

MNFR SAFE- 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.

MNFR SAFE Advanced Hand Sanitizer

Active Ingredients

Ethyl Alcohol 70%

Purpose

Antiseptic, Hand Sanitizer

Uses

Helps reduce bacteria on the skin that could cause diseases.

Warnings

Flammable. Keep 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 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, carbomer, aminomethyl propanol



Drug Fact: Active Ingredient.....Purpose Ethyl Alcohol 70%Antimicrobial Uses: Helps reduce bacteria on the skin that could cause diseases.	Drug Fact (continued): Directions: Place enough product in the palm of your hands to thoroughly cover you hands. Rub hands together briskly until product is completely absorbed and hands are dry.
Warnings: Flammable. Keep away from fire or flame. For external use only. 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.	Inactive Ingredients: Purified Water, Glycerin, Carbomer, AminoMethyl Propanol.
Manufactured For And Distributed By: MNFR, LLC www.mnfrsafe.com	
Made in USA  	

MNFR SAFE

alcohol gel

Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:61577-1115
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: 059QF0K00R)	
GLYCERIN (UNII: PDC6A3C0OX)	
CARBOMER HOMO POLYMER TYPE C (UNII: 4Q93RCW27E)	
AMINOMETHYLPROPANOL (UNII: LU49E6626Q)	

Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:61577-1115-8	236 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	06/30/2020	
2	NDC:61577-1115-1	3785 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	06/29/2020	

Marketing Information			
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date

OTC monograph not final	part333A	06/22/2020
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Labeler - SOMBRA COSMETICS (097464309)

Establishment

Name	Address	ID/FEI	Business Operations
SOMBRA COSMETICS		097464309	manufacture(6 1577-1115) , label(6 1577-1115)

Revised: 6/2020

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