

**HAND SANITIZER- ethyl alcohol gel**  
**CARAVAN CANOPY INT'L INC.**

*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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**Hand Sanitizer**

**Active Ingredient(s)**

Ethyl Alcohol 71% v/v. Purpose: Antimicrobial

**Purpose**

Antimicrobial, Hand Sanitizer

**Use**

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

Recommended for repeated use

**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**

Water, Glycerin, Humi-fulvate, Fragrance, Carbomer, Arginine, Sodium Hyaluronate, Calendula Officinalis Flower Extract, Carica Papaya (Papaya) Fruit Extract, Olea Europaea (Olive) Leaf Extract

**Package Label - Principal Display Panel**



500 ml NDC: 74464-001-10

<b>HAND SANITIZER</b>			
ethyl alcohol gel			
<b>Product Information</b>			
<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:74464-001
<b>Route of Administration</b>	TOPICAL		
<b>Active Ingredient/Active Moiety</b>			
	<b>Ingredient Name</b>	<b>Basis of Strength</b>	<b>Strength</b>
	ALCOHOL (UNII: 3K9958V90M) (ALCOHOL - UNII:3K9958V90M)	ALCOHOL	71 mL in 100 mL
<b>Inactive Ingredients</b>			
	<b>Ingredient Name</b>	<b>Strength</b>	
	CARBOMER 934 (UNII: Z135WT9208)	0.3 mL in 100 mL	
	ARGININE (UNII: 94ZLA3W45F)		
	HYALURONATE SODIUM (UNII: YSE9PPT4TH)		
	WATER (UNII: 059QF0K00R)		
	CALENDULA OFFICINALIS FLOWER (UNII: P0M7O4Y7YD)		

CARICA PAPAYA LEAF (UNII: 66J7636Z2I)	
OLEA EUROPAEA LEAF (UNII: MJ95C30H47)	
GLYCERIN (UNII: PDC6A3C0OX)	5 mL in 100 mL
FRAGRANCE LAVENDER & CHIA F-153480 (UNII: SXS9CO2TZK)	0.4 mL in 100 mL

### Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:74464-001-10	500 mL in 1 BOTTLE; Type 0: Not a Combination Product	04/03/2020	

### Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part333A	04/03/2020	

**Labeler** - CARAVAN CANOPY INT'L INC. (800224003)

**Registrant** - CARAVAN CANOPY INT'L INC. (800224003)

### Establishment

Name	Address	ID/FEI	Business Operations
CARAVAN CANOPY INT'L INC.		800224003	manufacture(74464-001)

Revised: 11/2020

CARAVAN CANOPY INT'L INC.