

OPALINE HAND SANITIZER- alcohol gel
Ganzhou Olivee Cosmetic 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.

OPALINE HAND SANITIZER

Drug Facts

Active ingredient

Alcohol 75% w/w

Purpose

Antiseptic

Use

Decrease bacteria on hands.

Warnings

For external use only.

Flammable.Keep product away from fire or flame.

When using this product

avoid contact with eyes; in case of contact, flush eyes with water.

Stop use and ask a doctor if

irritation or redness develops and persists.

Keep out of reach of children.

If swallowed, get medical help or contact a Poison Control Center right away.

Small Parts. Not for children under 3 years.

Directions

Wet hands thoroughly with product and allow to dry.

Inactive ingredients

Water (Aqua), Acrylates/C10-30 Alkyl Acrylate Crosspolymer, Aminomethyl Propanol, Glycerin

Packaging

OPALINE™ Hand Sanitizer

KILLS 99.9 % GERMS

RINSE & FRAGRANCE FREE & NON STICKY



8.4 FL.OZ(250 ML)

Drug Facts	Stop use & ask a doctor if irritation or redness develops and persists.
Active Ingredient: Alcohol 75% Purpose: Antiseptic	⚠️WARNING - CHOKING HAZARD Small Parts. Not for children under 3 years.
Use: Decreases bacteria on hands	If swallowed, get medical help or contact a Poison Control Center right away.
Warnings: For external use only.	Directions: Wet hands thoroughly with product and allow to dry.
Warnings: (additional) Flammable- Keep product away from fire or flame.	Inactive Ingredients: Water (Aqua), Glycerin, Acrylates/C10-30 Alkyl Acrylate Crosspolymer, Aminomethyl Propanol.
When using this product avoid contact with eyes; in case of contact, flush eyes with water. ▶	

ITEM NO: 19038



MFG: April 20, 2020 EXP: April 20, 2022
LOT#: 200425 Made in China



OPALINE HAND SANITIZER

alcohol gel

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:56 136-302
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
ALCOHOL (UNII: 3K9958 V90M) (ALCOHOL - UNII:3K9958 V90M)	ALCOHOL	75 mL in 100 mL

Inactive Ingredients

Ingredient Name	Strength
WATER (UNII: 059QF0KO0R)	
CARBOMER INTERPOLYMER TYPE A (ALLYL SUCROSE CROSSLINKED) (UNII: 59TL3WG5CO)	
AMINOMETHYLPROPANOL (UNII: LU49E6626Q)	
CARBOMER COPOLYMER TYPE A (UNII: 71DD5V995L)	
.ALPHA.-TOCOPHEROL ACETATE, DL- (UNII: WR1WPI7EW8)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:56 136-302-01	250 mL in 1 BOTTLE; Type 0: Not a Combination Product	04/16/2020	
2	NDC:56 136-302-02	500 mL in 1 BOTTLE; Type 0: Not a Combination Product	04/16/2020	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part333E	04/16/2020	

Labeler - Ganzhou Olivee Cosmetic Co., Ltd. (543008195)

Registrant - Ganzhou Olivee Cosmetic Co., Ltd. (543008195)

Establishment

Name	Address	ID/FEI	Business Operations
Ganzhou Olivee Cosmetic Co., Ltd.		543008195	manufacture(56136-302)

Revised: 4/2020

Ganzhou Olivee Cosmetic Co., Ltd.