

SOMBRA 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.

Sombra Antibacterial Hand Sanitizer

Active Ingredients

Ethyl Alcohol 65% v/v

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.

Do not use

avoid contact with broken skin. Do not inhale or ingest. Children under 6, use only under adult supervision. Not recommended for infants.

When Using

When using this product, keep out of the eyes. In case of contact with eyes, flush thoroughly with water.

Stop use if irritation and redness develop or if condition persists for more than 72 hours.

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.

Storage and Handling

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

Inactive ingredients

glycerin, purified water, isopropyl alcohol, aminomethyl propanol, 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.

Purpose

Antiseptic

Drug Facts NDC 61577-4130-8

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. ▶



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Made in USA • Manufactured by Sombra, Inc.
5951 Office Blvd. NE, Albq., NM 87109
800-225-3963 • www.sombraUSA.com



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

SOMBRA ANTIBACTERIAL HAND SANITIZER

alcohol gel

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:61577-4130
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
WATER (UNII: 059QF0KO0R)	
GLYCERIN (UNII: PDC6A3C0OX)	
ISOPROPYL ALCOHOL (UNII: ND2M416302)	
LEMON PEEL (UNII: 72O054U628)	
ORANGE OIL (UNII: AKN3KSD11B)	
AMINOMETHYLPROPANOL (UNII: LU49E6626Q)	
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:61577-4130-1	3785 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	07/29/2020	
2	NDC:61577-4130-6	473 mL in 1 BOTTLE, PUMP; Type 0: Not a Combination Product	07/29/2020	
3	NDC:61577-4130-8	237 mL in 1 BOTTLE, PUMP; 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(61577-4130)

Revised: 7/2020

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