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.

SD KLEEN RX HAND SANITIZER

Drug Facts

Active Ingredient(s)

Alcohol 80% v/v

Purpose

Antiseptic

Use(s)

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

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.

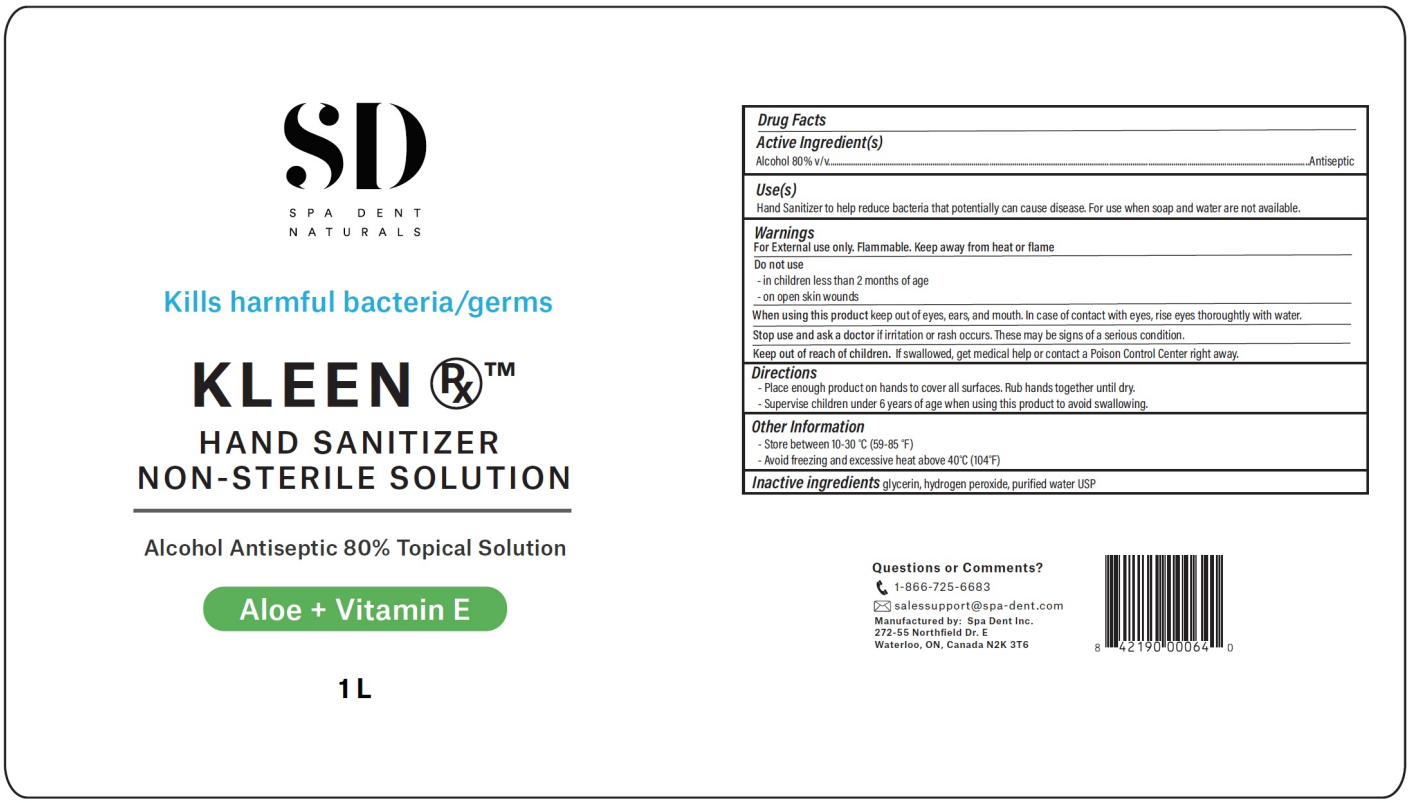
Other Information

- 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:



SD KLEEN RX HAND SANITIZER

alcohol solution

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:79147-001
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety		
Ingredient Name	**Basis of Strength**	**Strength**
ALCOHOL (UNII: 3K9958V90M) (ALCOHOL - UNII:3K9958V90M)	ALCOHOL	0.8 mL in 1 mL

Inactive Ingredients	
Ingredient Name	**Strength**
GLYCERIN (UNII: PDC6A3C0OX)	
HYDROGEN PEROXIDE (UNII: BBX060AN9V)	
WATER (UNII: 059QF0KO0R)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:79147-001-33	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(79147-001)

Revised: 7/2020 Spa Dent Inc.