

GENTLE HANDS SANITIZER CALMING CITRUS- hand sanitizer spray calming citrus liquid
Southern Distilling Company 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.

Active Ingredient(s)

Alcohol 80% v/v. Purpose: Antiseptic

Purpose

Antiseptic, Hand Sanitizer

Use(s)

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

- 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

- Store between 15-30C (59-86F)
- Avoid freezing and excessive heat above 40C (104F)

Inactive Ingredients

Glycerin, hydrogen peroxide, purified water USP, fragrance containing essential oil

Gentle Hands Sanitizer Spray Calming Citrus 2 oz 59 mL



- ANTIMICROBIAL
- ALCOHOL-BASED
- NON-TOXIC



DRUG FACTS

Active Ingredient[s]	Purpose
Alcohol 80% v/v	Antiseptic

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Inactive Ingredients:
Glycerin, hydrogen peroxide, purified water USP, fragrance containing essential oils



Spray product on your hands



Rub over palms and back of hands



Rub in between fingers



Rub until dry



NDC# 74299-281-01
Manufactured for Gentle Brands
Las Vegas, Nevada



www. BuyGentle.com

Gentle Hands Sanitizer Spray Calming Citrus 3.4 oz 100 mL



- ANTIMICROBIAL
- ALCOHOL-BASED
- NON-TOXIC



DRUG FACTS

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Inactive Ingredients: Glycerin, hydrogen peroxide, purified water USP, fragrance containing essential oils



Directions:



Spray product on your hands



Rub over palms and back of hands



Rub in between fingers



Rub until dry



NDC# 74299-281-02
Manufactured for Gentle Brands, LLC
Las Vegas, Nevada



www.BuyGentle.com

Gentle Hands Sanitizer Spray Calming Citrus 32 oz 946.35 mL



- ANTIMICROBIAL
- ALCOHOL-BASED
- NON-TOXIC



DRUG FACTS

Active Ingredient[s]	Purpose
Alcohol 80% v/v	Antiseptic

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

Warnings:
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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:
-Store between 15-30C (59-86F)
-Avoid freezing and excessive heat over 40C (104F)

Inactive Ingredients: Glycerin, hydrogen peroxide, purified water USP, fragrance containing essential oils



Directions:



Spray product on your hands



Rub over palms and back of hands



Rub in between fingers



Rub until dry



NDC# 74299-281-03
Manufactured for Gentle Brands, LLC
Las Vegas, Nevada



www.BuyGentle.com

GENTLE HANDS SANITIZER CALMING CITRUS

hand sanitizer spray calming citrus liquid

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:74299-281
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
ALCOHOL (UNII: 3K9958V90M) (ALCOHOL - UNII:3K9958V90M)	ALCOHOL	80 mL in 100 mL

Inactive Ingredients

Ingredient Name	Strength
GLYCERIN (UNII: PDC6A3C0OX)	
BERGAMOT OIL (UNII: 39W1PKE3J1)	
HYDROGEN PEROXIDE (UNII: BBX060AN9V)	
WATER (UNII: 059QF0KO0R)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:74299-281-01	59 mL in 1 BOTTLE, SPRAY; Type 0: Not a Combination Product	09/01/2020	
2	NDC:74299-281-02	100 mL in 1 BOTTLE, SPRAY; Type 0: Not a Combination Product	09/01/2020	
3	NDC:74299-281-03	946.35 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	09/01/2020	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part333A	09/01/2020	

Labeler - Southern Distilling Company LLC (046275910)**Establishment**

Name	Address	ID/FEI	Business Operations
Southern Distilling Company LLC		046275910	manufacture(74299-281)

Revised: 9/2020

Southern Distilling Company LLC