

**VITIUGEN ANTI BACTERIAL SPREY- alcohol spray**  
**PHARMEST SAGLIK URUNLERI SANAYI VE TICARET LIMITED SIRKETI**

*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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**Active Ingredient(s)**

Ethyl Alcohol 80%

**Purpose**

Antiseptic

**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.

**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**

Butan, Isobutan, Propan, Glycerin, Aloe Barbadensis Leaf Extract, Vitamin E

**Package Label - Principal Display Panel**

Vitiugen

Anti Bacterial Sprey

Hygenic-Surgical

Alcohol Based

Hand and Skin Antiseptic

It kills 99.9% of the tested bacteria.

It kills the tested bacteria in 1 minute.

It provides antibacterial protection against tested bacteria.

It is formulated in the pH range compatible with the skin.

Pharmest Saglik Urunleri San. ve Tic. Ltd. Sti.

Orhan Gazi Mah. 18. Yol Sok. No: 12 Esenyurt/Istanbul TURKEY

**VITIUGEN**

**ANTI BACTERIAL SPREY**

**HYGIENIC-SURGICAL**

Alcohol Based  
Hand and Skin Antiseptic

- ✓ It kills 99.9% of the tested bacteria.
- ✓ It kills the tested bacteria in 1 minute.
- ✓ It provides antibacterial protection against tested bacteria.
- ✓ It is formulated in the pH range compatible with the skin.

150ml e

**Drug Facts**

<b>Active ingredient</b> Ethyl Alcohol 80%.....	<b>Purpose</b> Antiseptic
<b>Uses</b> Hand Sanitizer Spray to help reduce bacteria that potentially can cause disease. For use when soap and water are not available.	
<b>Warnings</b> For external use only. Flammable, keep away from heat or flame.	
<b>Do not use</b> <ul style="list-style-type: none"><li>• in children less than 2 months of age</li><li>• on open skin wounds</li></ul>	
<b>When using this product</b> , keep out of eyes, ears, and mouth. In case of contact with eyes, rinse eyes thoroughly with water.	
<b>Stop use and ask a doctor</b> if irritation or rash occurs. These may be signs of a serious condition.	
<b>Keep out of reach of children</b> . If swallowed, get medical help or contact a Poison Control Center right away.	
<b>Directions:</b> <ul style="list-style-type: none"><li>• Place enough product on hands to cover all surfaces. Rub hands together until dry.</li><li>• Supervise children under 6 years of age when using this product to avoid swallowing.</li></ul>	
<b>Other information:</b> <ul style="list-style-type: none"><li>• Store between 15-30C (59-86F)</li><li>• Avoid freezing and excessive heat above 40C (104F)</li></ul>	
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Pharmest Saglik Urunleri  
San. ve Tic. Ltd. Sti.  
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Esenyurt/Istanbul TURKEY

**150ml e**  
**5.07 fl.oz**

**MADE IN TURKEY**

8 694587 577691

**FLAMMABLE**

## VITIUGEN ANTI BACTERIAL SPREY

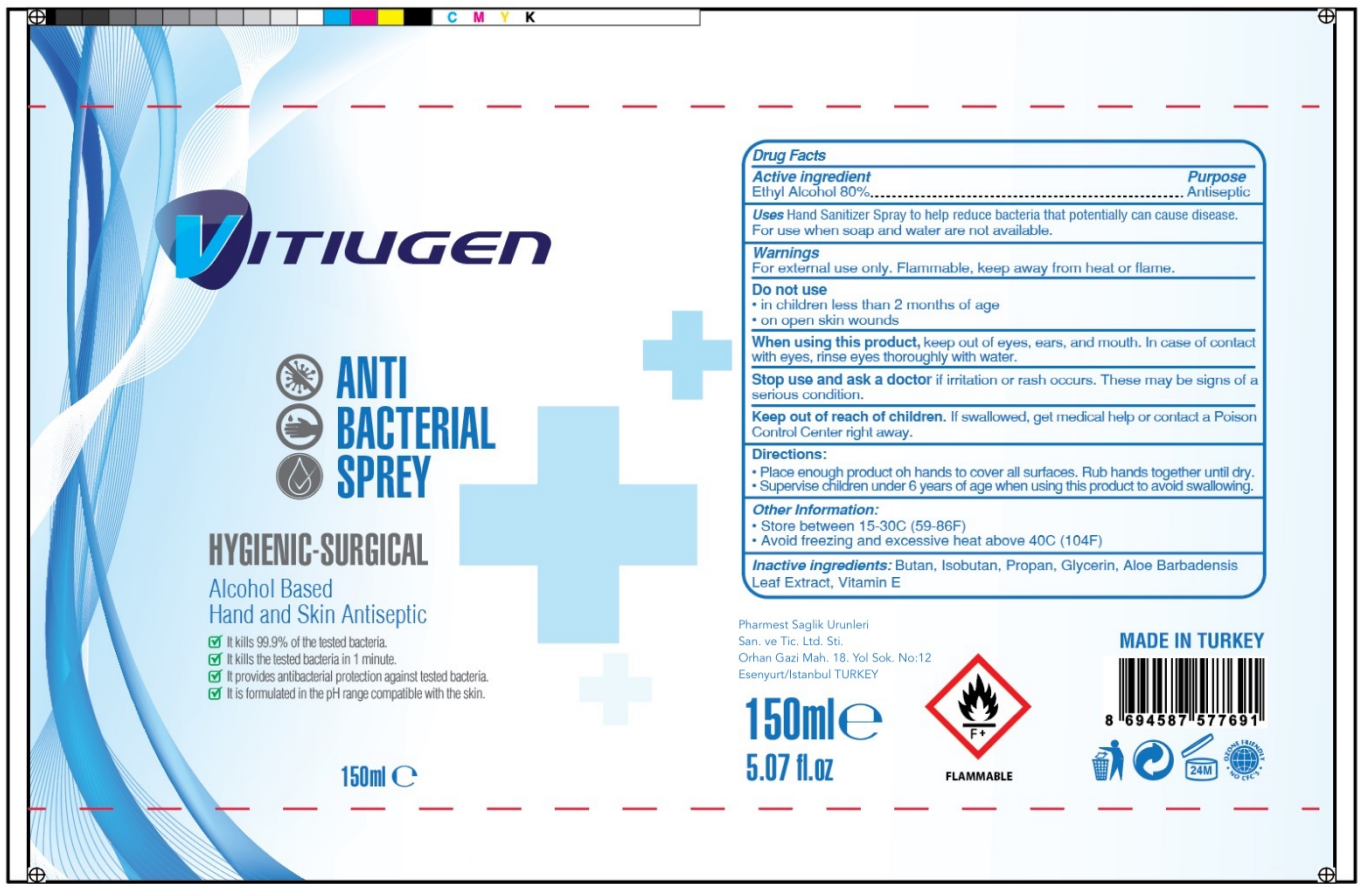
alcohol spray

### Product Information

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:78984-002
<b>Route of Administration</b>	TOPICAL		

**Active Ingredient/Active Moiety**

Ingredient Name		Basis of Strength	Strength	
ALCOHOL (UNII: 3K9958V90M) (ALCOHOL - UNII:3K9958V90M)		ALCOHOL	80 mL in 100 mL	
Inactive Ingredients				
Ingredient Name			Strength	
GLYCERIN (UNII: PDC6A3C0OX)				
BUTANE (UNII: 6LV4FOR43R)				
.ALPHA.-TOCOPHEROL (UNII: H4N855PNZ1)				
ALOE VERA LEAF (UNII: ZY81Z83H0X)				
ISOBUTANE (UNII: BXR49TP611)				
PROPANE (UNII: T75W9911L6)				
Product Characteristics				
Color		Score		
Shape		Size		
Flavor		Imprint Code		
Contains				
Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:78984-002-15	150 mL in 1 BOTTLE, SPRAY; 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** - PHARMEST SAGLIK URUNLERI SANAYI VE TICARET LIMITED SIRKETI (519827126)

**Registrant** - HARDAL GLOBAL CONSULTING LLC (123584960)

## Establishment

Name	Address	ID/FEI	Business Operations
PHARMEST SAGLIK URUNLERI SANAYI VE TICARET LIMITED SIRKETI		519827126	manufacture(78984-002)

Revised: 6/2020

PHARMEST SAGLIK URUNLERI SANAYI VE TICARET LIMITED SIRKETI