# KLEEN HAND SANITIZER MANGO- alcohol gel SAIGON COSMETICS CORPORATION

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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Alcohol 70% v/v purpose: antiseptic

Antiseptic, hand sanitizer

Hand sanitizer to help decrease bacteria that can potentially cause disease. For use when soap and water are not available.

For external use only. Flammable. Keep away from heat and flame.

## Do not use

- In children without aldult supervision
- On open skin wound

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 serious conditions.

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 15-25oC(59-77oF)
- Avoid freezing and excessive heat above 40oC (104oF)

## +84-28-3742-1102

.Alpha.-hexylcinnamaldehyde, .Gamma.-undecalactone, 1-(2,3,8,8-Tetramethyl-1,2,3,4,5,6,7,8-octahydronaphthalen-2-Yl)ethanone, 2-(2-(4-Methylcyclohex-3-en-1-Yl)propyl)cyclopentan-1-one, 2-Tert-butylcyclohexyl acetate, 3-Hexenyl salicylate, cis-, 4-(P-hydroxyphenyl)-2-butanone, Bornyl acetate, (-)-, Carbomer interpolymer type A (allyl sucrose crosslinked), Diethyl malonate, Ethyl linalool, Ethyl maltol, Hexahydro-4,7-methanoinden-6-yl propionate, Hexyl acetate, Hexyl salicylate, Polyoxyl 40 hydrogenated castor oil, Propylene glycol, Trolamine, Water



## **Drug Facts**

Active Ingredient

Alcohol 70% v/v.

Purpose .. Antiseptic

Uses: Hand sanitizer to help decrease bacteria that can potentially cause disease. For use when soap and water are not available.

#### Warnings

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#### Direction

- 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 15-25°C (59-77°F).
- Avoid freezing and excessive heat above 40°C (104°F).

Inactive ingredients: Alpha-hexylcinnamaldehyde, Gamma-undecalactone, 1-{2,3,8,8-Tetramethyl-1,2,3,4,5,6,7,8-octahydronaphthalen-2-yl) ethanone, 2-{2-{4-Methylcyclohex-3-en-1-yl]propyl)cyclopentan-1-one, 2-Tert-butylcyclohexyl acetate, 3-Hexenyl salicylate, cis-4-(P-hydroxyphenyl)-2-butanone, Bornyl acetate, (-)-, Carbomer interpolymer type A (allyl sucrose crosslinked), Diethyl malonate, Ethyl linalool, Ethyl maltol, Hexahydro-4,7-methanoinden-6-yl propionate, Hexyl acetate, Hexyl salicylate, Polyoxyl 40 hydrogenated castor oil, Propylene glycol, Trolamine, Water.

Question? +84-28-3742-1102 NDC Code 79741-003-09

SCC

FDA REGISTERED



Manufactured by:

SAIGON COSMETICS CORPORATION

930 Nguyen Thi Dinh Street, Cat Lai Industrial Zone (Block II),

Thanh My Loi Ward, District 2, Ho Chi Minh City 700000, Vietnam. www.saigoncosmetics.com

## **Drug Facts**

#### **Active Ingredient Purpose**

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

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## **Directions**

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



Hand Sanitizer





Alcohol Antiseptic 70%

3.4 fl oz (100 ml)

## **Drug Facts** (Continued)

## Other information:

- Store between 15-25°C (59-77°F).
- Avoid freezing and excessive heat above 40°C (104°F).

## Inactive ingredients:

Inactive ingredients:

Alpha-hexylcinnamaldehyde, .Gamma-undecalactone, .1-(2,3,8,8-Tetramethyl-1,2,3,4,5,6,7,8-octahydronaphthalen-2-yl) ethanone, .2-(2-(4-Methylcyclohex-3-en-1-yl)propyl)cyclopentan-1-one, .2-Tert-butylcyclohexyl acetate, .3-Hexenyl salicylate, .cis-, .4-(P-hydroxyphenyl)-2-butanone, Bornyl acetate, .)-, .Carbomer interpolymer type A (allyl sucrose crosslinked), .Diethyl malonate, Ethyl linalool, Ethyl maltol, Hexahydro-4, 7-methanoinden-6-yl propionate, Hexyl acetate, Hexyl salicylate, Polyoxyl 40 hydrogenated castor oil, Propylene glycol, Trolamine, Water.

## Question? +84-28-3742-1102

NDC Code 79741-003-10



REGISTERED

Manufactured by: SAIGON COSMETICS CORPORATION 930 Nguyen Thi Dinh Street, Cat Lai Industrial Zone (Block II), Thanh My Loi Ward, District 2, Ho Chi Minh City 700000, Vietnam. www.saigoncosmetics.com



## **Drug Facts**

Active Ingredient

Purpose

Alcohol 70% v/v

Uses: Hand sanitizer to help decrease bacteria that can potentially cause disease. For use when soap and water are not available.

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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 might signs

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.



**Hand Sanitizer** MANGO



Alcohol Antiseptic 70%

8.4 fl oz (250 ml)

## Drug Facts (Continued)

## Other information:

- Store between 15-25°C (59-77°F).
- Avoid freezing and excessive heat above 40°C (104°F).

Inactive ingredients: .Alpha.-hexylcinnamaldehyde, .Gamma.-undeca-1-(2,3,8,8-Tetramethyl-1,2,3,4,5,6,7,8-octahydronaphthalen-2-yl) 2-(2-(4-Methylcyclohex-3-en-1-yl)propyl)cyclopentan-1-one, 2-Tert-butylcyclohexyl acetate, 3-Hexenyl salicylate, cis-, 4-(P-hydroxy-2-tert-douth/cuonexyn acteate, 5-tertenry saurychiaet, Cs-, 4-(t-riyutoxy-phenyl)-2-butone, Bornyl acetate, (-), Carbomer interpolymer type A (ally sucrose crosslinked), Diethyl malonate, Ethyl linalool, Ethyl maltol, Healyhdro-4-7-methanoinden-6-yl propionate, Heoyl acetate, Heoyl salicylate, Polyoxyl 40 hydrogenated castor oil, Propylene glycol, Trolamine, Water.

Question? +84-28-3742-1102

NDC Code

SCCFDA



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930 Nguyen Thi Dinh Street, Cat Lai Industrial Zone (Block II), Thanh My Loi Ward, District 2, Ho Chi Minh City 700000, Vietnam. www.saigoncosmetics.com

MFG.

## **Drug Facts**

**Active Ingredient** Purpose . Antiseptic Alcohol 70% v/v .

Uses: Hand sanitizer to help decrease bacteria that can potentially cause disease. For use when soap and water are not available.

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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.



## Drug Facts (Continued)

#### Other information:

- Store between 15-25°C (59-77°F)
- Avoid freezing and excessive heat above 40°C (104°F).

Inactive ingredients: .Alpha.-hexylcinnamaldehyde, .Gamma.-undeca-1-(2,3,8,8-Tetramethyl-1,2,3,4,5,6,7,8-octahydronaphthalen-2-yl) lactone, 1-(2,3,8,8-letramethyl-1,2,3,4,5,6,/8-octahydronaphthalen-2-yl) ethanone, 2-1(2-4,Methyloc)doex-3 en-1-yl)propyl)(x)opentan-1-one, 2-Tert-butylcyclohexyl acetate, 3-Hexenyl salicylate, cis-, 4-(P-hydroxy-phenyl)-2-butanone, Bornyl acetate, (-)-, Carbomer interpolymer type A (allyl sucrose crossinked), Diethyl malonate, Ethyl linalool, Ethyl Ethy Polyoxyl 40 hydrogenated castor oil, Propylene glycol, Trolamine, Water

Question? +84-28-3742-1102

NDC Code 79741-003-32

SCC**FDA** 



Manufactured by :

SAIGON COSMETICS CORPORATION

930 Nguyen Thi Dinh Street, Cat Lai Industrial Zone (Block II). Thanh My Loi Ward, District 2, Ho Chi Minh City 700000, Vietnam.

EXP.

Drug Facts	
Active Ingredient Alcohol 70% v/v	Purpose Antiseptic
<b>Uses:</b> Hand sanitizer to help decrease bacteria that can potentially ca when soap and water are not available.	use disease. For use
Warnings: For external use only. Flammable. Keep away from heat and flame.	
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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



#### Drug Facts (Continued)

- Other information:

   Store between 15-25°C (59-77°F).

   Store between 40°C (104°F).

Question? +84-28-3742-1102

SCCFDA



## KLEEN HAND SANITIZER MANGO

alcohol gel

## **Product Information**

Product Type HUMAN OTC DRUG Item Code (Source) NDC:79741-003

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 **DIETHYL MALONATE** (UNII: 53A58 PA183) **BORNYL ACETATE, (-)-** (UNII: 24Q AP1VCUX) HEXYL ACETATE (UNII: 7U7KU3MWT0) 2-TERT-BUTYLCYCLOHEXYL ACETATE (UNII: 364FV60913) ETHYL LINALOOL (UNII: SF2JS9GF5T) ETHYL MALTOL (UNII: L6Q8K29L05)

HEXAHYDRO-4,7-METHANO INDEN-6-YL PRO PIO NATE (UNII: S3ASM14UAS)	
4-(P-HYDRO XYPHENYL)-2-BUTANO NE (UNII: 7QY1MH15BG)	
.ALPHAHEXYLCINNAMALDEHYDE (UNII: 7X6O37OK2I)	
2-(2-(4-METHYLCYCLOHEX-3-EN-1-YL)PROPYL)CYCLOPENTAN-1-ONE (UNII: P1K3Z8A8HJ)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
CARBOMER INTERPOLYMER TYPE A (ALLYL SUCROSE CROSSLINKED) (UNII: 59TL3WG5CO)	
POLYOXYL 40 HYDROGENATED CASTOR OIL (UNII: 7YC686GQ8F)	
HEXYL SALICYLATE (UNII: 8F78EY72YL)	
1-(2,3,8,8-TETRAMETHYL-1,2,3,4,5,6,7,8-O CTAHYDRO NAPHTHALEN-2-YL) ETHANO NE (UNII: 1GD7O DM28 Y)	
TROLAMINE (UNII: 9O3K93S3TK)	
.GAMMAUNDECALACTO NE (UNII: QB1T0 AG2YL)	
WATER (UNII: 059QF0KO0R)	
3-HEXENYL SALICYLATE, CIS- (UNII: C78 Y9 O R6 YH)	

Packaging					
#	Item Code	Package Description	Marketing Start Date	Marketing End Date	
1	NDC:79741-003- 09	90 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	09/15/2020		
2	NDC:79741-003- 10	100 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	09/15/2020		
3	NDC:79741-003- 25	250 mL in 1 BOTTLE, PUMP; Type 0: Not a Combination Product	09/15/2020		
4	NDC:79741-003- 32	320 mL in 1 BOTTLE, PUMP; Type 0: Not a Combination Product	09/15/2020		
5	NDC:79741-003- 50	500 mL in 1 BOTTLE, PUMP; Type 0: Not a Combination Product	09/15/2020		

Marketing Information					
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date		
OTC monograph not final	part333A	09/15/2020			

# Labeler - SAIGON COSMETICS CORPORATION (555265180)

# **Registrant** - SAIGON COSMETICS CORPORATION (555265180)

Establishment				
Name	Address	ID/FEI	Business Operations	
SAIGON COSMETICS CORPORATION		555265180	manufacture(79741-003)	

Revised: 8/2020 SAIGON COSMETICS CORPORATION