

SOMBRA HAND SANITZER- alcohol spray
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 Hand Sanitizer

Active Ingredient

Ethyl Alcohol 65%

Purpose

Antiseptic

Uses

To decrease bacteria and viruses on the skin that could cause disease. Recommended for repeated use.

Warnings

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

Do not use

Stop use and ask doctor if, irritation and redness develop condition persists for more than 72 hours.

When using this product

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

Stop use and ask 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

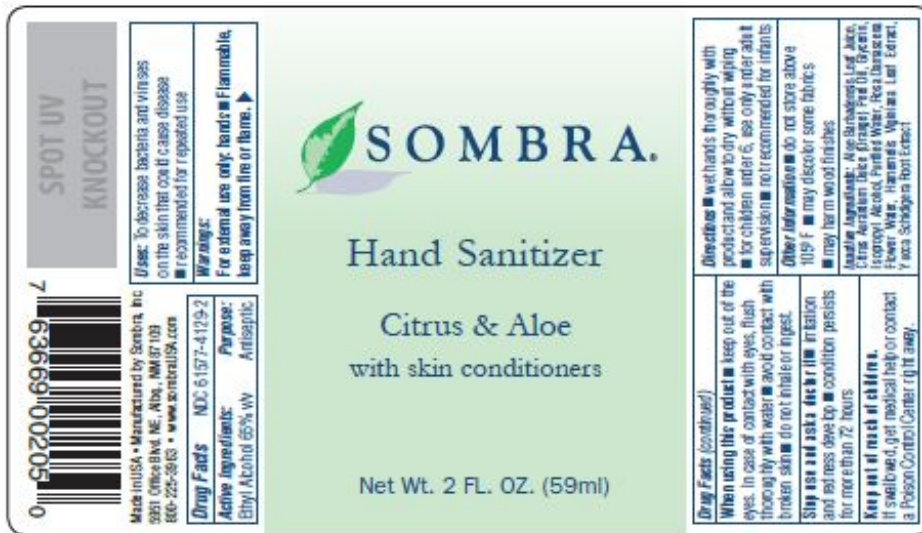
Wet hands thoroughly with product and allow to dry without wiping. For children under 6, use only under adult supervision. Not recommended for infants.

Other Information

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

Inactive ingredients

Aloe Barbados leaf juice, Citrus Aurantium Dulce (orange) Peel Oil, Glycerin, Isopropyl Alcohol, Purified Water, Rosa Damascena Flower Water, Hamamelis Virginiana Leaf Extract, Yucca Schidigera Root Extract.



SOMBRA HAND SANITIZER

alcohol spray

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:61577-4129
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)	
ORANGE PEEL (UNII: T19T76XD44)	
GLYCERIN (UNII: PDC6A3C0OX)	
WITCH HAZEL (UNII: 101I4J0U34)	
ISOPROPYL ALCOHOL (UNII: ND2M416302)	
WATER (UNII: 059QF0KO0R)	
ROSA DAMASCENA FLOWER (UNII: JWB78P295A)	
YUCCA SCHIDIGERA ROOT (UNII: E2H9ET15AT)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:61577-4129-	118 mL in 1 BOTTLE, SPRAY; Type 0: Not a Combination	07/22/2020	

2	Product	07/22/2020	
Marketing Information			
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part333A	07/22/2020	

Labeler - SOMBRA COSMETICS (097464309)

Establishment			
Name	Address	ID/FEI	Business Operations
SOMBRA COSMETICS		097464309	manufacture(6 1577-4129) , label(6 1577-4129)

Revised: 7/2020

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