

## **ALOE VERA CENTER 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.*

-----

### **Aloe Vera Center Hand Sanitizer**

#### **Active Ingredients**

Ethyl Alcohol 65%

#### **Uses**

Helps reduce bacteria on the skin that could cause diseases.

#### **Warnings**

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

#### **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**

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

Stop use and ask a doctor if irritation or rash appears and lasts.

Keep out of reach of children. If swallowed, get medical help or contact a Poison Control Center right away.

#### **Directions**

Place enough product in the palm of your hands to thoroughly cover your hands. Rub hands together briskly until product is completely absorbed and hands are dry.

#### **Other information**

Store between 15-30C (59-86F)

Avoid freezing and excessive heat above 40C (105F)


#### **Inactive ingredients**

glycerin, aloe barbadensis leaf extract, camellia sinensis (green tea) leaf extract, purified water, isopropyl alcohol, polyacrylate crosspolymer-6, rosa damascena flower water, hamamelis virginiana (witch hazel) leaf extract, citrus aurantium dulcis (orange) peel oil, filipendula ulmaria (queen of the prairie) extract, yucca schidigera root extract

**Purpose**

Antiseptic, Hand Sanitizer



<b>Drug Facts •</b>	<b>NDC 61577-1113-8</b>
<b>Active Ingredients</b> .....Ethanol 65%	
<b>Purpose</b> .....Antiseptic	
<b>Uses</b> • To decrease bacteria and viruses on the skin that could cause disease • recommended for repeated use	
<b>Warnings</b> • For external use only: hands . • Flammable, keep away from fire or flame.	
<b>Directions</b> • wet hands thoroughly with product and allow to dry without wiping • for children under 6, use only under adult supervision • not recommended for infants	
<b>Other information</b> • do not store above 105 °F may discolor some fabrics • harmful to wood finishes and plastics	
<b>Inactive Ingredients</b> • Purified Water, Isopropyl Alcohol, Glycerin, Aloe Barbadosis Leaf Juice, Witch Hazel, Yucca Extract, Rose Water, Green Tea Extract, Queen of the Prairie Extract, Citrus Aurantium Dulce (Orange) Peel Oil	
<b>Drug Facts (continued)</b> When using this product • keep out of the eyes. In case of contact with eyes, flush thoroughly with water • avoid contact with broken skin n do not inhale or ingest.	
<b>Stop use and ask a doctor if</b> • irritation and redness develop • condition persists for more that 72 hours . Keep out of reach of children. If swallowed, get medical help or contact a Poison Control Center right away.	
<b>Distributed by:</b> Aloe Vera Center 505-873-0856 www.Aloeveracentral.com	 0 83997 70077 1

**ALOE VERA CENTER HAND SANITIZER**

alcohol gel

**Product Information**

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:61577-1113
<b>Route of Administration</b>	TOPICAL		

**Active Ingredient/Active Moiety**

Ingredient Name	Basis of Strength	Strength
ALCOHOL (UNII: 3K9958V90M) (ALCOHOL - UNII:3K9958V90M)	ALCOHOL	65 mL in 100 mL

## Inactive Ingredients

Ingredient Name	Strength
WATER (UNII: 059QF0KO0R)	
GLYCERIN (UNII: PDC6A3C0OX)	
ISOPROPYL ALCOHOL (UNII: ND2M416302)	
ROSA DAMASCENA FLOWER (UNII: JWB78P295A)	
WITCH HAZEL (UNII: 101I4J0U34)	
ORANGE OIL (UNII: AKN3KSD11B)	
CAMELLIA SINENSIS FLOWER (UNII: 9I2BJY2J17)	
FILIPENDULA ULMARIA WHOLE (UNII: 3LH0M209LN)	
AMMONIUM ACRYLOYLDIMETHYLTAURATE, DIMETHYLACRYLAMIDE, LAURYL METHACRYLATE AND LAURETH-4 METHACRYLATE COPOLYMER, TRIMETHYLOLPROPANE TRIACRYLATE CROSSLINKED (45000 MPA.S) (UNII: Q7UI015FF9)	
YUCCA SCHIDIGERA STEM (UNII: N59C6T6D72)	

## Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:61577-1113-8	236 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	06/15/2020	
2	NDC:61577-1113-4	118 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	06/15/2020	
3	NDC:61577-1113-2	54 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	06/01/2020	

**Labeler** - SOMBRA COSMETICS (097464309)

## Establishment

Name	Address	ID/FEI	Business Operations
SOMBRA COSMETICS		097464309	manufacture(61577-1113)

Revised: 7/2020

SOMBRA COSMETICS