

## **SANITIZER ADVANCED HAND- alcohol gel**

**Glowbal Citizen 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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### **Sanitizer Advanced Hand Gel**

#### **Drug Facts:**

##### **Active Ingredient**

Ethyl Alcohol 70.00%

##### **Purpose**

Antimicrobial

##### **Uses:**

Helps reduce bacteria on the skin that could cause diseases.

##### **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, rinse eyes 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 right away.


##### **Directions:**



Place enough product in the palm of your hands to thoroughly cover your hands. Rub hands together briskly until product is completely absorbed and hands are dry.

##### **Inactive Ingredients:**

Aqua, Glycerin, \*CO Glycerin, \*CO Humulus Lupulus (Hops) Extract, \*CO Lavandula Angustifolia (Lavender) Flower/Leaf/Stem Extract, \*CO Calendula Officinalis Flower Extract, \*CO Chamomilla Recutita (Matricaria) Flower Extract, \*CO Citrus Limon (Lemon) Peel Extract, \*CO Camellia Sativus (Cucumber) Seed Extract, \*CO Camellia Sinensis Leaf Extract, \*CO Pyrus Malus (Apple) Fruit Extract, \*CO Spirulina Platensis Extract, Carbomer. \*CO Certified Organic

##### **Package Labeling:**



Drug Fact:	
<b>Active Ingredient</b> ..... <b>Purpose</b> Ethyl Alcohol 70.00%.....Antimicrobial	<b>Drug Fact (continued):</b> <b>Directions:</b> Place enough product in the palm of your hands to thoroughly cover you hands. Rub hands together briskly until product is completely absorbed and hands are dry.
<b>Uses:</b> Helps reduce bacteria on the skin that could cause diseases.	
<b>Warnings:</b> 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, rinse eyes 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 right away.	
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Manufactured For And Distributed By: <b>Polarized, LLC</b> <a href="http://www.sanidermproducts.com">www.sanidermproducts.com</a>	
<div style="display: flex; justify-content: space-between; align-items: center;"> <div style="text-align: center;">             Made in USA         </div> <div style="text-align: center;">             8 60003 63390 8         </div> </div>	

## SANITIZER ADVANCED HAND

alcohol gel

### Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:77449-001
Route of Administration	TOPICAL		

### Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
ALCOHOL (UNII: 3K9958V90M) (ALCOHOL - UNII:3K9958V90M)	ALCOHOL	0.7 mL in 1 mL

### Inactive Ingredients

Ingredient Name	Strength
WATER (UNII: 059QF0KO0R)	
GLYCERIN (UNII: PDC6A3C0OX)	
HOPS (UNII: 01G73H6H83)	
LAVANDULA ANGUSTIFOLIA SUBSP. ANGUSTIFOLIA FLOWERING TOP (UNII: 9YT4B71U8P)	
CALENDULA OFFICINALIS FLOWER (UNII: P0M7O4Y7YD)	
CHAMOMILE (UNII: FGL3685T2X)	
LEMON PEEL (UNII: 72O054U628)	
CUCUMBER (UNII: YY7C30VXJT)	
GREEN TEA LEAF (UNII: W2ZU1RY8B0)	
APPLE (UNII: B423VGH5S9)	
CARBOMER HOMOPOLYMER, UNSPECIFIED TYPE (UNII: 0A5MM307FC)	

### Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:77449-001-08	236 mL in 1 BOTTLE; Type 0: Not a Combination Product	05/01/2020	

## Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part333E	05/01/2020	

**Labeler** - Glowbal Citizen LLC (117501584)

## Establishment

Name	Address	ID/FEI	Business Operations
Glowbal Citizen LLC		117501584	manufacture(77449-001)

Revised: 5/2020

Glowbal Citizen LLC