

WASH-FREE HAND SANITIZER- hand sanitizer gel
Zhongshan DermeY Commodity Co., Ltd.

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.

Keep away from heat and flame.

Water

Glycerin

Carbomer

Triethanolamine

Squeeze 3-4 drops each time on palm then gently rub evenly to clean and disinfect the surface of the hands, and rub until dry.

Alcohol

keep out of children

Avoid direct contact with eyes and damaged skin. This product is for external use.

The front of the hand sanitizer bottle features a blue and white design. At the top, a blue banner contains the logo 'JM&HFBI' with 'DISINFECTION' written below it. In the center, there is a graphic of a purple virus-like particle with blue spikes, with two crossed surgical instruments behind it. Below the virus, a blue circle contains the text '75% ALCOHOL'. The main product name 'INSTANT HAND SANITIZER' is written in large, bold, pink and blue letters. Below this, a blue banner reads 'RINSE FREE & NON-STICKY' and 'EFFECTIVE STERILIZATION RATE UP TO 99.9%'. At the bottom, a blue banner states 'For External Use Only' and '8.36FL.OZ./237ML e'.

The back of the hand sanitizer bottle features a blue and white design. At the top, a blue banner contains the logo 'JM&HFBI' with 'DISINFECTION' written below it. To the right, the text 'INSTANT HAND SANITIZER' is written in large, bold, pink and blue letters. Below this, a blue banner reads 'EFFECTIVE STERILIZATION RATE UP TO 99.9%'. The 'USE GUIDE' section is enclosed in a blue box and contains the text: 'Squeeze 3-4 drops each time on palm, then gently rub evenly to clean and disinfect the surface of the hands, and rub until dry. It is non-sticky after use and leaves a pleasure smell.' The 'MAIN INGREDIENTS' section is also in a blue box and lists: 'Alcohol, Aqua, Glycerol, Carbomer, Triethanolamine, Parfum.' The 'CAUTIONS' section is in a blue box and states: 'Avoid direct contact with eyes and damaged skin. This product is for external use.' Below this, the manufacturer's name 'DERMEY COMMODITY CO.,LTD' and address 'No.1, Yongyi 6th Road, Henglan Town, ZhongShan City, Guangdong' are listed. A barcode is present with the number '6 972570 850672'. At the bottom, a blue banner reads 'MADE IN CHINA' and features a recycling symbol and a 'NO RINSE' logo.

WASH-FREE HAND SANITIZER

hand sanitizer gel

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:55028-005
Route of Administration	EXTRACORPOREAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
ALCOHOL (UNII: 3K9958V90M) (ALCOHOL - UNII:3K9958V90M)	ALCOHOL	177.75 mL in 237 mL

Inactive Ingredients

Ingredient Name	Strength
TROLAMINE (UNII: 9O3K93S3TK)	
GLYCERIN (UNII: PDC6A3C0OX)	
CARBOMER HOMO POLYMER, UNSPECIFIED TYPE (UNII: 0A5MM307FC)	
WATER (UNII: 059QF0KO0R)	

Product Characteristics

Color		Score	
Shape		Size	
Flavor		Imprint Code	JMHFB
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:55028-005-01	237 mL in 1 BOTTLE; Type 0: Not a Combination Product	04/20/2020	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part333E	04/20/2020	

Labeler - Zhongshan Dermey Commodity Co., Ltd. (550280464)

Establishment

Name	Address	ID/FEI	Business Operations
Zhongshan Dermey Commodity Co., Ltd.		550280464	manufacture(55028-005)