

SIAMS ANTISEPTIC HAND SANITIZER- ethyl alcohol gel

Creaciones Iguazú, 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.

SIAM'S HAND SANITIZER

Drug Facts

Active ingredient

Ethyl alcohol 70% v/v

Purpose

Antiseptic

Uses

- hand sanitizer to decrease bacteria on the skin
- recommended for repeated use
- for use when soap and water are not available

Warnings

Flammable, keep away from fire/flame

For external use only

Do not use

- in children less than 2 months of age
- on open skin wounds

When using this product • do not get into eyes. In case of contact, rinse eyes thoroughly with water

Stop use and ask a doctor if

- irritation and redness develop
- condition persists for more than 72 hours

Keep out of reach of children. If swallowed, get medical help or contact a Poison Control Center right away.

Directions

- wet hands thoroughly with product and allow to dry without wiping
- supervise children under 6 years of age when using this product to avoid swallowing

Other information

- store between 15-30⁰C (59-86⁰F)
- avoid freezing and excessive heat above 40⁰C (104⁰F)

Inactive ingredients carbomer, glycerin, triethanolamine, water

Questions? +1-786-817-4738

You may also report serious side effects to this phone number.

Mon-Fri 9:00 AM-5:00 PM

With Glycerin

Distributed by:

O & R Trading Group INC., 5277 NW 161 St, Miami Lake, FL 33014

Made in Mexico

Drug Listing

SIAM'S

**ANTISEPTIC
HAND SANITIZER GEL**
With Glycerin

Alcohol
70%

40.58 fl. oz (1 qt 8.58 fl oz) (1.2 L)

Drug Facts	
Active ingredient Ethyl alcohol 70% v/v.....	Purpose Antiseptic
Uses <ul style="list-style-type: none">hand sanitizer to decrease bacteria on the skinrecommended for repeated usefor use when soap and water are not available	
Warnings Flammable, keep away from fire/ flame For external use only	
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Stop use and ask a doctor if <ul style="list-style-type: none">irritation and redness developcondition persists for more than 72 hours	
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Directions <ul style="list-style-type: none">wet hands thoroughly with product and allow to dry without wipingsupervise children under 6 years of age when using this product to avoid swallowing	
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O & R Trading Group INC., 5277 NW 161 St, Miami Lake, FL 33014
Made in Mexico

MFD: 04/2020
EXP: 04/2022
Lot: 02560/20
6M
7 502277 720740

SIAM'S

**ANTISEPTIC
HAND SANITIZER GEL**
With Glycerin

Alcohol
70%

1 gal 1qt 8.96 fl.oz (5L)

Drug Facts	
Active ingredient Ethyl alcohol 70% v/v.....	Purpose Antiseptic
Uses <ul style="list-style-type: none">hand sanitizer to decrease bacteria on the skinrecommended for repeated usefor use when soap and water are not available	
Warnings Flammable, keep away from fire/ flame For external use only	
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When using this product • do not get into eyes. In case of contact, rinse eyes thoroughly with water	
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Questions? +1-786-817-4738 You may also report serious side effects to this phone number. Mon-Fri 9:00 AM - 5:00 PM	

**ANTISEPTIC
HAND SANITIZER GEL**
With Glycerin

6M
MFD: 04/2020
EXP: 04/2022
Lot: 02561/20

Distributed by:
O & R Trading Group INC., 5277 NW 161
St, Miami Lake, FL 33014
Made in Mexico

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SIAMS ANTISEPTIC HAND SANITIZER

ethyl alcohol gel

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:77420-001
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
ALCOHOL (UNII: 3K9958V90M) (ALCOHOL - UNII:3K9958V90M)	ALCOHOL	70 L in 100 L

Inactive Ingredients

Ingredient Name	Strength
CARBOMER HOMO POLYMER, UNSPECIFIED TYPE (UNII: 0A5MM307FC)	
GLYCERIN (UNII: PDC6A3C0OX)	
TROLAMINE (UNII: 9O3K93S3TK)	
WATER (UNII: 059QF0KO0R)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:77420-001-01	1.2 L in 1 BOTTLE; Type 0: Not a Combination Product	05/12/2020	
2	NDC:77420-001-02	5 L in 1 BOTTLE; Type 0: Not a Combination Product	05/12/2020	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part333A	05/12/2020	

Labeler - Creaciones Iguazú, S.A. de C.V. (812930097)

Establishment

Name	Address	ID/FEI	Business Operations
Creaciones Iguazú, S.A. de C.V.		812930097	manufacture(77420-001)

Revised: 5/2020

Creaciones Iguazú, S.A. de C.V.