

**CANDO HAND SANITIZER- alcohol gel**  
**SOMBRA COSMETICS**

*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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**CanDo Hand Sanitizer**

**Active Ingredients**

Ethyl Alcohol 70%

**Uses**

To decrease bacteria and viruses on the skin that could cause disease. Recommended for repeated use.

**Warnings**

Flammable. Keep away from fire or flame. For external use only: hands.

**Do not use**

When using this product, do not use in or near the eyes. In case of contact, rinse eyes thoroughly with water.

**When Using**

Keep out of the eyes. In case of contact with eyes, flush thoroughly with water. Avoid contact with broken skin. Do not inhale or ingest

Stop use and ask a doctor if irritation and redness develop. Condition persists more than 72 hours.

Keep out of reach of children. If swallowed, get medical help or contact a Poison Control Center right away. For children under 6, use only under adult supervision. Not recommended for infants.

**Directions**

Wet hands thoroughly with product and allow to dry without wiping.

**Other information**


Do not store above 105F. May discolor some fabrics. Harmful to wood finishes and plastics.

**Inactive ingredients**

glycerin, purified water, isopropyl alcohol, polyacrylate crosspolymer-6, rosa damascena flower water, hamamelis virginiana (witch hazel) leaf extract, aloe barbadensis leaf juice, citrus aurantium dulcis (orange) peel oil, citrus limon (lemon) peel, oil, yucca schidigera stem extract, filipendula rubra extract, camellia sinensis (green tea) leaf extract.

**Purpose**

Antiseptic


  
 Authorized CE representative:
   
 A.V.V. Technology Consulting GmbH
   
 Königswalle 106
   
 40215 Düsseldorf (Germany)

EC REP

Manufactured for:
   
**Fabrication Enterprises Inc**
  
 250 Clearbrook Road, Suite 240
   
 Elmstord, NY 10523 (USA)
   
 tel: +1-914-345-9300 • 800-431-2890
   
 fax: +1-914-345-9800 • 800-634-5370
   
 FabEnt.com

REF 15-1192

# CANDO Hand Sanitizer

Citrus and Aloe with skin conditioners

Net Wt. 4 FL. OZ. (118ml)



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NDC 61577-1116-4	
<b>DRUG FACTS</b>	<b>WARNINGS</b> <ul style="list-style-type: none"> <li>• For external use only: Hands</li> <li>• Flammable, keep away from fire or flame</li> </ul>
<b>ACTIVE INGREDIENTS Purpose:</b> Ethyl Alcohol 70% v/v ... Antiseptic	<b>OTHER INFORMATION</b> <ul style="list-style-type: none"> <li>• Do not store above 105°F</li> <li>• May discolor some fabrics</li> <li>• Harmful to wood finishes and plastics</li> </ul>
<b>USES</b> <ul style="list-style-type: none"> <li>• To decrease bacteria and viruses on the skin that could cause disease</li> <li>• Recommended for repeated use</li> </ul>	<b>KEEP OUT OF REACH OF CHILDREN</b> <ul style="list-style-type: none"> <li>• If swallowed, get medical help or contact a Poison Control Center right away</li> </ul>
<b>STOP USE AND ASK A DOCTOR IF</b> <ul style="list-style-type: none"> <li>• Irritation and redness develop</li> <li>• Condition persists for more than 72 hours</li> </ul>	<b>WHEN USING THE PRODUCT</b> <ul style="list-style-type: none"> <li>• Keep out of eyes. In case of contact with eyes, flush thoroughly with water</li> <li>• Avoid contact with broken skin</li> <li>• Do not inhale or ingest</li> </ul>
<b>DIRECTIONS</b> <ul style="list-style-type: none"> <li>• Wet hands thoroughly with product and allow to dry without wiping</li> <li>• For children under 6, use only under adult supervision</li> <li>• Not recommended for infants</li> </ul>	<b>INACTIVE INGREDIENTS</b> Purified Water, Glycerin, Citrus Limon (Lemon) Peel Oil, Isopropyl Alcohol, Polyacrylate Crosspolymer-6, Citrus Aurantium Dulcis (Orange) Peel Oil, Rosa Damascena Flower Water, Hamamelis Virginiana (Witch Hazel) Leaf Extract, Yucca Schidigera Stem Extract, Filipendula Ulmaria (Queen of the Prairie) Extract, Camellia Sinensis (Green Tea) Leaf Extract, Aloe Barbadensis Leaf Extract.

## CANDO HAND SANITIZER

alcohol gel

Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:61577-1116
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
WATER (UNII: 059QF0KO0R)	
GLYCERIN (UNII: PDC6A3C0OX)	
ISOPROPYL ALCOHOL (UNII: ND2M416302)	
CAMELLIA SINENSIS FLOWER (UNII: 9I2BJY2J17)	
ORANGE PEEL (UNII: T19T76XD44)	
AMMONIUM ACRYLOYLDIMETHYLTAURATE, DIMETHYLACRYLAMIDE, LAURYL METHACRYLATE AND LAURETH-4 METHACRYLATE COPOLYMER, TRIMETHYLOLPROPANE TRIACRYLATE CROSSLINKED (45000 MPA.S) (UNII: Q7UI015FF9)	
ROSA DAMASCENA FLOWER (UNII: JWB78P295A)	
WITCH HAZEL (UNII: 101I4J0U34)	
ALOE VERA LEAF (UNII: ZY81Z83H0X)	
YUCCA SCHIDIGERA ROOT (UNII: E2H9ET15AT)	
FILIPENDULA RUBRA WHOLE (UNII: MT26BL24AZ)	
LEMON PEEL (UNII: 720054U628)	

## Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:61577-1116-8	236 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	06/15/2020	
2	NDC:61577-1116-2	59 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	06/15/2020	
3	NDC:61577-1116-3	946 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	06/15/2020	
4	NDC:61577-1116-4	118 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	06/15/2020	
5	NDC:61577-1116-6	473 mL in 1 BOTTLE, PUMP; Type 0: Not a Combination Product	06/15/2020	
6	NDC:61577-1116-1	3785 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	06/15/2020	

## Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part333A	06/15/2020	

**Labeler** - SOMBRA COSMETICS (097464309)

## Establishment

Name	Address	ID/FEI	Business Operations
SOMBRA COSMETICS		097464309	manufacture(61577-1116)

Revised: 7/2020

SOMBRA COSMETICS