KLEEN HAND SANITIZER RELAXING LAVENDER- acohol 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.

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.

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)

.Alpha.-terpinyl acetate, (+/-)-, .Beta.-pinene, .Beta.-caryophyllene oxide, 1-Octen-3-ol, 1-Octen-3-yl acetate, 3,5,5-Trimethylhexyl acetate, 3-Carene, 4-Terpineol, (+/-)-,4-Tert-butylcyclohexyl acetate, Benzoic acid, Butylated hydroxytoluene, Camphene, Camphor (synthetic), Carbomer interpolymer type a (allyl sucrose crosslinked), Caryophyllene, Coumarin, Dihydromyrcenol, Diphenyl ether, Eucalyptol, Geraniol, Geranyl acetate, Hexamethylindanopyran, Limonene, (+)-, Linalool, (+/-)-, Linalyl acetate, (+)-, Musk ketone, Nerol, Neryl acetate, P-cymene, Pinene, Polyoxyl 40 hydrogenated castor oil, Propylene glycol, Terpineol, Terpinolene, Trolamine, Water.

+84-28-3742-1102

Keep out of reach of children. If swallowed, get medical help or contact a poison control center right away.



Drug Facts

Active Ingredient

Alcohol 70% v/v

Purpose

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Inactive ingredients: .Alpha.-terpinyl acetate, (+/-)-, .Beta.-caryophyllene oxide, .Beta.-pinene, 1-Octen-3-ol, 1-Octen-3-yl acetate, 3,5,5-Trimethylhexyl acetate, 3-Carene, 4-Terpineol, (+/-)-, 4-Tert-butylcyclohexyl acetate, Benzoic acid, Butylated hydroxytoluene, Camphene, Camphor (synthetic), Carbomer interpolymer type A (allyl sucrose crosslinked), Caryophyllene, Coumarin, Dihydromyrcenol, Dipheryl ether, Eucalyptol, Geraniol, Geranyl acetate, Hexamethylindanopyran, Limonene, (+)-, Linalool, (+/-)-, Linalyl acetate, (+)-, Musk ketone, Nerol. Neryl acetate. Peymene. Pinene. Polyoxyl 40 hydrogenated Nerol, Neryl acetate, P-cymene, Pinene, Polyoxyl 40 hydrogenated castor oil, Propylene glycol, Terpineol, Terpinolene, Trolamine,

Question? +84-28-3742-1102 NDC Code 79741-004-09

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

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Drug Facts (Continued)

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Inactive ingredients:

Alpha-terpinyl acetate, (+/-)-, Beta-caryophyllene oxide, Beta-pinene, 1-Octen-3-ol, 1-Octen-3-yl acetate, 3,5,5-Trimethylhexyl acetate, 3-Carene, Nerol, Neryl acetate, P-cymene, Pinene, Polyoxyl 40 hydrogenated castor oil, Propylene glycol, Terpineol, Terpinolene, Trolamine, Water.

Question? +84-28-3742-1102

NDC Code 79741-004-10

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. www.saigoncosmetics.com



Drug Facts

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Drug Facts (Continued)

Other information:

- Store between 15-30°C (59-86°F)
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Question? +84-28-3742-1102

NDC Code 79741-004-25

SCCFDA



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

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Drug Facts (Continued)

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Question? +84-28-3742-1102

NDC Code 79741-004-32





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

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Drug Facts (Continued)

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 and excessive heat above 40°C (104°F).

Question? +84-28-3742-1102

NDC Code 79741-004-50

SCC**FDA**

KLEEN HAND SANITIZER RELAXING LAVENDER

TOPICAL

acohol gel

Product Information

Route of Administration

Product Type HUMAN OTC DRUG Item Code (Source) NDC:79741-004

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

HEXAMETHYL INDANO PYRAN (UNII: 14170060AT)

3-CARENE (UNII: H2M15SNR6N)

.BETA.-CARYOPHYLLENE O XIDE (UNII: S2XU9K448U)

WATER (UNII: 059QF0KO0R)

CAMPHENE (UNII: G3VG94Z26E)

COUMARIN (UNII: A4VZ22K1WT)

CAMPHOR (SYNTHETIC) (UNII: 5TJD82A1ET)
DIPHENYL ETHER (UNII: 3O695R5M1U)
4-TERPINEOL, (+/-)- (UNII: L65MV77ZG6)
4-TERT-BUTYLCYCLOHEXYL ACETATE (UNII: 21EUM2B8UC)
LIMO NENE, (+)- (UNII: GFD7C86Q1W)
1-OCTEN-3-YL ACETATE (UNII: 2PZ32LCA02)
.BETAPINENE (UNII: 4MS8 VHZ1HJ)
GERANYL ACETATE (UNII: 3W81YG7P9R)
TERPINO LENE (UNII: N9830 X5KSL)
PINENE (UNII: 996299PUKB)
CARBOMER INTERPOLYMER TYPE A (ALLYL SUCROSE CROSSLINKED) (UNII: 59TL3WG5CO)
LINALYL ACETATE, (+)- (UNII: 3ID3M89AV9)
LINALOOL, (+/-)- (UNII: D81QY6188E)
BUTYLATED HYDRO XYTOLUENE (UNII: 1P9 D0 Z171K)
TROLAMINE (UNII: 903K93S3TK)
BENZOIC ACID (UNII: 8 SKN0 B0 MIM)
1-OCTEN-3-OL (UNII: WXB511GE38)
NEROL (UNII: 38 G5P53250)
NERYL ACETATE (UNII: OF82IJU18H)
P-CYMENE (UNII: 1G1C8T1N7Q)
.ALPHATERPINYL ACETATE, (+/-)- (UNII: 9 RXE0 I9 F2J)
DIHYDRO MYRCENO L (UNII: 46L1B02ND9)
EUCALYPTOL (UNII: RV6J6604TK)
3,5,5-TRIMETHYLHEXYL ACETATE (UNII: 9HMD71U17Z)
GERANIOL (UNII: L837108USY)
MUSK KETONE (UNII: 483V3E1L6J)
CARYOPHYLLENE (UNII: BHW853AU9H)
POLYOXYL 40 HYDROGENATED CASTOR OIL (UNII: 7YC686GQ8F)
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)
TERPINEOL (UNII: R53Q4ZWC99)

Packaging					
#	Item Code	Package Description	Marketing Start Date	Marketing End Date	
1	NDC:79741-004- 09	90 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	09/15/2020		
2	NDC:79741-004- 10	100 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	09/15/2020		
3	NDC:79741-004- 25	250 mL in 1 BOTTLE, PUMP; Type 0: Not a Combination Product	09/15/2020		
4	NDC:79741-004- 32	320 mL in 1 BOTTLE, PUMP; Type 0: Not a Combination Product	09/15/2020		
5	NDC:79741-004- 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(79741-004)		

Revised: 8/2020 SAIGON COSMETICS CORPORATION