

MEDICALLY MINDED- alcohol gel
SBL LLC

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.

HAND SANITIZER

ANTIMICROBIAL FORMULA

8.5 FL OZ (250 ML)



MEDICALLY MINDED™



8.5 FL OZ (250 mL)

Active Ingredient(s)

Drug Facts

Active Ingredients

Ethyl Alcohol 70% v/v.....

Purpose

Antimicrobial

Use: Hand sanitizer to help reduce bacteria on skin.

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, flush 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 immediately.

Directions: Put enough product in your palm to cover hands and rub hands together briskly until dry. Children under 6 years of age should be supervised when using.

Other Information: Store below 110°F (43°C)

Inactive Ingredients: Water (Aqua), Glycerin, Carbomer, Triethanolamine

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Use

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

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- in children less than 2 months of age
- on open skin wounds

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

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

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Directions

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

- Store between 15-30C (59-86F)
- Avoid freezing and excessive heat above 40C (104F)
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Package Label - Principal Display Panel

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MEDICALLY MINDED

alcohol gel

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:766 19-120
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
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ALCOHOL (UNII: 3K9958V90M) (ALCOHOL - UNII:3K9958V90M)			ALCOHOL	0.7 mL in 1 mL
Inactive Ingredients				
Ingredient Name			Strength	
WATER (UNII: 059QF0KO0R)			0.2956 mL in 1 mL	
TRIETHANOLAMINE LAURYL SULFATE (UNII: E8458C1KAA)			0.0004 mL in 1 mL	
CARBOMER 934 (UNII: Z135WT9208)			0.004 mL in 1 mL	
Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:76619-120-02	4000 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	04/28/2020	
Marketing Information				
Marketing Category		Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final		part333A	04/28/2020	

Labeler - SBL LLC (117341346)

Revised: 4/2020

SBL LLC