

## **HAND SANITIZER- alcohol spray**

### **Balm of Gilead**

*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.*

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### **Hand Sanitizer**

The hand sanitizer is manufactured using only the following United States Pharmacopoeia (USP) grade ingredients in the preparation of the product (percentage in final product formulation) consistent with World Health Organization (WHO) recommendations:

- a. Alcohol (ethanol) (USP or Food Chemical Codex (FCC) grade) (80%, volume/volume (v/v)) in an aqueous solution denatured according to Alcohol and Tobacco Tax and Trade Bureau regulations in 27 CFR part 20.
- b. Glycerol (1.45% v/v).
- c. Hydrogen peroxide (0.125% v/v).
- d. Sterile distilled water or boiled cold water.

### **Active Ingredient(s)**

Alcohol 80% v/v. Purpose: Antiseptic

### **Purpose**

Antiseptic, Hand Sanitizer

### **Use**

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**

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

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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.

**Other information**


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

**Inactive ingredients**

citrus aurantium bergamia (bergamot) peel oil, glycerin, hydrogen peroxide, purified water USP, pelargonium graveolens (geranium) oil, tanacetum annu l. (blue tansy) oil

**Package Label - Principal Display Panel**

NDC 74843-2256-2



06/22  
Balm of Gilead  
Rusk, TX 75785 USA

**Drug Facts**

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BALSAM OF GILEAD™  
allnaturalbalm.com  
SOOTHE - PROTECT - REPAIR

ALLNATURALBALM.COM

Alcohol Antiseptic 80%  
Topical Non-sterile solution  
with super-moisturizing glycerin

ALCOHOL based  
**Hand Sanitizer**

NO RINSE WASH | SAFE | EFFECTIVE



2 fl. oz. (59 ml)

If your skin came with instructions, it would say,  
**“USE BALM OF GILEAD”**

BLUE TANSY & GERANIUM

<b>HAND SANITIZER</b>			
alcohol spray			
<b>Product Information</b>			
<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:74843-2256
<b>Route of Administration</b>	TOPICAL		
<b>Active Ingredient/Active Moiety</b>			

Ingredient Name		Basis of Strength	Strength	
ALCOHOL (UNII: 3K9958V90M) (ALCOHOL - UNII:3K9958V90M)		ALCOHOL	80 mL in 100 mL	
<b>Inactive Ingredients</b>				
Ingredient Name		Strength		
TANSY OIL (UNII: 43J2812KE1)		0.15 mL in 100 mL		
GERANIUM OIL, ALGERIAN TYPE (UNII: 5Q1I94P4WG)		0.3 mL in 100 mL		
BERGAMOT OIL (UNII: 39W1PKE3JI)		1.3 mL in 100 mL		
GLYCERIN (UNII: PDC6A3C0OX)		1.45 mL in 100 mL		
HYDROGEN PEROXIDE (UNII: BBX060AN9V)		0.125 mL in 100 mL		
WATER (UNII: 059QF0K00R)				
<b>Packaging</b>				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:74843-2256-2	59 mL in 1 BOTTLE, SPRAY; Type 0: Not a Combination Product	03/30/2020	
<b>Marketing Information</b>				
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date	
OTC monograph not final	part333A	03/30/2020		

**Labeler** - Balm of Gilead (099144632)

### Establishment

Name	Address	ID/FEI	Business Operations
Balm of Gilead		099144632	manufacture(74843-2256)

Revised: 5/2020

Balm of Gilead