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 Ingredients Purpose
Ethyl Alcohol 70% v/v.....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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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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alcohol gel

Product illiorillation		Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:76619-110		
Route of Administration	TOPICAL				

Active	Ingre	die nt/	Active	Moiety
LICUIT	THETC	uiciid	1 1 C C I V C	11101661

Ingredient Name	Basis of Strength	Strength

ALCOHOL (UNII: 3K9958 V90 M) (ALCOHOL - UNII: 3K9958 V90 M)	ALCOHOL	0.7 mL in 1 mL
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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		

ı	P	Packaging			
	#	Item Code	Package Description	Marketing Start Date	Marketing End Date
	1	NDC:76619-110- 01	250 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	04/23/2020	

Labeler - SBL LLC (117341346)

Revised: 4/2020 SBL LLC