

HAND SANITIZER- alcohol gel
Quality Innovations 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.

Hand Sanitizer Gel

Alcohol 75% v/v. Purpose: Antiseptic

Antiseptic, Hand Sanitizer

Help decrease bacteria on skin.

Recommended for repeated use

For external use only

Flammable, keep away from fire or flame

Do not apply around eyes.

When using this product, avoid contact with eyes. In case of contact, flush eyes with water.

Stop use and ask a doctor if irritation or redness develops & condition persists for more than 72 hours.

Keep out of reach of Children. Children must be supervised in use of this product.

Pump as needed into your palms & thoroughly spread on both hands.

Do not store above 110F

Water, Glycerin, Triethanolamine, Carbomer, Dimethylamino

Package Label - Principal Display Panel

60 mL NDC: 74235-001-01



HAND SANITIZER

alcohol gel

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:74235-001(NDC:74742-002)
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
CARBOMER HOMO POLYMER, UNSPECIFIED TYPE (UNII: 0A5MM307FC)	
TROLAMINE (UNII: 9O3K93S3TK)	
WATER (UNII: 059QF0KO0R)	
DIMETHYLAMINE (UNII: ARQ8157E0Q)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:74235-001-01	60 mL in 1 BOTTLE; Type 0: Not a Combination Product	04/29/2020	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part333A	04/29/2020	

Labeler - Quality Innovations Inc. (079258818)

Establishment

Name	Address	ID/FEI	Business Operations
Yangzhou Jiefeiao Tourism-plastic Products Chemical Plant		527742625	manufacture(74235-001) , relabel(74235-001)

Revised: 4/2020

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