAN AND SAFE 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.

Active Ingredient

Ethyl Alcohol 75%

Purpose

Antiseptic

Uses

To decrease bacteria on the skin.

Recommended for repeated use.

Warnings

Flammable. Keep away from fire or flame.

For external use only.

Avoid contact with broken skin.

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.

Directions

Not recommended for infants.

Wet hands thoroughly with product and allow to dry without wiping.

Children under 6 years of age should be supervised when using this product.

Other Information

Do not store above 110°F. May discolor some fabrics.

Inactive Ingredients

Water, Glycerin, Acrylates/C10-30 Alkyl Acrylate crosspolymer, Triethanoamine, Fragrance.



HAND SANITIZER

ethyl alcohol gel

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:776 16-002
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)	
GLYCERIN (UNII: PDC6A3C0OX)	
CARBOMER INTERPOLYMER TYPE A (55000 CPS) (UNII: 59TL3WG5CO)	
TROLAMINE (UNII: 9O3K93S3TK)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:776 16-002-01	60 mL in 1 BOTTLE; Type 0: Not a Combination Product	05/18/2020	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part333E	05/18/2020	

Labeler - KLEAN AND SAFE LLC (117517889)

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