HAND SANITIZER- hand sanitizer gel Brands International

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.

GermOut Hand Sanitizer

Drug Facts

Active Ingredient

Ethyl alcohol 62%.

Purpose

Antiseptic

For handwashing to decrease bacteria on the skin.

Warnings

Flammable, keep away from fire or flame. For external use only.

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

Stop use and ask a doctor If redness or irritation develop and persist for more than 72 hours.

Keep out of reach of children. If swallowed get medical help or contact a Poison Control Center right away.

Directions

Spread on both hands, rub in, let dry.

Inactive Ingredients: Water, Isopropyl Alcohol, Glycerin, Carbomer, Aminomethyl Propanol, Fragrance, Propylene Glycol, Isopropyl Myristate, Aloe Barbadensis Leaf Juice (Aloe Vera) Tocopheryl Acetate (Vitamin E)

Packaging



HAND SANITIZER

hand sanitizer gel

Product Information				
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:50157-501	
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	
CARBOMER COPOLYMER TYPE A (UNII: 71DD5V995L)		
GLYCERIN (UNII: PDC6A3C0OX)		
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)		
.ALPHATO CO PHERO L ACETATE (UNII: 9E8X80D2L0)		
AMINOMETHYLPROPANOL (UNII: LU49E6626Q)		
ISOPROPYL MYRISTATE (UNII: 0 RE8 K4LNJS)		
ALOE (UNII: V5VD430 YW9)		
TROLAMINE (UNII: 9O3K93S3TK)		
WATER (UNII: 059QF0KO0R)		

Packaging				
# Item Code	Package Description	Marketing Start Date	Marketing End Date	
1 NDC:50157-501-59	96 in 1 CASE	03/04/2020		
1	59 mL in 1 BOTTLE; Type 0: Not a Combination Product			

Marketing Information				
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date	
OTC monograph not final	part333A	03/04/2020		

Labeler - Brands International (243748238)

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