

**KLEEN HAND SANITIZER- alcohol gel
79741**

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

Carbomer Interpolymer Type A (Allyl Sucrose Crosslinked), Propylene Glycol, Trolamine, Water
+84-28-3742-1102

Kleen Hand Sanitizer 90mL



Kleen Hand Sanitizer 100mL

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: For external use only. Flammable. Keep away from heat and flame. Do not use: • in children without adult 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 might 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 15-25°C (59-77°F). • Avoid freezing and excessive heat above 40°C (104°F).	
Inactive ingredients: Carbomer Interpolymer Type A (Allyl Sucrose Crosslinked), Propylene Glycol, Trolamine, Water.	
Question? +84-28-3742-1102	NDC Code 79741-000-09
S C C <small>SAIGON COSMETICS CORPORATION</small>	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	

<p>Drug Facts</p>	 <p>Hand Sanitizer Alcohol Antiseptic 70%</p>  <p>3.4 fl oz (100 ml)</p>	<p>Drug Facts (Continued)</p>
<p>Active Ingredient Purpose Alcohol 70% v/v Antiseptic</p> <p>Uses: Hand sanitizer to help decrease bacteria that can potentially cause disease. For use when soap and water are not available.</p> <p>Warnings: For external use only. Flammable. Keep away from heat and flame. Do not use: • in children without adult 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 might be signs of serious conditions. Keep out of reach of children. If swallowed, get medical help or contact a Poison Control Center right away.</p> <p>Directions</p> <ul style="list-style-type: none"> 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. 		<p>Other information:</p> <ul style="list-style-type: none"> Store between 15-25°C (59-77°F). Avoid freezing and excessive heat above 40°C (104°F). <p>Inactive ingredients: Carbomer Interpolymer Type A (Allyl Sucrose Crosslinked), Propylene Glycol, Trolamine, Water.</p> <p>Question? +84-28-3742-1102</p> <p>NDC Code 79741-000-10</p> <p>SCC FDA <small>SAIGON COSMETICS CORPORATION</small> <small>REGISTERED</small></p> <p>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</p>  <p>8 9 3 4 6 6 2 1 3 8 4 0 9 8</p>

Kleen Hand Sanitizer 250mL

<p>Drug Facts</p> <p>Active Ingredient Purpose Alcohol 70% v/v Antiseptic</p> <p>Uses: Hand sanitizer to help decrease bacteria that can potentially cause disease. For use when soap and water are not available.</p> <p>Warnings: For external use only. Flammable. Keep away from heat and flame. Do not use: • in children without adult 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 might be signs of serious conditions. Keep out of reach of children. If swallowed, get medical help or contact a Poison Control Center right away.</p> <p>Directions</p> <ul style="list-style-type: none"> 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. 	 <p>Hand Sanitizer Alcohol Antiseptic 70%</p>  <p>8.4 fl oz (250 ml)</p>	<p>Drug Facts (Continued)</p> <p>Other information:</p> <ul style="list-style-type: none"> Store between 15-25°C (59-77°F). Avoid freezing and excessive heat above 40°C (104°F). <p>Inactive ingredients: Carbomer Interpolymer Type A (Allyl Sucrose Crosslinked), Propylene Glycol, Trolamine, Water.</p> <p>Question? +84-28-3742-1102 NDC Code 79741-000-25</p> <p>SCC FDA <small>SAIGON COSMETICS CORPORATION</small> <small>REGISTERED</small></p>  <p>8 9 3 4 6 6 2 1 3 8 4 1 5 9</p> <p>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</p> <p>MFG. EXP.</p>
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Kleen Hand Sanitizer 320mL

Drug Facts		Drug Facts (Continued)
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.		Inactive ingredients: Carbomer Interpolymer Type A (Allyl Sucrose Crosslinked), Propylene Glycol, Trolamine, Water.
Warnings: For external use only. Flammable. Keep away from heat and flame. Do not use: • in children without adult supervision • on open skin wound.		Question? +84-28-3742-1102
When using this product keep out of eyes, ears, and mouth. In case of contact with eyes, rinse eyes thoroughly with water.		NDC Code 79741-000-32
Stop use and ask a doctor if irritation or rash occurs. These might signs of serious conditions.		
Keep out of reach of children. If swallowed, get medical help or contact a Poison Control Center right away.		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 70000, Vietnam. www.saigoncosmetics.com
Directions <ul style="list-style-type: none"> • 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. 		MFG. EXP.

Kleen Hand Sanitizer 500mL

Drug Facts		Drug Facts (Continued)
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.		Inactive ingredients: Carbomer Interpolymer Type A (Allyl Sucrose Crosslinked), Propylene Glycol, Trolamine, Water.
Warnings: For external use only. Flammable. Keep away from heat and flame. Do not use: • in children without adult supervision • on open skin wound.		Question? +84-28-3742-1102
When using this product keep out of eyes, ears, and mouth. In case of contact with eyes, rinse eyes thoroughly with water.		NDC Code 79741-000-50
Stop use and ask a doctor if irritation or rash occurs. These maybe signs of serious conditions.		
Keep out of reach of children. If swallowed, get medical help or contact a Poison Control Center right away.		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 70000, Vietnam. www.saigoncosmetics.com
Directions <ul style="list-style-type: none"> • 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. 		MFG. EXP.

KLEEN HAND SANITIZER

alcohol gel

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:79741-000
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
CARBOMER INTERPOLYMER TYPE A (ALLYL SUCROSE CROSSLINKED) (UNII: 59TL3WG5CO)	
TROLAMINE (UNII: 9O3K93S3TK)	
WATER (UNII: 059QF0K00R)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:79741-000-50	500 mL in 1 BOTTLE, PUMP; Type 0: Not a Combination Product	08/25/2020	
2	NDC:79741-000-32	320 mL in 1 BOTTLE, PUMP; Type 0: Not a Combination Product	08/25/2020	
3	NDC:79741-000-10	100 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	08/25/2020	
4	NDC:79741-000-09	90 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	08/25/2020	
5	NDC:79741-000-25	250 mL in 1 BOTTLE, PUMP; Type 0: Not a Combination Product	08/25/2020	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part333A	08/25/2020	

Labeler - 79741 (555265180)

Registrant - SAIGON COSMETICS CORPORATION (555265180)

Establishment

Name	Address	ID/FEI	Business Operations
SAIGON COSMETICS CORPORATION		555265180	manufacture(79741-000)