

**ENCHANTMENT 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.*

-----

**Enchantment Hand Sanitizer**

**Active Ingredients**

Alcohol 65%

**Uses**

Helps reduce bacteria on the skin that potentially can cause disease. For use when soap and water are not available.

**Warnings**

Flammable. Keep away from heat and flame. For external use only.

**Do not use**

In children less than 2 months of age. On open skin wounds

**When Using**

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 serious condition.

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

**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.

**Storage**

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

Avoid freezing and excessive heat above 40C (104F)

**Inactive ingredients**

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

\*organic

**Purpose**  
Antiseptic

**ENCHANTMENT**  
Made in the USA



**Hand Sanitizer**  
Ethyl Alcohol 65%  
2 grams / 2 mL

**Keeping you sanitized  
one pack at a time**

Brian McKeever (505) 239-0758  
Richard Guerrero (505) 235-9141

<b>Drug Facts</b>	
<b>Active ingredient(s)</b> Alcohol 65% w/v	<b>Purpose</b> Antiseptic
<b>Uses</b> Hand Sanitizer to help reduce bacteria that ordinarily can cause disease. For use when soap and water are not available.	
<b>Warnings</b> For external use only. Flammable. Keep away from heat and flame.	
<b>Do not use</b> • In children less than 2 months of age. • on open skin wounds.	
<b>When using this product</b> keep out of eyes, ears, and mouth. In case of contact with eyes, rinse eyes thoroughly with water.	
<b>Stop use and ask doctor</b> if irritation or rash occurs. There may be signs of serious condition. Keep out of reach of children if swallowed, get medical help or contact a Poison Control right away.	
<b>Directions</b> • 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.	
<b>Other information</b> • Store between 15-30C (59-86F) • Avoid freezing and excessive heat above 40C (104F)	
<b>Inactive ingredients:</b> Purified Water, Glycerin, Isopropyl Alcohol, Citrus Limonif (Zest) Peel Oil, Polysorbate Crosspolymer-6, Rosa Damascena Flower Water, Citrus Aurantium Dulcis (Orange) Peel Oil, Hamamelis Virginiana (Witch Hazel) Leaf Extract, Yucca Schidigera Stem Extract, Filipendula Ulmaria (Queen of the Prairie) Extract, Camellia Sinensis (Green Tea) Leaf Extract, Aloe Barbadosensis Leaf Extract.	

## ENCHANTMENT HAND SANITIZER

alcohol gel

### Product Information

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:61577-1119
<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)	
LEMON PEEL (UNII: 720054U628)	
ORANGE OIL (UNII: AKN3KSD11B)	
AMMONIUM ACRYLOYLDIMETHYLTAURATE, DIMETHYLACRYLAMIDE, LAURYL METHACRYLATE AND LAURETH-4 METHACRYLATE COPOLYMER, TRIMETHYLOLPROPANE TRIACRYLATE CROSSLINKED (45000 MPAS) (UNII: Q7UI015FF9)	
ROSA DAMASCENA FLOWER (UNII: JWB78P295A)	
WITCH HAZEL (UNII: 10114J0U34)	
YUCCA SCHIDIGERA STEM (UNII: N59C6T6D72)	
FILIPENDULA ULMARIA WHOLE (UNII: 3LH0M209LN)	

**GREEN TEA LEAF** (UNII: W2ZU1RY8B0)

**ALOE VERA LEAF** (UNII: ZY81Z83H0X)

### Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:61577-1119-2	2 mL in 1 PACKET; Type 0: Not a Combination Product	07/29/2020	

### Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part333A	07/29/2020	

**Labeler** - SOMBRA COSMETICS (097464309)

### Establishment

Name	Address	ID/FEI	Business Operations
SOMBRA COSMETICS		097464309	manufacture(61577-1119)

Revised: 11/2020

SOMBRA COSMETICS