

SANIKIT- hand sanitizer gel gel
Renopac, S.A. de C.V.

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.

ACTIVE INGREDIENT - OTC - ACTIVE INGREDIENT SECTION

Ethyl Alcohol 70% (w/w)

PURPOSE - OTC - PURPOSE SECTION

Antiseptic

USES - INDICATIONS AND USAGE SECTION

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

WARNINGS - WARNINGS SECTIONS

For external use only.

Flammable.

Kepp away from heat or flame.

DO NOT USE - DO NOT USE SECTION

WHEN USING THIS PRODUCT - WHEN USING SECTION

Keep out of eyes, ears, and mouth.

In case of contact with eyes, rinse eyes thoroughly with water.

STOP USE AND ASK A DOCTOR - STOP USE SECTION

If irritation or rash occur. These may be signs of a serious condition.

KEEP OUT OF REACH OF CHILDREN - KEEP OUT OF REACH OF CHILDREN SECTION

If swallowed, get medical help por contact a Poison Control right away.

DIRECTIONS - DOSAGE AND ADMINISTRATION SECTION

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 - STORAGE AND HANDLING SECTION

Store between 15-30°C (59-86°F)

Avoid freezing and excessive heat above 40°C (104°F)

INACTIVE INGREDIENTS - INACTIVE INGREDIENT SECTION

Purified water, carbomer, glycerin, triethanolamine.

PACKAGE LABEL. PRINCIPAL DISPLAY PANEL



Hand Sanitizer
Gel

NET WT. 0.176 oz (5 gr)

Drug facts

Active Ingredient
Ethyl Alcohol 70%

Purpose
Antiseptic

Use (s)

Health care personal 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, 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 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 15-30C° (59-86F°).
- Avoid freezing and excessive heat above 40C (104F)

Inactive ingredients

Purified water, carbomer, glycerin, triethanolamine

Made in Mexico for: Renopac, S.A. de C.V.

Periferico Sur No. 4889-A, Col. Arenal Tepepan,
Alcaldía Tlalpan, C.P. 14610, Ciudad de México,
México. Email: mmillan@grupocoraza.com



Made in Mexico

SANIKIT 5g NDC - 79067-004-01

SANIKIT

hand sanitizer gel gel

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:79067-004
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 HOMOPOLYMER, UNSPECIFIED TYPE (UNII: 0A5MM307FC)	
GLYCERIN (UNII: PDC6A3C00X)	
TROLAMINE (UNII: 9O3K93S3TK)	
WATER (UNII: 059QF0KO0R)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:79067-004-01	5 mL in 1 POUCH; Type 0: Not a Combination Product	09/20/2023	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part333A	09/20/2023	

Labeler - Renopac, S.A. de C.V. (811085489)

Establishment

Name	Address	ID/FEI	Business Operations
Renopac, S.A. de C.V.		811085489	manufacture(79067-004) , pack(79067-004) , label(79067-004)

Revised: 7/2023

Renopac, S.A. de C.V.