SAUBER KARE 1 GALLON- alcohol gel SSN Solutions LLC

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.

SAUBER KARE 1 gallon

Active ingredient

Fthanol 70%

Uses

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

Purpose

Antibacterial

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

avoid contact with 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 a serious condition.

Keep out of reach of children. If swallowed, get medical help or contact a Poison Control Center (1-800-222-1222) 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.

Inactive ingredients

Glycerin, Carbomer, Triethanol Amine, Aloe extract, Lemon oil, Purified water.

Keep out of reach of children

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SAUBER KARE 1 gallon



SAUBER KARE 1 GALLON

alcohol gel

Product Information				
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:80704-101	

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 934 (UNII: Z135WT9208)				
GLYCERIN (UNII: PDC6A3C0OX)				
WATER (UNII: 059QF0KO0R)				
TROLAMINE (UNII: 903K93S3TK)				
ALOE (UNII: V5VD430YW9)				
LEMON OIL (UNII: 19GRO824LL)				

Packaging					
	#	Item Code	Package Description	Marketing Start Date	Marketing End Date
	1	NDC:80704- 101-01	3780 mL in 1 BOTTLE; Type 0: Not a Combination Product	10/02/2020	

Marketing Information				
Application Number or Monograph Citation	Marketing Start Date	Marketing End Date		
part333E	10/02/2020			
	Application Number or Monograph Citation	Application Number or Monograph Marketing Start Citation Date		

Labeler - SSN Solutions LLC (116677552)

Establishment				
Na me	Address	ID/FEI	Business Operations	
Korea Medicare Co., Ltd.		695832135	manufacture(80704-101)	

Revised: 1/2022 SSN Solutions LLC