

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.

Active Ingredient(s)

<i>Drug Facts</i>	
<i>Active Ingredients</i>	<i>Purpose</i>
Ethyl Alcohol 70% v/v.....	Antimicrobial
<i>Use:</i> 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.	
<i>Directions:</i> 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.	
<i>Other Information:</i> Store below 110°F (43°C)	
<i>Inactive Ingredients:</i> Water (Aqua), Glycerin, Carbomer, Triethanolamine	

Antimicrobial

Purpose

Alcohol 70% v/v. Purpose:

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

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

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

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

Inactive ingredients

water. TRIETHANOLAMINE LAURYL SULFATE, carbomer

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Package Label - Principal Display Panel



MEDICALLY MINDED™



1.05 GALLON (4 L)

4
Sanitizer Gel

000 ml Hand

MEDICALLY MINDED
alcohol gel

Product Information				
Product Type		HUMAN OTC DRUG	Item Code (Source)	NDC:766 19 -110
Route of Administration		TOPICAL		
Active Ingredient/Active Moiety				
Ingredient Name			Basis of Strength	Strength
ALCOHOL (UNII: 3K9958 V90M) (ALCOHOL - UNII:3K9958 V90M)			ALCOHOL	0.7 mL in 1 mL
Inactive Ingredients				
Ingredient Name			Strength	
TRIETHANOLAMINE LAURYL SULFATE (UNII: E8458C1KAA)			0.0004 mL in 1 mL	
CARBOMER 934 (UNII: Z135WT9208)			0.004 mL in 1 mL	
WATER (UNII: 059QF0KO0R)			0.2956 mL in 1 mL	
Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:766 19 -110 -03	4000 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	03/26/2020	
Marketing Information				
Marketing Category		Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final		part333A	03/26/2020	

Labeler - SBL LLC (117341346)