

**CHAMP- alcohol gel**  
**Champ Products, Ltd**

*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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**Active Ingredient**

Ethyl Alcohol 70%

**Purpose**

Antiseptic

**Uses**

Hand Sanitizer to help reduce bacteria that potentially can cause disease.

**Directions**

Apply liberally to front and back of hands. Allow to dry. Recommended for repeated use.

**Warnings**

**For external use only: hands.**

**Flammable, keep away from fire or flame.**

**When using this product** avoid contact with the eyes. In case of contact, Rinse eyes thoroughly with water.

**Stop use and ask a doctor if** irritation or redness appears and lasts.

**If swallowed**, get medical help or contact a Poison Control Center immediately.

**Do not use:** in children less than 2 months of age and on open wounds. Do not inhale or ingest.

Supervise children under 6 years of age when using the product to avoid swallowing.

**Other information**

Store between 0<sup>0</sup>C (32<sup>0</sup>F) – 41<sup>0</sup>C (105<sup>0</sup>F)

**Inactive ingredients**

Glycerin, Hydrogen Peroxide, Distilled Water, Polymer, Fragrance.

**Customer service**

1-833-SANITIZE

**Package Label - Principal Display Panel**



ADVANCED FORMULA

# HAND SANITIZER GEL

PROTECTS AGAINST  
GERMS

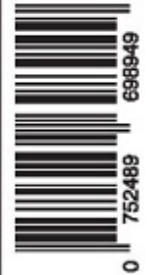
KILLS 99.99% OF MOST  
ILLNESS CAUSING GERMS

CITRUS SCENT

1 GAL (3.78L)  
Proudly made in the USA

Drug Facts	
<b>Active ingredient</b>	<b>Purpose</b>
Ethyl Alcohol 70%	Antiseptic
<b>Uses</b>	
Hand sanitizer to help reduce bacteria on the skin that can cause illness.	
<b>Directions</b>	
Apply liberally to front and back of hands. Allow to dry. Recommended for repeated use.	
<b>Warnings</b>	
For external use only; hands.	
Flammable, keep away from fire or flame.	
When using this product avoid contact with the eyes. In case of contact, rinse eyes thoroughly with water.	
Stop use and ask a doctor if irritation or redness appears and lasts.	
If swallowed, get medical help or contact a Poison Control Center immediately.	
Do not use in children less than 2 months of age and on open wounds. Do not inhale or ingest. Supervise children under 6 years of age when using this product to avoid swallowing.	
<b>Other information</b>	
Store between 0°C (32°F) - 41°C (105°F)	
<b>Inactive ingredients</b>	
Glycerin, Hydrogen Peroxide, Distilled Water, Polymer, Fragrance	
<b>Customer Service</b>	
1-833-SANITIZE	

Distributed By:  
Champ Products, Ltd.  
Scottsdale, AZ  
[www.ChooseChamp.com](http://www.ChooseChamp.com)



## CHAMP

alcohol gel

### Product Information

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:78658-001
<b>Route of Administration</b>	TOPICAL		

### Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
ALCOHOL (UNII: 3K9958V90M) (ALCOHOL - UNII:3K9958V90M)	ALCOHOL	70 mL in 100 mL

### Inactive Ingredients

Ingredient Name	Strength
WATER (UNII: 059QF0KO0R)	
HYDROGEN PEROXIDE (UNII: BBX060AN9V)	
GLYCERIN (UNII: PDC6A3C0OX)	

GUARAPROLOSE (3500 MPAS AT 1%) (UNI: 3A1I7376TC)

FRAGRANCE LAVENDER & CHIA F-153480 (UNI: SXS9CO2TZK)

### Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:78658-001-01	30 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	05/24/2020	
2	NDC:78658-001-02	59 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	05/24/2020	
3	NDC:78658-001-03	104 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	05/24/2020	
4	NDC:78658-001-04	118 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	05/24/2020	
5	NDC:78658-001-05	177 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	05/24/2020	
6	NDC:78658-001-06	236 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	05/24/2020	
7	NDC:78658-001-07	296 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	05/24/2020	
8	NDC:78658-001-08	473 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	05/24/2020	
9	NDC:78658-001-09	1000 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	05/24/2020	
10	NDC:78658-001-10	3785 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	05/24/2020	
11	NDC:78658-001-11	208198 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	05/24/2020	
12	NDC:78658-001-12	1040990 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	05/24/2020	

### Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part333A	05/24/2020	

**Labeler** - Champ Products, Ltd (117509904)

### Establishment

Name	Address	ID/FEI	Business Operations
Aegle Nutrition LLC		079354415	manufacture(78658-001)

Revised: 5/2020

Champ Products, Ltd