

AROMA GUARDIAN- anti bacterial instant hand sanitizer gel
Opal Cosmetics (Huizhou) 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.

Opal, Hand Sanitizer, Gel, 75% Ethyl alcohol, 500mL

Active Ingredient(s)

Ethyl Alcohol 75% v/v. Purpose: Antiseptic

Purpose

Antiseptic, Hand Sanitizer

Use

Hand Sanitizer to help reduce bacteria that potentially can cause disease. For use when soap and water are not available.

Warnings

Flammable. For external use only. Keep away from heat or flame.

Do not use

- on children less than 2 months of age
- on open skin wounds

When using this product 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 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.

Directions

- Place enough product on hands to cover all surfaces. Rub hands together until dry.
- Supervise children under 6 years of age when using this product to avoid swallowing.

Other information

- Do not store above 105° (40.6°)
- May discolor some fabrics
- Harmful to wood finishes and plastics

Inactive ingredients

Water, Glycerin, Acrylates/C10-30 Alkyl Acrylate Crosspolymer, Fragrance, t-Butyl Alcohol, Aminomethyl Propanol, Aloe Barbadensis Leaf Extract, Maltodextrin, Denatonium Benzoate.

Package Label - Principal Display Panel



AROMA GUARDIAN			
anti bacterial instant hand sanitizer gel			
Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:42477-2028
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
ALCOHOL (UNII: 3K9958V90M) (ALCOHOL - UNII:3K9958V90M)	ALCOHOL	375 mL in 500 mL

Inactive Ingredients

Ingredient Name	Strength
CARBOMER INTERPOLYMER TYPE A (ALLYL SUCROSE CROSSLINKED) (UNII: 59TL3WG5CO)	2.5 mL in 500 mL
WATER (UNII: 059QF0KO0R)	113 mL in 500 mL
GLYCERIN (UNII: PDC6A3C0OX)	8 mL in 500 mL
TERT-BUTYL ALCOHOL (UNII: MD83SFE959)	1.5 mL in 500 mL

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:42477-2028-1	500 mL in 1 BOTTLE, PUMP; Type 0: Not a Combination Product	04/17/2020	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part333E	04/17/2020	

Labeler - Opal Cosmetics (Huizhou) Limited (528178475)**Registrant** - A03 Lab of BTS (548009541)**Establishment**

Name	Address	ID/FEI	Business Operations
Opal Cosmetics (Huizhou) Limited		528178475	label(42477-2028) , manufacture(42477-2028)

Revised: 4/2020

Opal Cosmetics (Huizhou) Limited