TEEM HOGAR- alcohol gel Saniklyn, S. de R.L. de M.I.

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(s)

Alcohol 72% v/v. Purpose: Antiseptic

Purpose

Antiseptic, Hand Sanitizer

Use

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, 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 right away.

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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

Water USP, glycerine, triethalonamine and carbomer.

Package Label - Principal Display Panel

60 mL NDC: 79004-003-01



473 mL NDC: 79004-003-02

Drugs Facts

Active ingredient[s] Ethyl Alcohol 72% v/v.....

Purpose . Antiseptic

Use[s]

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Stop use and ask a doctor If redness or irritation develop and persist for more than 72 hours.

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Other Information •Store between 15-30°C (59-86°F)

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

Inactive Ingredients: Water USP, glycerine, triethanomamine and carbomer.

MANUFACTURED BY: Sani-Klyn, S. de R.L. Priv. Cedro No. 2103 Col. Reforma Monterrey, N.L. C.P. 64550 Tels. (81) 8355 2395, 8354 7902 www.saniklyn.com.mx ventas@saniklyn.com

MADE IN MEXICO





Drugs Facts

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1000 mL NDC: 79004-003-03



3785 mL NDC: 79004-003-04



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TEEM HOGAR

alcohol gel

Product Information

NDC:79004-004 Product Type HUMAN OTC DRUG Item Code (Source)

TOPICAL Route of Administration

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
ALCOHOL (UNII: 3K9958V90M) (ALCOHOL - UNII:3K9958V90M)	ALCOHOL	72 mL in 100 mL

Inactive Ingredients		
Ingredient Name	Strength	
CARBOMER 1342 (UNII: 809 Y72KV36)	0.4 mL in 100 mL	

GLYCERIN (UNII: PDC6A3C0OX)	0.75 mL in 100 mL
TRIETHANO LAMINE HYDRIO DIDE (UNII: DT98IT03JK)	0.4 mL in 100 mL
WATER (UNII: 059QF0KO0R)	26.45 mL in 100 mL

P	Packaging			
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:79004-004- 03	60 mL in 1 BOTTLE; Type 0: Not a Combination Product	03/30/2020	
2	NDC:79004-004- 02	473 mL in 1 BOTTLE; Type 0: Not a Combination Product	03/30/2020	
3	NDC:79004-004- 04	1000 mL in 1 BOTTLE; Type 0: Not a Combination Product	03/30/2020	
4	NDC:79004-004- 05	3785 mL in 1 BOTTLE; Type 0: Not a Combination Product	03/30/2020	

Marketing Information			
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part333A	03/30/2020	

Labeler - Saniklyn, S. de R.L. de M.I. (816628069)

Establishment			
Name	Address	ID/FEI	Business Operations
Saniklyn, S. de R.L. de M.I.		816628069	manufacture(79004-004), pack(79004-004), label(79004-004)

Revised: 7/2020 Saniklyn, S. de R.L. de M.I.