## GOODEARTH- sanitizer gel gel GoodEarth Distribution LLC

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.

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# GoodEarth-Louding Sanitizer Gel 300mL

# **Active Ingredient(s)**

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**

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

### Do not use

- in 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.

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#### **Directions**

Put enough product in your palm to cover hands and rub hands together briskly until dry.

Children under 6 years of age should be supervised when using products.

# Other information

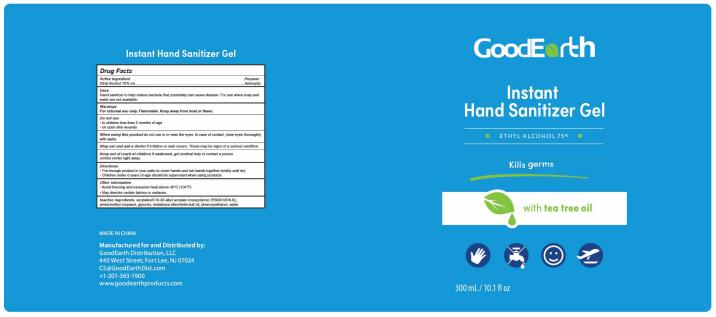
Avoid freezing and excessive heat above 40C (104F)

May discolor certain fabrics or surfaces

#### **Inactive ingredients**

acrylates/C10-30 alky acrylate crosspolymer (55000 MPA.S), aminomethyl propanol, glycerin, melaleuca alternifolia leaf oil, phenoxyethanol, water

# Package Label - Principal Display Panel



300 mL NDC: 71745-128-01

# GOODEARTH sanitizer gel gel

Product Information				
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:71745-128	
Route of Administration	TOPICAL			

ı	Active Ingredient/Active Moiety		
ı	Ingredient Name	Basis of Strength	Strength
ı	ALCOHOL (UNII: 3K9958V90M) (ALCOHOL - UNII:3K9958V90M)	ALCOHOL	75 mL in 100 mL

Inactive Ingredients	
Ingredient Name	Strength
GLYCERIN (UNII: PDC6 A3C0 OX)	
CARBOMER INTERPOLYMER TYPE A (55000 CPS) (UNII: 59TL3WG5CO)	
WATER (UNII: 059QF0KO0R)	
PHENOXYETHANOL (UNII: HIE492ZZ3T)	
AMINOMETHYLPROPANOL (UNII: LU49E6626Q)	
TEA TREE OIL (UNII: VIF565UC2G)	

Pac	ckaging			
#	Item Code	Package Description	<b>Marketing Start Date</b>	<b>Marketing End Date</b>

1 NDC:71745-128-01	$300\ mL$ in $1BOTTLE;$ Type 0: Not a Combination Product	07/01/2020	
2 NDC:71745-128-02	500 mL in 1 BOTTLE; Type 0: Not a Combination Product	07/01/2020	
3 NDC:71745-128-03	1000 mL in 1 BOTTLE; Type 0: Not a Combination Produc	07/01/2020	
Marketing Inf	formation		
Marketing Inf		Marketing Start Date	Marketing End Date
	ry Application Number or Monograph Citation	Marketing Start Date 07/01/2020	Marketing End Date

# **Labeler -** GoodEarth Distribution LLC (079808558)

Establishment				
Name	Address	ID/FEI	<b>Business Operations</b>	
Luoding Quality Amenities Supply Limited		528126807	manufacture(71745-128)	

Revised: 7/2020 GoodEarth Distribution LLC