

## **LATHER 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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## **Lather Hand Sanitizer**

### **Active Ingredients**

Ethyl Alcohol 65%

### **Uses**

To decrease bacteria and viruses on the skin that could cause disease. Recommended for repeated use, when hand washing is not available.

### **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 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, yucca schidigera stem extract, filipendula rubra extract, camellia sinensis (green tea) leaf extract.

### **Purpose**

Antiseptic

**LATHER®**

**hand sanitizer**

with moisturizing aloe

clean skin for a radiant life®

10 fl oz / 295 ml

<b>Drug Facts</b>		NDC 61577-1114-3
<b>Active ingredients</b>	<b>Purpose</b>	
Ethyl Alcohol 65%	Antiseptic	
<b>Uses</b> • To decrease bacteria and viruses on the skin that could cause disease, • recommended for repeated use, when hand washing is not available.		
<b>Warnings</b>		
For external use only: hands.		
Flammable, keep away from fire or flame.		
<b>When using this product</b> • 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.		
<b>Stop use and ask a doctor if</b> • irritation and redness develop • condition persists for more than 72 hours.		
<b>Keep out of reach of children.</b> If swallowed, get medical help or contact a Poison Control Center right away.		
<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, Glycerin, Isopropyl Alcohol, Citrus Aurantium Dulcis (Orange) Peel Oil, Polyacrylate Crosspolymer-6, Rosa Damascena Flower Water, Hamamelis Virginiana (Witch Hazel) Leaf Extract, Aloe Barbadensis Leaf Juice, Yucca Schidigera Stem Extract, Filipendula Rubra Extract, Camellia Sinensis (Green Tea) Leaf Extract		

LATHER, Inc., Dist. Pasadena, CA 91105  
877-6-LATHER lather.com Made in USA



Effective against 99.99% of many common harmful germs and bacteria.

**LATHER HAND SANITIZER**

alcohol gel

**Product Information**

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:61577-1114
<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: 059QF0K00R)	
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: 10114J0U34)	
ALOE VERA LEAF (UNII: ZY81Z83H0X)	
YUCCA SCHIDIGERA ROOT (UNII: E2H9ET15AT)	
FILIPENDULA RUBRA WHOLE (UNII: MT26BL24AZ)	

**Packaging**

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:61577-1114-4	236 mL in 1 BOTTLE, PUMP; Type 0: Not a Combination Product	06/15/2020	
2	NDC:61577-1114-3	296 mL in 1 BOTTLE, PUMP; Type 0: Not a Combination Product	06/15/2020	
3	NDC:61577-1114-6	473 mL in 1 BOTTLE, PUMP; Type 0: Not a Combination Product	06/15/2020	
4	NDC:61577-1114-2	59 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(61577-1114)

Revised: 7/2020

SOMBRA COSMETICS