HAND SANITIZER- hand sanitizer gel Jinhua City Wellmae Cosmetics 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.

75427-018

☐ HAND SANITIZER

ACTIVE INGREDIENT

Alcohol Denat.75% v/v

Purpose

Antiseptic

Uses

- Hand sanitizer to help reduce bacteria on the skin that could cause disease.
- For use when soap and water are not available.

WARNINGS

For external use only.

•Flammable. Keep away from heat or flame.

When using this poduct

●Keep out of eyes, ears, and mouth, in case of contact with eyes, rinse eyes thoroughly with water.

Stop use and ask a Doctor

•If irrition 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

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Directions

- Place enough product in your palm to thoroughly cover your hands. Rub hands together briskly until dry.
- Children under 6 years of age should be supervised when using this product to avoid swallowing.

Other Information

- Store at 68°to 77°F (20°~25°C)
- Do not store above 110°F (43°C)
- \bullet You may report a serious adverse reaction to Centric Beauty LLC, 3505th Avenue, New York, NY 10118

Inactive Ingredients

Water, Glycerin, Fragrance, Acrylates/C10-30 Alkyl Acrylate Crosspolymer, Polysrbate 20, Aminomethyl Propanol, Blue 1, Yellow 5, Red 28, Red 40.

Package Label Principal Display Panel



FRONT



DO NOT PRINT BLUE DIE LINE

BACK











CS553HBAZAPNK



COCONUT **SCENTED**

PMS 225 C



CLEAR

FILL COLOR



PMS 236 C @ 50%

HAND SANITIZER

hand sanitizer gel

Product Information

Product Type HUMAN OTC DRUG Item Code (Source) NDC:75427-018

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	
POLYSORBATE 20 (UNII: 7T1F30V5YH)		
D&C RED NO. 28 (UNII: 767IP0Y5NH)		
WATER (UNII: 059QF0KO0R)		
AMINOMETHYLPROPANOL (UNII: LU49E6626Q)		
GLYCERIN (UNII: PDC6A3C0OX)		
CARBOMER INTERPOLYMER TYPE A (55000 CPS) (UNII: 59TL3WG5CO)		
FRAGRANCE CLEAN ORCO600327 (UNII: 329LCV5BTF)		
FD&C BLUE NO. 1 (UNII: H3R47K3TBD)		
FD&C YELLOW NO. 5 (UNII: I753WB2F1M)		
FD&C RED NO. 40 (UNII: WZB9127XOA)		

ı	Packaging			
	# Item Code	Package Description	Marketing Start Date	Marketing End Date
	1 NDC:75427-018-	29 mL in 1 BOTTLE; Type 0: Not a Combination Product	09/16/2020	

Marketing Information				
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date	
OTC monograph not final	part333A	09/16/2020		

Labeler - Jinhua City Wellmae Cosmetics Co., Ltd. (543459963)

Registrant - Jinhua City Wellmae Cosmetics Co., Ltd. (543459963)

Establishment				
Name	Address	ID/FEI	Business Operations	
Jinhua City Wellmae Cosmetics Co., Ltd.		543459963	manufacture(75427-018)	

Revised: 1/2022 Jinhua City Wellmae Cosmetics Co., Ltd.