

SANIGEL- ethyl alcohol gel

Higley Industries, Inc.

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.

SaniGel

Drug Facts

Active ingredient

Ethyl alcohol 62%

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 15-30°C (59-86°F)

- avoid freezing and excessive heat above 40°C (104°F)
- do not reuse container. Dispose of properly

Inactive ingredients 2-carboxyethyl acrylate crosspolymer, Acryloyldimethyltaurate, Ammonium, Glycerol, Water

MADE IN THE USA

NEED GEL?

SaniStationola.com

(504) 609-2255

MANUFACTURED BY:

HIGLEY INDUSTRIES, INC.

DUBUQUE, IA 52003

WWW.HIGLEYINC.COM

Packaging



NDC 65584-200-10

1 Gallon (3.79L)

Drug Facts	
Active ingredient	Purpose
Ethyl alcohol 62%	Antiseptic
Uses	
<ul style="list-style-type: none"> • 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	
<ul style="list-style-type: none"> • in children less than 2 months of age • on open skin wounds 	
When using this product	
<ul style="list-style-type: none"> • do not get into eyes. In case of contact, rinse eyes thoroughly with water 	
Stop use and ask a doctor if	
<ul style="list-style-type: none"> • 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	
<ul style="list-style-type: none"> • 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	
<ul style="list-style-type: none"> • store between 15-30°C (59-86°F) • avoid freezing and excessive heat above 40°C (104°F) • do not reuse containers. Dispose of properly 	
Inactive ingredients	
2-carboxyethyl acrylate cross polymer, Acryloyldimethyltaurate, Ammonium, Glycerol, Water	



NEED GEL?



SaniStationola.com
(504)609-2255



MANUFACTURED BY:
HIGLEY INDUSTRIES, INC.
DUBUQUE, IA 52003
WWW.HIGLEYINC.COM

SANIGEL

ethyl alcohol gel

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:65584-200
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name		Basis of Strength	Strength	
ALCOHOL (UNII: 3K9958V90M) (ALCOHOL - UNII:3K9958V90M)		ALCOHOL	0.62 mL in 1 mL	
Inactive Ingredients				
Ingredient Name			Strength	
2-CARBOXYETHYL ACRYLATE (UNII: KM1E1216WR)				
AMMONIUM ACRYLOYLDIMETHYLTAURATE (UNII: KBC00G95HI)				
GLYCERIN (UNII: PDC6A3C0OX)				
WATER (UNII: 059QF0K00R)				
Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:65584-200-10	3790 mL in 1 BOTTLE; Type 0: Not a Combination Product	09/16/2020	
Marketing Information				
Marketing Category		Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final		part333A	09/16/2020	

Labeler - Higley Industries, Inc. (005467626)

Establishment			
Name	Address	ID/FEI	Business Operations
Higley Industries, Inc.		005467626	manufacture(65584-200)