CANDO 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.

CanDo Hand Sanitizer

Active Ingredients

Ethyl Alcohol 70%

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

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 with product and allow to dry without wiping.

Other information

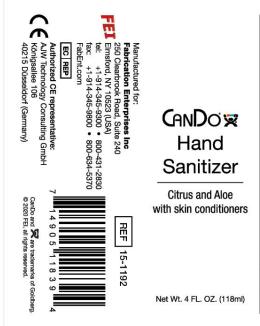
Do not store above 105F. May discolor some fabrics. Harmful to wood finishes and plastics.

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, citrus limon (lemon) peel, oil, yucca schidigera stem extract, filipendula rubra extract, camellia sinensis (green tea) leaf extract.

Purpose

Antiseptic



DRUG FACTS	NDC 61577-1116-4
	WARNINGS
ACTIVE INGREDIENTS Purpose:	Purpose: • For external use only: Hands
Ethyl Alcohol 70% v/v Antiseptic	 Flammable, keep away from
	fire or flame
USES	OTHER INFORMATION
 To decrease bacteria and 	 Do not store above 105°F
viruses on the skin that could	 May discolor some fabrics
cause disease	 Harmful to wood finishes
 Recommended for repeated use 	and plastics
STOP USE AND ASK A	KEEP OUT OF REACH OF
DOCTOR IF	CHILDREN
 Irritation and redness develop 	 If swallowed, get medical
 Condition persists for more 	help or contact a Poison
than 72 hours	Control Center right away
DIRECTIONS	WHEN USING THE PRODUCT
 Wet hands thoroughly with 	 Keep out of eyes. In case
product and allow to dry	of contact with eyes, flush
without wiping	thoroughly with water
 For children under 6, use only 	 Avoid contact with
under adult supervision	broken skin
 Not recommended for infants 	 Do not inhale or ingest
INACTIVE INGREDIENTS	
Purified Water, Glycerin, Citrus Limon (Lemon) Peel Oil, Isopropyl	on (Lemon) Peel Oil, Isopropyl
Alcohol, Polyacrylate Crosspolymer-6, Citrus Aurantium Dulcis	-6, Citrus Aurantium Dulcis
(Orange) Peel Oil, Rosa Damascena Flower Water, Hamamelis	Flower Water, Hamamelis
Virginiana (Witch Hazel) Leaf Extract, Yucca Schidigera Stem	t, Yucca Schidigera Stem
Extract, Flipendula Ulmaria (Queen of the Prairie) Extract, Camellia	of the Prairie) Extract, Camellia
Sinensis (Green lea) Leaf Extract, Aloe Barbadensis Leaf Extract.	loe Barbadensis Leaf Extract.

CANDO HAND SANITIZER

alcohol gel

Product Information				
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:61577-1116	
Route of Administration	TOPICAL			

Active Ingredient/Active Moiety			
Ingredient Name	Basis of Strength	Strength	
ALCOHOL (UNII: 3K9958V90M) (ALCOHOL - UNII:3K9958V90M)	ALCOHOL	70 mL in 100 mL	

Inactive Ingredients				
Ingredient Name	Strength			
WATER (UNII: 059QF0KO0R)				
GLYCERIN (UNII: PDC6A3C0OX)				
ISOPROPYL ALCOHOL (UNII: ND2M416302)				
CAMELLIA SINENSIS FLOWER (UNII: 912BJY2J17)				
ORANGE PEEL (UNII: TI9T76XD44)				
AMMO NIUM ACRYLO YLDIMETHYLTAURATE, DIMETHYLACRYLAMIDE, LAURYL METHACRYLATE AND LAURETH-4 METHACRYLATE COPOLYMER, TRIMETHYLOLPROPANE TRIACRYLATE CROSSLINKED (45000 MPA.S) (UNII: Q7UI0 15FF9)				
ROSA DAMASCENA FLOWER (UNII: JWB78P295A)				
WITCH HAZEL (UNII: 10 114J0 U34)				
ALOE VERA LEAF (UNII: ZY81Z83H0X)				
YUCCA SCHIDIGERA ROOT (UNII: E2H9 ET15AT)				
FILIPENDULA RUBRA WHO LE (UNII: MT26BL24AZ)				
LEMON PEEL (UNII: 720054U628)				

Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	8	236 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	06/15/2020	
	2	59 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	06/15/2020	
3	NDC:61577-1116-3	946 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	06/15/2020	
4	NDC:61577-1116-	118 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	06/15/2020	
5	NDC:61577-1116-6	473 mL in 1 BOTTLE, PUMP; Type 0: Not a Combination Product	06/15/2020	
6	NDC:61577-1116-1	$3785\ mL$ 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(61577-1116)		

Revised: 7/2020 SOMBRA COSMETICS