

**PURE ESSENTIAL MINERALS ANTIBACTERIAL 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.

PURE & ESSENTIAL MINERALS ANTIBACTERIAL HAND SANITIZER

Active Ingredient

Ethyl Alcohol 65%

Purpose

Antiseptic

Uses

To decrease bacteria and viruses on the skin that could cause disease

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 this product

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

Stop use and ask a doctor

Stop use and ask a doctor if irritation or rash appears and lasts. Condition persists for more than 72 hours.

Keep out of reach of children

If swallowed, get medical help or contact a Poison Control Center right away.

Directions

Wet hands thoroughly with product and allow to dry without wiping. For children under 6, use only under adult supervision. Not recommended for infants.

Other Information

Do not store above 105F. May discolor some fabrics. May harm wood finishes.

Inactive ingredients

Aloe Barbadensis Leaf Extract, Aminomethyl Propanol, Camellia Sinensis (Green Tea) Leaf Extract, Carbomer, Citrus Aurantium Dulcis (Orange) Peel Oil, Citrus Limon (Lemon) Peel Oil, Filipendula Ulmaria, (Queen of the Prairie) Extract, Glycerin, Hamamelis Virginiana (Witch Hazel) Leaf Extract, Isopropyl Alcohol, Purified Water, Rosa Damascena Flower Water, Yucca Schidigera Stem Extract

Drug Facts NDC 61577-1118-8

Active Ingredients: Ethyl Alcohol 65% v/v
Purpose: Antiseptic

Uses: To decrease bacteria and viruses on the skin that could cause disease ■ recommended for repeated use

Warnings:
For external use only: hands
■ Flammable, keep away from fire or flame. ►

Distributed by
Pure & Essential Minerals LLC
PO Box 1308
Cedar Crest, NM 87008 (USA)



PURE
& ESSENTIAL MINERALS™



ANTIBACTERIAL
**HAND
SANITIZER**

**CITRUS
& ALOE**
with skin
conditioners

Net Wt. 8 FL. OZ. (236.6ml)



Drug Facts (continued)

When using this product ■ 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 for more than 72 hours

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

Directions ■ wet hands thoroughly with product and allow to dry without wiping ■ for children under 6, use only under adult supervision ■ not recommended for infants

Other Information ■ do not store above 105° F ■ may discolor some fabrics ■ may harm wood finishes

Inactive Ingredients: Aloe Barbadensis Leaf Extract, Aminomethyl Propanol, Camellia Sinensis (Green Tea) Leaf Extract, Carbomer, Citrus Aurantium Dulcis (Orange) Peel Oil, Citrus Limon (Lemon) Peel Oil, Filipendula Ulmaria (Queen of the Prairie) Extract, Glycerin, Hamamelis Virginiana (Witch Hazel) Leaf Extract, Isopropyl Alcohol, Purified Water, Rosa Damascena Flower Water, Yucca Schidigera Stem Extract

PURE ESSENTIAL MINERALS ANTIBACTERIAL HAND SANITIZER

alcohol gel

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:61577-1118
Route of Administration	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
ALOE VERA LEAF (UNII: ZY81Z83H0X)	
AMINOMETHYLPROPANOL (UNII: LU49E6626Q)	
CAMELLIA SINENSIS FLOWER (UNII: 9I2BJY2J17)	
CARBOMER HOMOPOLYMER TYPE C (UNII: 4Q93RCW27E)	

ORANGE PEEL (UNII: T19T76XD44)	
CITRUS LIMON FRUIT OIL (UNII: 0HNC1J1YED)	
FILIPENDULA ULMARIA WHOLE (UNII: 3LH0M209LN)	
GLYCERIN (UNII: PDC6A3C0OX)	
WITCH HAZEL (UNII: 10114J0U34)	
ISOPROPYL ALCOHOL (UNII: ND2M416302)	
WATER (UNII: 059QF0K00R)	
ROSA DAMASCENA FLOWER (UNII: JWB78P295A)	
YUCCA SCHIDIGERA STEM (UNII: N59C6T6D72)	

Product Characteristics

Color	white	Score	
Shape		Size	
Flavor		Imprint Code	
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:61577-1118-8	237 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	07/16/2020	
2	NDC:61577-1118-4	118 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	07/16/2020	
3	NDC:61577-1118-6	474 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	07/16/2020	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part333A	07/16/2020	

Labeler - SOMBRA COSMETICS (097464309)

Establishment

Name	Address	ID/FEI	Business Operations
SOMBRA COSMETICS		097464309	manufacture(61577-1118) , label(61577-1118)