

AMERICAS CHOICE HAND SANITIZER- isopropyl alcohol liquid

Draga Laboratories

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.

AC Hand Sanitizer Spray

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 (isopropyl) (USP or Food Chemical Codex (FCC) grade) (70%, 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)

Isoprophyl 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

60 mL NDC: 75748-4510 - 1



MANUFACTURED IN THE USA FOR
VSM
Dania Beach, FL 33004



Drug Facts Active ingredient Isopropyl Alcohol 70% v/v...Antiseptic	Drug Facts(Continued) Stop use and ask a doctor if • imitation and redness develop • condition persists for more than 72 hours	Drug Facts(Continued) Other Information • Do not store above 105°F • May discolor some fabrics • Harmful to wood finishes and Plastics
Uses • to decrease bacteria on skin that could cause disease • recommended for repeated use	Keep out of reach of children. If swallowed, get medical help or contact a Polson Control Center right away.	Inactive Ingredients Aqua (Water) Cymbopogon martinii (Palmarosa) Essential Oil Glycerin Parfum (Fragrance) Pelargonium graveolens (Geranium) Essential Oil
Warnings For external use only: hands Flammable, keep away from fire or flame	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	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 #80321-0660-1
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.		

BLACK ROSE

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



**WE WANT YOU!
TO SANITIZE**



LIGHTLY SCENTED WITH
ESSENTIAL OILS
2 FL OZ 60ML

60 mL NDC: 75748-4510 - 2



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 60ML

60 mL NDC: 75748-4510 - 3



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

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**

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

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.

Product and allow to dry 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: 75748-4510 - 4



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

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

Drug Facts (Continued)

Other Information

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

- 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.

Caution:
If swallowed, get medical help or contact a Poison 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

Inactive 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

AMERICAS CHOICE HAND SANITIZER

isopropyl alcohol liquid

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:75748-4510
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
WATER (UNII: 059QF0K00R)	
GLYCERIN (UNII: PDC6A3C0OX)	1.4 mL in 100 mL

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:75748-4510-1	10000 mL in 1 BOTTLE, SPRAY; Type 0: Not a Combination Product	10/19/2020	
2	NDC:75748-4510-2	10000 mL in 1 BOTTLE, SPRAY; Type 0: Not a Combination Product	10/19/2020	
3	NDC:75748-4510-3	10000 mL in 1 BOTTLE, SPRAY; Type 0: Not a Combination Product	10/19/2020	
4	NDC:75748-4510-4	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 - Draga Laboratories (610096534)**Establishment**

Name	Address	ID/FEI	Business Operations
Draga Laboratories		610096534	manufacture(75748-4510)

Revised: 5/2020

Draga Laboratories