

## **HAND SANITIZER- alcohol gel**

### **CA-Botana International**

*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 Dr Bump**

This is a hand sanitizer manufactured according to the Temporary Policy for Preparation of Certain Alcohol-Based Hand Sanitizer Products During the Public Health Emergency (CoViD-19); Guidance for Industry.

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.

The firm does not add other active or inactive ingredients. Different or additional ingredients may impact the quality and potency of the product.

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

Alcohol 65% 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.

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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**

purified water USP, Aloe barbadensis extract, Hamamelis virginiana (Whitchhazel) extract, Polyquaternium-37, Cucumis sativus (Cucumber) extract, Centella asiatica (Gotu kola) extract, Equisetum fluviatile (Horsetail) extract, Rosmarinus officinalis (Rosemary) extract, Aesculus hippocastanum (Horse chestnut) extract, Camellia sinensis (Green tea) extract, Olea europaea (Olive) extract, Eucalyptus globulus extract, Propanediol, Phenoxyethanol, Potassium Sorbate, Ethylhexylglycerin, Sodium Phytate, Benzalkonium Chloride.



Waxness Dr Bump Natural Botanical Sanitizer will sanitize your hands without drying them. Alcohol is infused with 10 concentrated botanical extracts that will help keeping your hands moisturized and protected.

DRUG FACTS	
<b>Active ingredient:</b>	<b>Purpose</b>
Ethyl alcohol 65% v/v	Antiseptic
<b>Use:</b> Hand sanitizer to help reduce bacteria that potentially can cause disease. Also for use when soap and water are not available.	
<b>Warnings:</b> For external use only. Keep away from fire or flame.	
- Do not use -in children less than 2 months of age - on open skin wounds.	
- When using this product -keep out of the 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.	
<b>Directions:</b> Place a small amount of 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.	
<b>Other information:</b> Store between 15 - 30C (59 - 86F) Avoid freezing and excessive heat above 40C (104F)	
<b>Inactive ingredients:</b> Water (Aqua), Aloe barbadensis Extract, Hamamelis virginiana (Witchhazel) Extract, Polyquaternium-37, Cucumis sativus (Cucumber) Extract, Centella asiatica (Gotu Kola) Extract, Equisetum fluviatile (Horsetail) Extract, Rosmarinus officinalis (Rosemary) Extract, Aesculus hippocastanum (Horse Chestnut) Extract, Camellia sinensis (Green Tea) Extract, Olea europaea (Olive) Leaf Extract, Eucalyptus globulus Extract, Propanediol, Phenoxyethanol, Potassium Sorbate, Ethylhexylglycerin, Sodium Phytate, Benzalkonium Chloride.	

NON STERILE SOLUTION! NOT TESTED ON ANIMALS!  
NDC 35192-036-04

Distr. by 1Beauty US LLC, Palm Desert, CA, 92211  
waxness.com (United States)  
waxness.de (EU, Germany)  
Made in USA



**HAND SANITIZER**

alcohol gel

**Product Information**

Product Type

HUMAN OTC DRUG

Item Code (Source)

NDC:35192-036

<b>Route of Administration</b>	TOPICAL
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### Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
ALCOHOL (UNII: 3K9958V90M) (ALCOHOL - UNII:3K9958V90M)	ALCOHOL	65 mL in 100 mL

### Inactive Ingredients

Ingredient Name	Strength
CAMELLIA SINENSIS WHOLE (UNII: C5M4585ZBZ)	
PROPANEDIOL (UNII: 5965N8W85T)	
POTASSIUM SORBATE (UNII: 1VPU26JZZ4)	
EQUISETUM FLUVIATILE WHOLE (UNII: D6MQP77VTM)	
ROSEMARY (UNII: IJ67X351P9)	
HEXASODIUM PHYTATE (UNII: ZBX50UG81V)	
CENTELLA ASIATICA LEAF (UNII: 6810070TYD)	
HORSE CHESTNUT (UNII: 3C18L6RJAZ)	
WITCH HAZEL (UNII: 10114J0U34)	
BENZALKONIUM CHLORIDE (UNII: F5UM2KM3W7)	
POLYQUATERNIUM 37 (200 MPA.S) (UNII: 67C1D6YV24)	
GREEN OLIVE (UNII: 6HD2W46UEG)	
ALOE VERA LEAF (UNII: ZY81Z83H0X)	
ETHYLHEXYLGLYCERIN (UNII: 147D247K3P)	
PHENOXYETHANOL (UNII: HIE492ZZ3T)	
CUCUMBER (UNII: YY7C30VXJT)	
EUCALYPTUS GLOBULUS LEAF (UNII: S546YLW6E6)	
WATER (UNII: 059QF0KO0R)	

### Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:35192-036-04	59.1 mL in 1 BOTTLE; Type 0: Not a Combination Product	05/18/2020	

### Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part333A	05/18/2020	

**Labeler** - CA-Botana International (106276728)

**Registrant** - Rodolfo Ugelstad (106276728)

### Establishment

Name	Address	ID/FEI	Business Operations
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Revised: 5/2020

CA-Botana International