UNIVERSITY OF MICHIGAN- hand sanitizer gel Double Body Biotech Limited

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.

University of Michigan Hand Sanitizer

Active ingredient

Alcohol 75%

Purpose

Antiseptic

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.

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.

Do not use

- In children less than 2 months of age.
- On open skin wounds.

Directions

- Wet hands thoroughly with gel, rub vigorously and allow to dry without wiping.
- Children under 6 years of age should be supervised when using this product.

Other information

• Store below 106 F(410)

Inactive ingredients

Water, Glycereth-26, Carbomer, Sodium Hydroxide, Aloe Barbadensis Leaf Extract



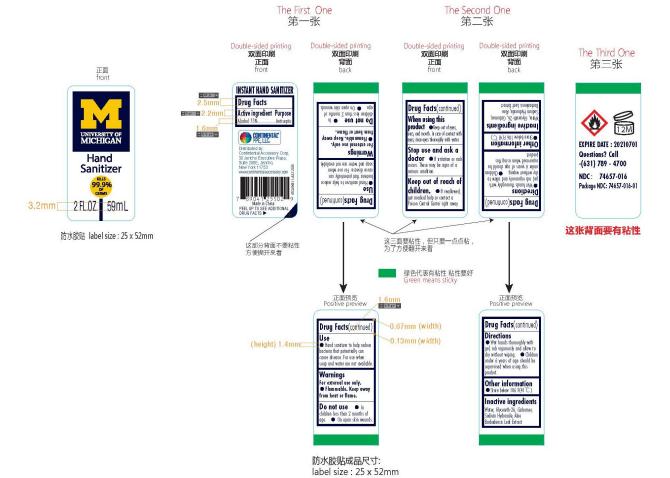


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UNIVERSITY OF MICHIGAN

hand sanitizer gel

Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:74657-016
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		
SODIUM HYDROXIDE (UNII: 55X04QC32I)			
GLYCERETH-26 (UNII: NNE56F2N14)			
CARBOMER 980 (UNII: 4Q93RCW27E)			
ALOE VERA LEAF (UNII: ZY8 1Z8 3H0 X)			
WATER (UNII: 059QF0KO0R)			

Packaging				
l	# Item Code	Package Description	Marketing Start Date	Marketing End Date
l	1 NDC:74657-016-01	59 mL in 1 BOTTLE; Type 0: Not a Combination Product	07/08/2020	

Marketing Information				
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date	
OTC monograph not final	part333A	07/08/2020		

Labeler - Double Body Biotech Limited (560246954)

Registrant - Double Body Biotech Limited (560246954)

Establishment					
Name	Address	ID/FEI	Business Operations		
Double Body Biotech Limited		560246954	manufacture(74657-016)		

Revised: 7/2020 Double Body Biotech Limited