

## **ANTISEPTIC HAND SANITIZER GEL- 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.*

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### **Antiseptic HAND SANITIZER gel**

#### ***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° (59-86°F)
- super avoid freezing and excessive heat above 40°C (104°F)
- do not reuse container. Dispose of properly

## Inactive ingredients

Water, Glycerol, Ammonium acryloyldimethyltaurate, 2-carboxyethyl acrylate crosspolymer

## Questions?

+1-800-535-5053

You may also report serious side effects to this phone number. Mon-Fri 9.00 AM - 5.00 PM

Since **H** 1923

Manufactured by: Higley Industries, Inc. 585 Huff St., Dubuque IA, 52003

[WWW.HIGLEYINC.COM](http://WWW.HIGLEYINC.COM)

## Packaging



<b>Drug Facts</b>	
<b>Active ingredient</b> Ethyl alcohol 62%	<b>Purpose</b> Antiseptic
<b>Uses</b> <ul style="list-style-type: none"><li>• hand sanitizer to decrease bacteria on the skin</li><li>• recommended for repeated use</li><li>• for use when soap and water are not available</li></ul>	
<b>Warnings</b> <b>Flammable, keep away from fire/ flame</b> <b>For external use only</b>	
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<b>When using this product</b> • do not get into eyes. In case of contact, rinse eyes thoroughly with water	
<b>Stop use and ask a doctor if</b> <ul style="list-style-type: none"><li>• irritation and redness develop</li><li>• condition persists for more than 72 hours</li></ul>	
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## ANTISEPTIC HAND SANITIZER GEL

ethyl alcohol gel

### Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:65584-100
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	
<b>Inactive Ingredients</b>				
Ingredient Name			Strength	
WATER (UNII: 059QF0K00R)				
GLYCERIN (UNII: PDC6A3C0OX)				
AMMONIUM ACRYLOYLDIMETHYLTAURATE (UNII: KBC00G95HI)				
2-CARBOXYETHYL ACRYLATE (UNII: KM1E1216WR)				
<b>Packaging</b>				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:65584-100-12	59 mL in 1 BOTTLE; Type 0: Not a Combination Product	03/19/2020	
<b>Marketing Information</b>				
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date	
OTC monograph not final	part333A	03/19/2020		

**Labeler** - Higley Industries, Inc. (005467626)

### Establishment

Name	Address	ID/FEI	Business Operations
Higley Industries, Inc.		005467626	manufacture(65584-100)

Revised: 3/2020

Higley Industries, Inc.