

**SD KLEEN RX HAND SANITIZER- alcohol solution**  
**Spa Dent Inc.**

*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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**SD KLEEN RX HAND SANITIZER GEL**

***Drug Facts***

**ACTIVE INGREDIENT**

Alcohol 70% v/v

**PURPOSE**

Antiseptic

***USE(S)***

• Antiseptic (skin) cleanser • Medicated (skin) cleanser • Antibacterial (skin) cleanser • Effective in destroying (harmful) bacteria to provide antiseptic cleansing • For personal hand hygiene to help prevent the spread of bacteria

**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, rise 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° - 30 °C (59° - 85°F) out of direct sunlight.
- Avoid freezing and excessive heat above 40° C (104° F).

Do not use this product if tamper-resistant seal is broken when opened.

### Inactive ingredients

Water, Glycerin, Acrylates/C10-30 Alkyl Acrylate Crosspolymer, Aminomethyl propanol, Aloe barbadensis Leaf Juice, dl-alpha Tocopheryl acetate

### Package Labeling:

 <p><b>Kills harmful bacteria/germs</b></p> <p><b>KLEEN <sup>®</sup>™</b> <b>HAND SANITIZER GEL</b></p> <p>70% Ethyl alcohol</p> <p><b>Aloe + Vitamin E</b></p> <p><b>1 L</b></p>	<table border="1"><tr><td colspan="2"><b>Drug Facts</b></td></tr><tr><td><b>ACTIVE INGREDIENT</b></td><td><b>PURPOSE</b></td></tr><tr><td>Alcohol 70% v/v</td><td>Antiseptic</td></tr><tr><td colspan="2"><b>USE(S)</b> • Antiseptic (skin) cleanser • Medicated (skin) cleanser • Antibacterial (skin) cleanser • Effective in destroying (harmful) bacteria to provide antiseptic cleansing • For personal hand hygiene to help prevent the spread of bacteria</td></tr><tr><td colspan="2"><b>WARNINGS</b> • For external use only. Flammable. Keep away from heat or flame. <b>Do not use</b> • in children less than 2 months of age • on open skin wounds. <b>When using this product</b> • keep out of eyes, ears, and mouth • In case of contact with eyes, rinse eyes thoroughly with water. <b>Stop use and ask a doctor</b> if irritation or rash occurs. These may be signs of a serious condition. <b>Keep out of reach of children.</b> If swallowed, get medical help or contact a Poison Control Center right away.</td></tr><tr><td colspan="2"><b>DIRECTIONS</b> • 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.</td></tr><tr><td colspan="2"><b>OTHER INFORMATION</b> • Store between 15° - 30° C (59° - 86° F) out of direct sunlight • Avoid freezing and excessive heat above 40° C (104° F).</td></tr><tr><td colspan="2">Do not use this product if tamper-resistant seal is broken when opened.</td></tr><tr><td colspan="2"><b>INACTIVE INGREDIENTS</b> Water, Glycerin, Acrylates/C10-30 Alkyl Acrylate Crosspolymer, Aminomethyl propanol, Aloe barbadensis Leaf Juice, dl-alpha Tocopheryl acetate</td></tr></table>	<b>Drug Facts</b>		<b>ACTIVE INGREDIENT</b>	<b>PURPOSE</b>	Alcohol 70% v/v	Antiseptic	<b>USE(S)</b> • Antiseptic (skin) cleanser • Medicated (skin) cleanser • Antibacterial (skin) cleanser • Effective in destroying (harmful) bacteria to provide antiseptic cleansing • For personal hand hygiene to help prevent the spread of bacteria		<b>WARNINGS</b> • For external use only. Flammable. Keep away from heat or flame. <b>Do not use</b> • in children less than 2 months of age • on open skin wounds. <b>When using this product</b> • keep out of eyes, ears, and mouth • In case of contact with eyes, rinse eyes thoroughly with water. <b>Stop use and ask a doctor</b> if irritation or rash occurs. These may be signs of a serious condition. <b>Keep out of reach of children.</b> If swallowed, get medical help or contact a Poison Control Center right away.		<b>DIRECTIONS</b> • 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.		<b>OTHER INFORMATION</b> • Store between 15° - 30° C (59° - 86° F) out of direct sunlight • Avoid freezing and excessive heat above 40° C (104° F).		Do not use this product if tamper-resistant seal is broken when opened.		<b>INACTIVE INGREDIENTS</b> Water, Glycerin, Acrylates/C10-30 Alkyl Acrylate Crosspolymer, Aminomethyl propanol, Aloe barbadensis Leaf Juice, dl-alpha Tocopheryl acetate	
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<p>Questions or Comments? 1-866-725-6683 salesupport@spa-dent.com Manufactured by: Spa Dent Inc. 272-55 Northfield Dr. E Waterloo, ON, Canada N2K 3T6</p>	 <p>8 42190 00061 9</p>																		

79147-002-01



Kills harmful bacteria/germs

# KLEEN <sup>®</sup>™ HAND SANITIZER GEL

70% Ethyl alcohol

Aloe + Vitamin E

59 mL

## Drug Facts

ACTIVE INGREDIENT	PURPOSE
Alcohol 70% v/v	Antiseptic

**USE(S)**  
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### Questions or Comments?

1-866-725-6683

salesupport@spa-dent.com

Manufactured by: Spa Dent Inc.  
272-55 Northfield Dr. E  
Waterloo, ON, Canada N2K 3T6

79147-002-02



Kills harmful bacteria/germs

# KLEEN <sup>®</sup>™ HAND SANITIZER GEL

70% Ethyl alcohol

Aloe + Vitamin E

236 mL

## Drug Facts

ACTIVE INGREDIENT	PURPOSE
Alcohol 70% v/v	Antiseptic

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### Questions or Comments?

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Manufactured by: Spa Dent Inc.  
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79147-002-03



Kills harmful bacteria/germs

**KLEEN** <sup>®</sup><sub>Rx</sub>™  
HAND SANITIZER GEL

70% Ethyl alcohol

Aloe + Vitamin E

473 mL

**Drug Facts**

ACTIVE INGREDIENT	PURPOSE
Alcohol 70% v/v	Antiseptic
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**Questions or Comments?**

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 Waterloo, ON, Canada N2K 3T6

79147-002-04



Kills harmful bacteria/germs

**KLEEN** <sup>®</sup><sub>Rx</sub>™  
HAND SANITIZER GEL

70% Ethyl alcohol

Aloe + Vitamin E

946 mL

**Drug Facts**

ACTIVE INGREDIENT	PURPOSE
Alcohol 70% v/v	Antiseptic
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79147-002-05



Kills harmful bacteria/germs

# KLEEN<sup>®</sup><sub>X</sub>™ HAND SANITIZER GEL

70% Ethyl alcohol

Aloe + Vitamin E

3.78 L

## Drug Facts

ACTIVE INGREDIENT	PURPOSE
Alcohol 70% v/v	Antiseptic

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## SD KLEEN RX HAND SANITIZER

alcohol solution

### Product Information

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:79147-002
<b>Route of Administration</b>	TOPICAL		

### Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
ALCOHOL (UNII: 3K9958V90M) (ALCOHOL - UNII:3K9958V90M)	ALCOHOL	0.7 mL in 1 mL

### Inactive Ingredients

Ingredient Name	Strength
WATER (UNII: 059QF0KO0R)	
GLYCERIN (UNII: PDC6A3C0OX)	
CARBOMER INTERPOLYMER TYPE A (ALLYL SUCROSE CROSSLINKED) (UNII: 59TL3WG5CO)	
AMINOMETHYLPROPANOL (UNII: LU49E6626Q)	
ALOE VERA LEAF (UNII: ZY81Z83H0X)	
.ALPHA.-TOCOPHEROL ACETATE, DL- (UNII: WR1WPI7EW8)	

### Packaging

#	Item Code	Package Description	Marketing Start	Marketing End
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#	Item Code	Package Description	Date	Date
1	NDC:79 147-002-33	1000 mL in 1 BOTTLE, PUMP; Type 0: Not a Combination Product	06/22/2020	
2	NDC:79 147-002-01	59 mL in 1 BOTTLE; Type 0: Not a Combination Product	07/16/2020	
3	NDC:79 147-002-02	236 mL in 1 BOTTLE, PUMP; Type 0: Not a Combination Product	07/16/2020	
4	NDC:79 147-002-03	473 mL in 1 BOTTLE, PUMP; Type 0: Not a Combination Product	07/16/2020	
5	NDC:79 147-002-04	946 mL in 1 BOTTLE, PUMP; Type 0: Not a Combination Product	07/16/2020	
6	NDC:79 147-002-05	3780 mL in 1 BOTTLE; Type 0: Not a Combination Product	07/16/2020	

### Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part333E	06/22/2020	

**Labeler** - Spa Dent Inc. (203478896)

### Establishment

Name	Address	ID/FEI	Business Operations
Spa Dent Inc.		203478896	manufacture(79 147-002)

Revised: 8/2020

Spa Dent Inc.