MASCON MEDICAL HAND SANITIZING- alcohol gel Mascon, Inc.

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.

Mas con Medical Hand Sanitizing Gel

DRUG FACTS

Active Ingredient(s)

Ethyl Alcohol 70%

Purpose

Antimicrobial

Use(s)

Hand sanitizer to help reduce bacteria that potentially can cause disease. For use when soap and water are not available.

Warnings

- For external use only.
- Flammable.
- Keep away from heat or flame.

Do not use

- On children less than 2 months of age.
- On open skin wounds.

When using this product lkeep out of eyes, ears, and mouth. In case of contact with eyes, rinse eyes thoroughly with water.

Stop use or ask a doctor if irritation or rash occurs. These may be signs of a serious condition.

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

Directions

- Place enough product on hands to cover all surfaces. Rub hands together until dry.
- Supervise children under 6 years of age when using product to avoid swallowing.

Other Information

- Store between 15-30°C (59-86°F).
- Avoid freezing and excessive heat above 40°C (104°F).

Inactive Ingredients Water (Aqua), Isopropyl Alcohol, Carbomer, Triethanolamine, Glycerin, Isopropyl Myristate, Tocopheryl Acetate, Fragrance.

1 Gallon

NDC 78593-200-00





MASCON MEDICAL HAND SANITIZING

alcohol gel

Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:78593-200
Route of Administration	TOPICAL		

ı	Active Ingredient/Active Moiety			
ı	Ingredient Name	Basis of Strength	Strength	
ı	ALCOHOL (UNII: 3K9958 V90M) (ALCOHOL - UNII:3K9958 V90M)	ALCOHOL	0.7 mL in 1 mL	

Inactive Ingredients		
Ingredient Name	Strength	
ISOPROPYL MYRISTATE (UNII: 0 RE8 K4LNJS)		
CARBOMER HOMOPOLYMER, UNSPECIFIED TYPE (UNII: 0 A5MM307FC)		
WATER (UNII: 059QF0KO0R)		
TROLAMINE (UNII: 9O3K93S3TK)		
GLYCERIN (UNII: PDC6A3C0OX)		
ISOPROPYL ALCOHOL (UNII: ND2M416302)		
.ALPHATOCOPHEROL (UNII: H4N855PNZ1)		

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

1 NDC:78593-200-00	3785 mL in 1 BOTTLE; Type 0: Not a Combination Produc	08/10/2020		
Marketing Information				
Marketing Categor	y Application Number or Monograph Citation	Marketing Start Date	Marketing End Date	
OTC monograph not fin	al part333E	08/10/2020		

Labeler - Mascon, Inc. (106772338)

Establishment				
Name	Address	ID/FEI	Business Operations	
SBC International Group Inc.		117520462	manufacture(78593-200)	

Revised: 8/2020 Mascon, Inc.