

SD KLEEN RX ANTISEPTIC HAND RUB- 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.

SD KLEEN RX ANTISEPTIC HAND RUB

Drug Facts

Active Ingredient(s)

Alcohol 80% v/v

Purpose

Antiseptic

Use(s)

Health care personnel hand rub to help reduce bacteria that potentially can cause disease.

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


Other Information

- Store between 10-30 °C (59-85°F)
- Avoid freezing and excessive heat above 40°C (104°F)

Inactive ingredients

glycerin, hydrogen peroxide, purified water USP

Package Labeling:



Kills harmful bacteria/germs

KLEEN [®]™
ANTISEPTIC HAND RUB
NON-STERILE SOLUTION


Alcohol Antiseptic 80% Topical Solution

Aloe + Vitamin E

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Drug Facts	
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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 10-30 °C (50-85 °F) - Avoid freezing and excessive heat above 40°C (104°F)	
Inactive ingredients glycerin, hydrogen peroxide, purified water USP	

Questions or Comments?
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SD KLEEN RX ANTISEPTIC HAND RUB

alcohol solution

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:79 147-000
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
ALCOHOL (UNII: 3K9958 V90M) (ALCOHOL - UNII:3K9958 V90M)	ALCOHOL	0.8 mL in 1 mL

Inactive Ingredients

Ingredient Name	Strength
GLYCERIN (UNII: PDC6A3C0OX)	
HYDROGEN PEROXIDE (UNII: BBX060AN9V)	
WATER (UNII: 059QF0K00R)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:79 147-000-33	1000 mL in 1 BOTTLE, PUMP; Type 0: Not a Combination Product	06/22/2020	

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(79 147-000)

Revised: 7/2020

Spa Dent Inc.