HAND SANITIZER- ethyl alcohol gel
B Holding Group 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 62%

Purpose
Antiseptic

Uses

For hand washing to decrease bacteria on the skin.

Recommended for repeated use.

Warnings

For external use only.

Flammable. Keep away from fire or flame.

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

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

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

Store below 110°F. May cause discoloration to some fabrics or surfaces.

Inactive Ingredients

Water, Aloe Barbadensis Leaf Juice, Maltodextrin,Glycerin, Propylene Glycol, Acrylates/C1O-30 Alkyl Acrylate crosspolymer, Triethanoamine, Fragrance, Tocopheryl Acetate.

HAND SANITIZER

ethyl alcohol gel

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:78396-002
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety		
Ingredient Name	**Basis of Strength**	**Strength**
ALCOHOL (UNII: 3K9958V90M) (ALCOHOL - UNII:3K9958V90M)	ALCOHOL	62 mL in 100 mL

Inactive Ingredients	
Ingredient Name	**Strength**
MALTODEXTRIN (UNII: 7CVR7L4A2D)	

PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
WATER (UNII: 059QF0KO0R)	
ALOE VERA LEAF (UNII: ZY81Z83H0X)	
GLYCERIN (UNII: PDC6A3C0OX)	
CARBOMER INTERPOLYMER TYPE A (55000 CPS) (UNII: 59TL3WG5CO)	
TROLAMINE (UNII: 9O3K93S3TK)	
.ALPHA.-TOCOPHEROL ACETATE (UNII: 9E8X80D2L0)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:78396-002-01	59 mL in 1 BOTTLE; Type 0: Not a Combination Product	05/29/2020	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part333E	05/29/2020	

Labeler - B Holding Group LLC (006108561)

Revised: 5/2020 B Holding Group LLC