

## **HAND SANITIZER- ethyl alcohol gel**

**SJ Creations, Inc.**

*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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### **Drug Facts**

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

Ethyl Alcohol 62% 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.

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.

#### **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**

Water, Glycerin, Aloe Barbadensis Leaf Juice, Calendula Officinalis Flower Extract, Chamomilla

Recutita (Matricaria) Flower Extract, Citric Acid, Hydroxypropyl Guar.

Package Label - Principal Display Panel

**Brady**  
**Hand Sanitizer Gel**

KILLS 99.99% OF GERMS

MADE WITH MOISTURIZERS & VITAMIN E

NO WATER OR TOWEL NEEDED

CM9506

32 FL.OZ.  
(1 QT) 946 ML

**Drug Facts**

<b>Active ingredient</b>	<b>Purpose</b>
Ethyl alcohol 65% v/v.....	Antiseptic
<b>Use</b>	
Hand sanitizer to help reduce bacteria on the skin.	
<b>Warnings</b>	
For external use only.	
<b>Flammable. Keep away from fire and flame.</b>	
When using this product avoid contact with eyes. In case of contact, rinse eyes thoroughly with water.	
Stop use and ask a doctor if irritation and redness develop.	
<b>Keep out of reach of children.</b>	
If swallowed, get medical help or contact a Poison Control Center immediately.	
<b>Directions</b>	
<ul style="list-style-type: none"> <li>Put enough on your palm to cover hands and rub hands together briskly until dry</li> <li>Children under 6 years of age should be supervised when using this product</li> </ul>	
<b>Other information</b>	
<ul style="list-style-type: none"> <li>Store at 20°C to 25°C (68°F to 77°F).</li> <li>May discolor some fabrics or surfaces.</li> </ul>	
<b>Inactive ingredients</b>	
Water, Glycerin, Propylene Glycol, Isopropyl Alcohol, Carbomer, Fragrance, Isopropyl Palmitate, Aminomethyl Propanol, Tocopheryl Acetate.	
<b>Questions?</b>	
1-888-942-2280 Monday - Friday 9 AM - 5 PM PST	
<small>DIST. BY SJ CREATIONS, INC. P.O. BOX 232428 LEUCADIA, CA 92023, U.S.A. WWW.SJCREATIONSINC.COM MADE IN THE USA</small>	
 8 192592 052092	

946ml NDC: 43269-950-32

**HAND SANITIZER**

ethyl alcohol gel

**Product Information**

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:43269-956
<b>Route of Administration</b>	TOPICAL		

**Active Ingredient/Active Moiety**

Ingredient Name	Basis of Strength	Strength
ALCOHOL (UNII: 3K9958V90M) (ALCOHOL - UNII:3K9958V90M)	ALCOHOL	62 mL in 100 mL

**Inactive Ingredients**

Ingredient Name	Strength
CITRIC ACID ACETATE (UNII: DSO12WL7AU)	
WATER (UNII: 059QF0K00R)	
GLYCERIN (UNII: PDC6A3C0OX)	
HYDROXYPROPYL GUAR (2500-4500 MPAS AT 1%) (UNII: 3A1I7376TC)	
MATRICARIA CHAMOMILLA (UNII: G0R4UBI2ZZ)	
ALOE VERA LEAF (UNII: ZY81Z83H0X)	

CALENDULA OFFICINALIS FLOWER (UNII: P0M7O4Y7YD)

### Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:43269-956-32	946 mL in 1 BOTTLE, PUMP; Type 0: Not a Combination Product	05/12/2020	

### Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part333A	05/12/2020	

**Labeler** - SJ Creations, Inc. (146379495)

### Establishment

Name	Address	ID/FEI	Business Operations
Bell International Laboratories		967781555	manufacture(43269-956)

Revised: 5/2020

SJ Creations, Inc.