LOS POBLANOS LAVENDER 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.

Los Poblanos Lavender Hand Sanitizer

Active Ingredients

Ethyl Alcohol 65%

Uses

Helps reduce bacteria on the skin that could cause diseases.

Warnings

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

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

When using this product, do not use in or near the eyes. In case of contact, rinse eyes thoroughly with water.

Stop use and ask a doctor if irritation or rash appears and lasts.

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

Directions

Place enough product in the palm of your hands to thoroughly cover your hands. Rub hands together briskly until product is completely absorbed and hands are dry.

Other information

Store between 15-30C (59-86F) Avoid freezing and excessive heat above 40C (105F)

Inactive ingredients

glycerin, purified water, isopropyl alcohol, polyacrylate crosspolymer-6, lavandula angustifolia oil, lavandula hybrida (grosso) oil*, rosa damascena flower water, hamamelis virginiana (witch hazel) leaf extract

*organic

Purpose

Antiseptic, Hand Sanitizer



LOS POBLANOS LAVENDER HAND SANITIZER

alcohol gel

Product Information				
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:61577-1112	
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)				
LAVANDULA ANGUSTIFOLIA FLOWER (UNII: 19 AH1RAF4M)				
LAVANDIN O IL (UNII: 9RES347CKG)				
AMMONIUM ACRYLO YLDIMETHYLTAURATE, DIMETHYLACRYLAMIDE, LAURYL METHACRYLATE AND LAURETH-4 METHACRYLATE COPOLYMER, TRIMETHYLOLPROPANE TRIACRYLATE CROSSLINKED (45000 MPA.S) (UNII: Q7UI015FF9)				
ROSA DAMASCENA FLOWER (UNII: JWB78P295A)				
WITCH HAZEL (UNII: 10 1I4J0 U34)				

Packaging			
# Item Code	Package Description	Marketing Start Date	Marketing End Date

1	NDC:61577-1112-8	236 mL in 1 BOTTLE, PUMP; Type 0: Not a Combination Product	06/15/2020	
2	NDC:61577-1112- 1	3780 mL in 1 BOTTLE, PUMP; Type 0: Not a Combination Product	06/15/2020	
3	NDC:61577-1112-6	473 mL in 1 BOTTLE, PUMP; Type 0: Not a Combination Product	06/15/2020	
4	NDC:61577-1112-3	946 mL in 1 BOTTLE, PUMP; 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(61577-1112)	

Revised: 7/2020 SOMBRA COSMETICS