

## **PROTECT HAND SANITIZER- isopropyl alcohol gel**

**Dr. Brite**

*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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### **Active Ingredient(s)**

Isopropyl Alcohol 70% v/v.

### **Purpose**

Antiseptic

### **Use**

- Hand Sanitizer to help reduce bacteria that potentially can cause disease.
- When hand washing, water & soap are not available
- recommended for repeated use.

### **Warnings**

For external use only. Flammable. Keep away from heat or flame. Do not apply around eyes.

### **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.

### **Directions**

- pump or spray a small amount into your palms, and rub lightly into hands
- let air dry

### **Other information**

- store at 20C (68 to 77F)
- may discolor fabrics

## Inactive ingredients

vegetable glycerin, aloe barbadensis (aloe vera) juice, hydrogen peroxide, citrus aurantium dulcis (orange) peel oil, azadirachta indica (neem) extract, rosemarinus officinalis (rosemary) oil, carbomer

## Package Label - Principal Display Panel



FDA-hand-sanitizer-16oz-PRINT.pdf 1 3/23/20 5:30 PM




**Drug Facts**

**Active ingredient**.....**Purpose**  
Isopropyl Alcohol 70% (v/v).....Antiseptic

**Uses** = hand sanitizer to help decrease bacteria on the skin. = when hand washing, water & soap are not available. = recommended for repeated use.

**Warnings** For external use only.  
Flammable. Keep away from fire or flame.  
Do not apply around eyes.  
When using this product, avoid contact with eyes. In case of contact flush eyes with water.  
Stop use and ask a doctor if allergic reaction develops & persists more than 72 hours.  
Keep out of reach of children. Children must be supervised while using this product.

**Directions** = pump or spray a small amount into your palms, and rub lightly into hands  
= let air dry

**Other Information** = store at 20° C (68° to 77° F). = may discolor fabrics.

**Inactive ingredients** Vegetable Glycerin (non-soy), Aloe Barbadensis (Aloe Vera) Juice, Hydrogen Peroxide, Citrus Aurantium Dulcis (Orange) Peel Oil\*, Azadirachta Indica (Neem) Extract\*, Rosemarinus Officinalis (Rosemary) Oil, Carbomer \*organic ingredients

Rejuvenate  
BY DRo  
brite

**PROTECT**  
with alcohol & hydrogen peroxide



**CITRUS HAND SANITIZER**  
nourish | moisturize | shield  
473 ml / 16 oz

**DIRECTIONS**

Pump or spray a small "pea" size amount into your palms.

Rub lightly into hands.

Let air dry.

**FOR BEST USE**

Wash hands with soap & water prior to sanitizing.

WOMEN OWNED  MADE IN USA

NON GMO  GLE NO SLS



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**Drug Facts**

**Active Ingredient** ..... **Purpose**  
 Isopropyl Alcohol 70% (w/v)..... Antiseptic

**Uses** ■ hand sanitizer to help decrease bacteria on the skin. ■ when hand washing, water & soap are not available, ■ recommended for repeated use.

**Warnings** For external use only.  
 Flammable. Keep away from fire or flame.  
 Do not apply around eyes. Avoid contact with eyes.  
 In case of contact flush eyes with water.  
 Stop use and ask a doctor if allergic reaction develops & persists more than 72 hours.  
 Keep out of reach of children. Children must be supervised while using this product.

Rejuvenate  
 by DRo  
 briter

PROTECT  
 with alcohol & hydrogen peroxide



CITRUS HAND SANITIZER  
 nourish | moisturize | shield  
 118 ml / 4 oz

**Directions** ■ pump or spray a small amount into your palms, and rub lightly into hands ■ let air dry

**Other Information** ■ store at 20° C (68° to 77° F).  
 ■ may discolor fabrics.

**Inactive Ingredients** Vegetable Glycerin (non-soy), Aloe Barbadensis (Aloe Vera) Juice, Hydrogen Peroxide, Citrus Aurantium Dulcis (Orange) Peel Oil, Azadirachta indica (Neem) Extract, Rosmarinus Officinalis (Rosemary) Oil, Carbomer  
 \*organic ingredients

WOMEN OWNED USA  
 GLE 18 3 6  
 5395100648

# PROTECT HAND SANITIZER

isopropyl alcohol gel

## Product Information

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:74110-001
<b>Route of Administration</b>	TOPICAL		

## Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
ISOPROPYL ALCOHOL (UNII: ND2M416302) (ISOPROPYL ALCOHOL - UNII:ND2M416302)	ISOPROPYL ALCOHOL	70 mL in 100 mL

## Inactive Ingredients

Ingredient Name	Strength
AZADIRACHTA INDICA FLOWER (UNII: 3TE8A92UPM)	
ROSEMARY OIL (UNII: 8LGU7VM393)	
CARBOMER COPOLYMER TYPE A (UNII: 71DD5V995L)	
XANTHAN GUM (UNII: TTV12P4NEE)	
LEMON OIL (UNII: I9GRO824LL)	
GRAPEFRUIT OIL (UNII: YR377U58W9)	
GLYCERIN (UNII: PDC6A3C0OX)	
HYDROGEN PEROXIDE (UNII: BBX060AN9V)	
WATER (UNII: 059QF0KO0R)	
ORANGE OIL (UNII: AKN3KSD11B)	

## Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:74110-001-01	473 mL in 1 BOTTLE, PUMP; Type 0: Not a Combination Product	03/30/2020	
2	NDC:74110-001-02	7 mL in 1 BOTTLE, PUMP; Type 0: Not a Combination Product	03/30/2020	04/15/2020
3	NDC:74110-001-03	100 mL in 1 BOTTLE, PUMP; Type 0: Not a Combination Product	03/30/2020	

## Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part333A	03/30/2020	

**Labeler** - Dr. Brite (079902543)

## Establishment

Name	Address	ID/FEI	Business Operations
Dr. Brite		079902543	manufacture(74110-001)

Revised: 1/2022

Dr. Brite