

**HAND SANITIZER HAND SANITIZER- alcohol gel**  
**Dhaliwal Laboratories, 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.*

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**Hand Sanitizer**

**Active Ingredients**

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Active ingredient	Purpose
Ethyl Alcohol 70%	Antiseptic

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**Inactive Ingredients**

- Water (Aqua)
- Aloe Barbadosensis Leaf Juice (Stabilized\* Aloe Vera Gel)
- Isopropyl Alcohol
- Glycerin
- Tetrahydroxypropyl Ethylenediamine
- Acrylates/C10-30 Alkyl Acrylate Crosspolymer
- Tocopheryl Acetate
- Isopropyl Myristate.

**Purpose Section**

- Uses
- Hand sanitizer to help decrease bacteria on the skin.
  - When water, soap & towel are not available.
  - Recommended for repeated use.

**Warnings**

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

**Indications & Usage**

- When using this product, avoid contact with eyes.
- In case of contact flush eyes with water.
- Do not apply around eyes. Do not use in ears & mouth.

**Stop use and ask a doctor if**

Stop use and ask a doctor if

- Stop use and ask a doctor if redness or irritation develop and persist for more than 72 hours

### **Keep out of reach of children**

Keep out of reach of children. Children must be supervised in use of this product.

### **Dosage & Administration Directions**

Directions

- wet hands thoroughly with product
- briskly rub hands together until dry
- children under 6 years of age should be supervised when using this product

### **Other information**

- store at 20 °C to 25 °C (68°F to 77°F) when possible. Do not store above 40 °C (104° F).
- may discolor certain fabrics

### **Package Label Principal Display Panel**

<b>Drug Facts</b>
<b>Active ingredient(s).....Purpose</b> Ethyl Alcohol 70%.....Antiseptic
<b>Uses</b> <ul style="list-style-type: none"><li>• Hand sanitizer to help decrease bacteria on the skin.</li><li>• When water, soap &amp; towel are not available.</li><li>• Recommended for repeated use.</li></ul>
<b>Warnings For external use only.</b>
<b>Flammable. Keep away from fire or flame.</b>
<b>When using this product</b> , avoid contact with eyes. In case of contact flush eyes with water.
<b>Do not apply around eyes. Do not use</b> in ears & mouth.
<b>Stop use and ask a doctor</b> if redness or irritation develop and persist for more than 72 hours.
<b>Keep out of reach of children.</b> Children must be supervised in use of this product.
<b>Directions •</b> Put enough product in your palm to cover hands and rub hands together briskly until dry
<b>Other information •</b> Store at 20°C (68° to 77°F). • May discolor fabrics.
<b>Inactive Ingredients</b> Water (Aqua), IPA, Tetrahydroxypropyl Ethylenediamine, Carbomer, Glycerin, Aloe Barbadensis Inner Leaf Juice (Aloe Vera), Isopropyl Myristate, Tocopheryl Acetate, <i>Cymbopogon schoenanthus oil</i> .
<b>DISTRIBUTED BY:</b> Company Name Address Phone Website

alcohol gel

### Product Information

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:46432-121
<b>Route of Administration</b>	TOPICAL		

### Active Ingredient/Active Moiety

<b>Ingredient Name</b>	<b>Basis of Strength</b>	<b>Strength</b>
ALCOHOL (UNII: 3K9958V90M) (ALCOHOL - UNII:3K9958V90M)	ALCOHOL	0.7 g in 1 g

### Inactive Ingredients

<b>Ingredient Name</b>	<b>Strength</b>
EDETOL (UNII: Q4R969U9FR)	
WATER (UNII: 059QF0KO0R)	
ALOE VERA LEAF (UNII: ZY81Z83H0X)	
ISOPROPYL ALCOHOL (UNII: ND2M416302)	
CYMBOPOGON CITRATUS LEAF (UNII: 06JMS448M5)	
GLYCERIN (UNII: PDC6A3C0OX)	
CARBOMER 940 (UNII: 4Q93RCW27E)	
ALPHA-TOCOPHEROL ACETATE (UNII: 9E8X80D2L0)	
ISOPROPYL MYRISTATE (UNII: 0RE8K4LNJS)	

### Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:46432-121-01	60 g in 1 BOTTLE; Type 0: Not a Combination Product	01/01/2020	

### Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part333E	01/01/2020	

**Labeler** - Dhaliwal Laboratories, LLC (016754201)

### Establishment

Name	Address	ID/FEI	Business Operations
Dhaliwal Laboratories, LLC		016754201	manufacture(46432-121)

Revised: 1/2020

Dhaliwal Laboratories, LLC