# V-KLEAN- alcohol gel Asiaticon, S.A. de C.V.

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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# **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.

# Warnings

Flammable, keep away from fire and flames For external use only

# **Inactive ingredients**

Aminomethylpropanol, glycerin, polyacrylic acidc (Carbomer), purified water USP.

# Use

Hand sanitizer for hand-washing to decrease bacteria on the skin, only when water is not available Keep out of reach of children. If swallowed, get medical help or contact a Poison Control Center right away.

# **Purpose**

Antiseptic, Hand sanitizer

# Active Ingredient(s)

Alcohol 70% Purpose: Antiseptic

250 mL NDC: 75192-002-01





Alcohol 70%

8.5 fl oz (250mL)

# **Drug Facts**

# Active Ingredient (s)

Purpose

Alcohol 70% v/v.....

.Antiseptic

#### Use(s

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.

#### Directions

- Place enough product on hands to cover all surfaces. Rub hands together until dry
- together until dry.

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

#### Other information

- Store between 15-30C (56-86F)
- . Avoid freezing and excessive heat above 40C (104F)

Inactive ingredients aminomethylpropanol, glycerin, polyacrylic acid (Carbomer), purified water USP.

#### Manufactured by:

Asiaticon S.A de C.V Conkal 62, Jardines del Ajusco. Tlalpan Ciudad de México, México. 14200

Distributed by: Acadia Mercantil Corp. 8320 NW 68th ST, MIAMI FL 33166

Product of Mexico





EXP: 05/18/21 BATCH: 20052301

# Package Label - Principal Display Panel

500 mL NDC: 75192-002-02





Alcohol 70%

16.9 fl oz (500mL)

# **Drug Facts**

# Active Ingredient (s)

Purpose

Alcohol 70% v/v.....

.Antiseptic

#### Use(s

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.

#### 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 (56-86F)
- Avoid freezing and excessive heat above 40C (104F)

Inactive ingredients aminomethylpropanol, glycerin, polyacrylic acid (Carbomer), purified water USP.

#### Manufactured by:

Asiaticon S.A de C.V Conkal 62, Jardines del Ajusco. Tlalpan Ciudad de México, México. 14200

Distributed by: Acadia Mercantil Corp. 8320 NW 68th ST, MIAMI FL 33166

Product of Mexico





# Package Label - Principal Display Panel

1.5 mL NDC: 75192-002-04



#### **Drug Facts**

Active Ingredient (s) Purpose Alcohol 70% v/v... Antiseptic

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.

#### 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 (56-86F)
   Avoid freezing and excessive heat above 40C (104F)

Inactive ingredients aminomethylpropanol, carbomer, glycerin, purified water USP.

Manufactured by: Asiaticon S.A de C.V Conkal 62, Jardines del Ajusco. Tialpan Ciudad de México, México. 14200

Distributed by: Asiaticon SA de CV LLC Suncrest Dr 2190 Eagle Pass, Texas, USA. 78852

# V-KLEAN

alcohol gel

# **Product Information**

HUMAN OTC DRUG NDC:75192-002 Product Type Item Code (Source)

**Route of Administration** 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		
AMINOMETHYLPROPANOL (UNII: LU49E6626Q)	0.5 mL in 100 mL		
POLYACRYLIC ACID (8000 MW) (UNII: 73861X4K5F)	0.3 mL in 100 mL		
WATER (UNII: 059QF0KO0R)	28.35 mL in 100 mL		
GLYCERIN (UNII: PDC6A3C0OX)	0.85 mL in 100 mL		

P	Packaging				
#	Item Code	Package Description	<b>Marketing Start Date</b>	Marketing End Date	
1	NDC:75192-002-02	500 mL in 1 BOTTLE; Type 0: Not a Combination Product	06/16/2020		
2	NDC:75192-002-01	250 mL in 1 BOTTLE; Type 0: Not a Combination Product	06/16/2020		
3	NDC:75192-002-03	1000 mL in 1 BOTTLE; Type 0: Not a Combination Product	06/16/2020	08/20/2020	
4	NDC:75192-002-04	1.5 mL in 1 PACKET; Type 0: Not a Combination Product	06/26/2020		

Marketing Information				
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date	
OTC monograph not final	part333A	06/16/2020		

# Labeler - Asiaticon, S.A. de C.V. (951576254)

# Registrant - Asiaticon, S.A. de C.V. (951576254)

Establishment			
Name	Address	ID/FEI	<b>Business Operations</b>
ASIATICON, S.A de C.V.		951576254	manufacture(75192-002)

Revised: 8/2020 Asiaticon, S.A. de C.V.