

## **AMERICAS CHOICE HAND SANITIZER- isopropyl alcohol liquid**

### **Valco Sales & Marketing**

*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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### **America's Choice Hand Sanitizer**

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. Isopropyl Alcohol (75%, 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)**

Isopropyl Alcohol 70% 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

glycerin, purified water USP, fragrance <.0.7%

### Package Label - Principal Display Panel

 8 60005 08268 1	MANUFACTURED IN THE USA FOR <b>VSM</b> Dania Beach, FL 33004	<b>SKU #</b> HS 1004	 MADE IN USA	
<b>Drug Facts</b> <u>Active ingredient</u> Isopropyl Alcohol 70% v/v....Antiseptic	<b>Drug Facts(Continued)</b> Stop use and ask a doctor if • imitation and redness develop • condition persists for more than 72 hours	<b>Drug Facts(Continued)</b> <u>Other Information</u> • Do not store above 105°F • May discolor some fabrics • Harmful to wood finishes and Plastics		
<b>Uses</b> • to decrease bacteria on skin that could cause disease • recommended for repeated use	<b>Keep out of reach of children.</b> If swallowed, get medical help or contact a Polson Control Center right away.	<b>Inactive Ingredients</b> Aqua (Water) Cymbopogon martini (Palmarosa) Essential Oil Glycerin Parfum (Fragrance) Pelargonium graveolens (Geranium) Essential Oil		
<b>Warnings</b> <u>For external use only: hands</u> Flammable, keep away from fire or flame	<b>Directions</b> • Spray hands thoroughly with Product and allow to dry without wiping • For children under 6, use only under adult supervision. • Not recommended for infants	<b>FDA Registered</b> California Proposition 65 - This product does not contain any substances known to the state of California to cause cancer, developmental and/or reproductive harm. NDC #80321-0660-1		
<b>When using this product</b> • Keep out of eyes. In case of contact with eyes, flush thoroughly with water. Avoid contact with broken skin. Do not inhale or ingest.				

**BLACK ROSE**

**AMERICA'S CHOICE  
AND SANITIZER**  
"Special Edition"



**WE WANT YOU!  
TO SANITIZE**



LIGHTLY SCENTED WITH  
ESSENTIAL OILS

**2 FL OZ 60ML**

60 ml NDC: 80321-0660-1



MANUFACTURED IN THE USA FOR  
**VSM**  
Dania Beach, FL 33004

**SKU #**  
HS 1002



**Drug Facts**

**Active ingredient**

Isopropyl Alcohol 70% v/v....Antiseptic

**Uses**

- to decrease bacteria on skin that could cause disease
- recommended for repeated use

**Warnings**

**For external use only: hands**  
**Flammable, keep away from fire or flame**

**When using this product**

- Keep out of eyes. In case of contact with eyes, flush thoroughly with water. Avoid contact with broken skin. Do not inhale or ingest.

**Drug Facts(Continued)**

**Stop use and ask a doctor if**  
• imitation and redness develop  
• condition persists for more than 72 hours

**Keep out of reach of children.**

**If swallowed, get medical help or contact a Polson Control Center right away.**

**Directions**

- Spray hands thoroughly with Product and allow to dry without wiping
- For children under 6, use only under adult supervision.
- Not recommended for infants

**Drug Facts(Continued)**

**Other Information**

- Do not store above 105°F
- May discolor some fabrics
- Harmful to wood finishes and Plastics

**Inactive Ingredients**

Aqua (Water)  
Cedrus Atlantica (Cedarwood) Bark Essential Oil  
Citrus Medica Limonum (Lemon) Peel Essential Oil  
Glycerin  
Parfum (Fragrance)

**FDA Registered**

California Proposition 65 - This product does not contain any substances known to the state of California to cause cancer, developmental and/or reproductive harm.

**NDC #80321-0660-2**

FRESH RAIN

# AMERICA'S CHOICE HAND SANITIZER



## WE WANT YOU! TO SANITIZE



LIGHTLY SCENTED WITH  
ESSENTIAL OILS

2 FL OZ  $\square$  60ML

60 ml NDC: 80321-0660-2



MANUFACTURED IN THE USA FOR  
VSM  
Dania Beach, FL 33004

SKU #  
HS 1003



### Drug Facts

#### Active ingredient

Isopropyl Alcohol 70% v/v...Antiseptic

#### Uses

- to decrease bacteria on skin that could cause disease
- recommended for repeated use

#### Warnings

**For external use only: hands**  
Flammable, keep away from fire or flame

When using this product

### Drug Facts (Continued)

Stop use and ask a doctor if  
• irritation and redness develop  
• condition persists for more than 72 hours

Keep out of reach of children.

If swallowed, get medical help or contact a Poison Control Center right away.

#### Directions

- Spray hands thoroughly with Product and allow to dry

### Drug Facts (Continued)

#### Other Information

- Do not store above 105°F
- May discolor some fabrics
- Harmful to wood finishes and Plastics

#### Inactive Ingredients

Aqua (Water)  
Eucalyptus Globulus Leaf Essential Oil  
Glycerin  
Mentha Piperita (Peppermint) Essential Oil  
Parfum (Fragrance)  
Rosmarinus Officinalis (Rosemary) Leaf Essential Oil

• Keep out of eyes. In case of contact with eyes, flush thoroughly with water. Avoid contact with broken skin. Do not inhale or ingest.

without wiping  
 • For children under 6, use only under adult supervision.  
 • Not recommended for infants

**FDA Registered**  
 California Proposition 65 - This product does not contain any substances known to the state of California to cause cancer, developmental and/or reproductive harm.  
 NDC #80321-0660-3

**HERBAL MIST**

**AMERICA'S CHOICE  
 HAND SANITIZER**



**WE WANT YOU!  
 TO SANITIZE**



LIGHTLY SCENTED WITH  
**ESSENTIAL OILS**  
**2 FL OZ 60ML**

60 ml NDC: 80321-0660-3



MANUFACTURED IN THE USA FOR  
**VSM**  
 Dania Beach, FL 33004

**SKU #**  
**HS 1001**



**Drug Facts**  
**Active ingredient**  
 Isopropyl Alcohol 70% v/v...Antiseptic  
**Uses**  
 • to decrease bacteria on skin that could cause disease  
 • recommended for repeated

**Drug Facts (Continued)**  
 Stop use and ask a doctor if  
 • imitation and redness develop  
 • condition persists for more than 72 hours  
 Keep out of reach of children.  
 If swallowed, get medical help

**Drug Facts (Continued)**  
**Other Information**  
 • Do not store above 105°F  
 • May discolor some fabrics  
 • Harmful to wood finishes and Plastics  
**Inactive**

use

### Warnings

**For external use only: hands**  
Flammable, keep away from fire or flame

When using this product

- Keep out of eyes. In case of contact with eyes, flush thoroughly with water. Avoid contact with broken skin. Do not inhale or ingest.

or contact a Polson Control Center right away.

### Directions

- Spray hands thoroughly with Product and allow to dry without wiping
- For children under 6, use only under adult supervision.
- Not recommended for infants

### Ingredients

Aqua (Water)  
Citrus paradisi (Pink Grapefruit) Essential Oil  
Glycerin  
Lavandula Angustifolia (Lavender) Essential Oil

### FDA Registered

California Proposition 65 - This product does not contain any substances known to the state of California to cause cancer, developmental and/or reproductive harm.

NDC #80321-0660-4

**UNSCENTED**

**AMERICA'S CHOICE  
HAND SANITIZER**



**WE WANT YOU!  
TO SANITIZE**



**2 FL OZ 60ML**

60 ml NDC: 80321-0660-4

## AMERICAS CHOICE HAND SANITIZER

isopropyl alcohol liquid

### Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:80321-0660
Route of Administration	TOPICAL		

**Active Ingredient/Active Moiety**

Ingredient Name	Basis of Strength	Strength
ISOPROPYL ALCOHOL (UNII: ND2M416302) (ISOPROPYL ALCOHOL - UNII:ND2M416302)	ISOPROPYL ALCOHOL	70 mL in 100 mL

**Inactive Ingredients**

Ingredient Name	Strength
GLYCERIN (UNII: PDC6A3C0OX)	1.4 mL in 100 mL
WATER (UNII: 059QF0KO0R)	27.9 mL in 100 mL

**Packaging**

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:80321-0660-1	10000 mL in 1 BOTTLE, SPRAY; Type 0: Not a Combination Product	10/19/2020	
2	NDC:80321-0660-2	10000 mL in 1 BOTTLE, SPRAY; Type 0: Not a Combination Product	10/19/2020	
3	NDC:80321-0660-3	10000 mL in 1 BOTTLE, SPRAY; Type 0: Not a Combination Product	10/19/2020	
4	NDC:80321-0660-4	10000 mL in 1 BOTTLE, SPRAY; Type 0: Not a Combination Product	10/19/2020	

**Marketing Information**

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part333A	10/19/2020	

**Labeler** - Valco Sales & Marketing (094970995)**Establishment**

Name	Address	ID/FEI	Business Operations
Valco Sales & Marketing		094970995	label(80321-0660)

**Establishment**

Name	Address	ID/FEI	Business Operations
Draga Laboratories		610096534	manufacture(80321-0660)

Revised: 9/2020

Valco Sales &amp; Marketing