

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.

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.

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

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

Instant Hand Sanitizer Gel

GoodEarth

Instant Hand Sanitizer Gel

ETHYL ALCOHOL 75%

Kills germs

with tea tree oil

300 mL / 10.1 fl oz

Drug Facts	
Active Ingredient	Purpose
Ethyl Alcohol 75% v/v	Antiseptic
Uses	
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 do not use in or near the eyes. In case of contact, 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	
- 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 40°C (104°F)	
- May discolor certain fabrics or surfaces.	
Inactive ingredients: acrylates/C10-30 alkyl acrylate crosspolymer (55000 MPA.S), aminomethyl propanol, glycerin, melaleuca alternifolia leaf oil, phenoxyethanol, water	

MADE IN CHINA

Manufactured for and Distributed by:
GoodEarth Distribution, LLC
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www.goodearthproducts.com

300 mL NDC: 71745-128-01

GOODEARTH				
sanitizer gel				
Product Information				
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:71745-128	
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	
GLYCERIN (UNII: PDC6A3C0OX)				
CARBOMER INTERPOLYMER TYPE A (55000 CPS) (UNII: 59TL3WG5CO)				
WATER (UNII: 059QF0KO0R)				
PHENOXYETHANOL (UNII: HIE492ZZ3T)				
AMINOMETHYLPROPANOL (UNII: LU49E6626Q)				
TEA TREE OIL (UNII: VIF565UC2G)				
Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date

1	NDC:71745-128-01	300 mL in 1 BOTTLE; 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 Product	07/01/2020	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part333A	07/01/2020	

Labeler - GoodEarth Distribution LLC (079808558)

Establishment

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

Revised: 7/2020

GoodEarth Distribution LLC