

SAUBER KARE 500ML- 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 500ml

Active ingredient

Ethanol 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

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

SAUBER KARE 500ml

SAUBERKARE

**Moisturizing Gel
Hand Sanitizer**



70% Ethanol

Kills 99.9% of Germs


SauberKare.com

16.9oz / 500ml

Kills more than 99.9% of most common germs that may make you sick

Drug Facts	Purpose
Active Ingredient[s] Ethyl Alcohol 70% v/v	Antiseptic
Use[s] Hand sanitizer 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 damaged or broken skin	
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 doctor if irritation or rash occurs. These may be signs of a serious condition.	
Keep out of reach of children • Do not swallow. In case of accidental ingestion, get medical help or contact a Poison Control Center right away at 1-800-222-1222.	
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 59-86°F (15-30°C). • Avoid freezing and excessive heat above 104°F (40°C). • May discolor certain surfaces.	
Inactive Ingredients Aloe extract, Carbomer, Glycerin, Lemon Oil, Purified Water (Aqua), Triethanolamine (TEA)	

Manufactured for :
SSN Solutions
5900 Balcones Drive Suite 100,
Austin, TX 78731
TEL : 804-237-9045
Made in Korea
16.9oz / 500ml



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SAUBER KARE 500ML

alcohol gel

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:80704-102
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: 9O3K93S3TK)	
LEMON OIL (UNII: I9GR0824LL)	
ALOE (UNII: V5VD430YW9)	

Packaging

#	Item Code	Package Description	Marketing Start	Marketing End
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#	Item Code	Package Description	Date	Date
1	NDC:80704-102-01	500 mL in 1 BOTTLE; Type 0: Not a Combination Product	10/02/2020	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part333E	10/02/2020	

Labeler - SSN Solutions LLC (116677552)

Establishment

Name	Address	ID/FEI	Business Operations
Korea Medicare Co., Ltd.		695832135	manufacture(80704-102)

Revised: 1/2022

SSN Solutions LLC