

GENTLEHANDS ANTISEPTIC HAND SANITIZER- ethyl alcohol gel
ROLDAN INDUSTRIES

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.

Gentle Hands ANTISEPTIC Hand Sanitizer

Drug Facts

Active ingredient

Ethyl alcohol 70%

Purpose

Antiseptic

Use

- hand sanitizer to decrease bacteria on the skin
- recommended for repeated use
- for use when soap and water are not available

Warnings

Flammable, keep away from fire/flame

For external use only

Do not use

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

When using this product • do not get into eyes. In case of contact, rinse eyes thoroughly with water

Stop use and ask a doctor if

- irritation and redness develop
- condition persists for more than 72 hours.

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 without wiping
- supervise children under 6 years of age when using this product to avoid swallowing

Other information

- store between 15-30°C (59-86°F)
- avoid freezing and excessive heat above 40°C (104°F)

Inactive ingredients

carbomer, EDTA, glycerol, polysorbate, triethanolamine, water

Questions? +1-786-843-1308

You may also report serious side effects to this phone number. Mon - Fri 9:00 AM - 5:00 PM

LOT NO. AND EXPIRY

PRINTED ON BOTTLE

Distributed by: Roldan Industries

1500 E Tropicana Ave. Ste 154 Las Vegas NV 89119

COUNTRY OF ORIGIN: MEXICO

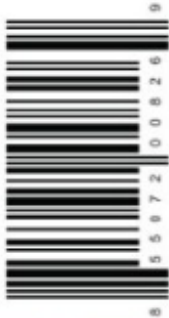
Packaging



8.45 fl oz (250 mL)

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GentleHands

GENTLEHANDS ANTISEPTIC HAND SANITIZER

ethyl alcohol gel

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:79 109-700
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
ALCOHOL (UNII: 3K9958V90M) (ALCOHOL - UNII:3K9958V90M)	ALCOHOL	70 mL in 100 mL

Inactive Ingredients

Ingredient Name	Strength
CARBOMER HOMO POLYMER, UNSPECIFIED TYPE (UNII: 0A5MM307FC)	
EDETIC ACID (UNII: 9G34HU7RV0)	
GLYCERIN (UNII: PDC6A3C0OX)	
POLYSORBATE 20 (UNII: 7T1F30V5YH)	
TROLAMINE (UNII: 9O3K93S3TK)	
WATER (UNII: 059QF0KO0R)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:79 109-700-22	2 mL in 1 POUCH; Type 0: Not a Combination Product	08/01/2020	
2	NDC:79 109-700-06	60 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	08/01/2020	
3	NDC:79 109-700-11	120 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	08/01/2020	
4	NDC:79 109-700-12	125 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	08/01/2020	
5	NDC:79 109-700-25	250 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	08/01/2020	
6	NDC:79 109-700-50	500 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	08/01/2020	
7	NDC:79 109-700-10	1000 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	08/01/2020	
8	NDC:79 109-700-37	3785 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	08/01/2020	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part333A	08/01/2020	

Labeler - ROLDAN INDUSTRIES (117553465)

