GINGERBREAD HOUSE SCENTED ANTI-BACTERIAL HAND SANITIZERalcohol 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.

HAND SANITIZER

Drug Facts

Active ingredient

Alcohol 62%

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.

Warning - Choking Hazard

Small Parts. Not for children under 3 years.

Keep out of reach of children.

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

□ Directions

Wet hands thoroughly with product and allow to dry.

Inactive ingredients

Water (Aqua), ACRYLATES/C10-30 ALKYL ACRYLATE CROSSCOPOLYMER, AMINOMETHYL PROPANOL, Fragrance (Parfum), May contain: D&C Red No. 33 (Cl 17200), FD&C Red No. 4 (Cl 14700), FD&C Yellow No. 5 (Cl 19140), FD&C Blue No. 1 (Cl 42090).

Packaging









GINGERBREAD HOUSE SCENTED ANTI-BACTERIAL HAND SANITIZER

alcohol gel

Product Information

Product Type HUMAN OTC DRUG Item Code (Source) NDC:56136-612

Route of Administration TOPICAL

Active Ingredient/Active Moiety

Ingredient Name

Basis of Strength

ALCOHOL (UNII: 3K9958V90M) (ALCOHOL - UNII:3K9958V90M)

ALCOHOL (UNII: 3K9958V90M) ALCOHOL 62 mL in 100 mL

Inactive Ingredients		
Ingredient Name	Strength	
WATER (UNII: 059QF0KO0R)		
CARBOMER COPOLYMER TYPE A (UNII: 71DD5V995L)		
AMINOMETHYLPROPANOL (UNII: LU49E6626Q)		

Other Ingredients		
Ingredient Kind	Ingredient Name	Quantity

May contain	D&C RED NO. 33 (UNII: 9DBA0SBB0L)	
May contain	FD&C RED NO. 4 (UNII: X3W0AM1JLX)	
May contain	FD&C YELLOW NO. 5 (UNII: I753WB2F1M)	
May contain	FD&C BLUE NO. 1 (UNII: H3R47K3TBD)	

l	Packaging			
	# Item Code	Package Description	Marketing Start Date	Marketing End Date
	1 NDC:56136-612-	29 mL in 1 BOTTLE; Type 0: Not a Combination Product	07/20/2021	

Marketing Information			
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part333E	07/20/2021	

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

Establishment			
Name	Address	ID/FEI	Business Operations
Ganzhou Olivee Cosmetic Co., Ltd.		543008195	manufacture(56136-612)

Revised: 7/2021 Ganzhou Olivee Cosmetic Co., Ltd.