

**HIGEEN ANTISEPTIC HAND SANITIZER GEL WITH VITAMIN BEADS RED FRUITS-ethyl alcohol gel**  
**SUKHTIAN-HTM ( HOUSEHOLDS & TOILETRIES MFG.CO)**

*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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**HiGeen Antiseptic Hand Sanitizer Gel with Vitamin Beads Red Fruits**

***Drug Facts***

***Active ingredient***

Ethyl alcohol 70% V/V

***Purpose***

Antiseptic

***Uses***

• for handwashing to decrease bacteria on the skin. • recommended for repeated use.

***Warnings***

**Flammable, keep away from fire or flame.**

**For external use only.**

**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 develops. • 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 in the use of this product.

***Inactive ingredients***

acrylates (c10-30 alkyl acrylate crosspolymer), benzophenone-3, carbomer, cellulose, D&C Red No. 33, fragrance, glycerin, hydroxypropyl methylcellulose, lactose, retinyl palmitate (vitamin A palmitate), tocopheryl acetate (vitamin E acetate), triethanolamine, water (aqua).

***Other information***

• store at 20° to 25° C (68° to 77° F). • may discolor certain fabrics.

***Questions or comments?***

call +1-419-322-4731

available from Monday to Friday (8 am – 4 pm).

You may report serious side effects to this phone number.

**NO WATER**

**NO SOAP**

**Manufactured by:**

Sukhtian Households and Toiletries Manufacturing Co. Al Hizam street, Abu Alanda, Amman, Jordan 11118

P.O.Box : 1027

**Made in Jordan**

**Packaging**

**Drug Facts (cont.)**  
**Questions or comments?**  
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**Made in Jordan**

Lot No:  
Expiry Date:

6 251007 161366 1 K2801319 R0  
Peel

**Drug Facts (cont.)**  
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**Drug Facts**  
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Ethyl alcohol 70% V/V .. Antiseptic

**Uses** ■ for handwashing  
to decrease bacteria on the  
skin. ■ recommended for  
repeated use.

**Warnings**  
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from fire or flame.**

**For external use only.**

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case of contact, rinse eyes  
thoroughly with water.

**Stop use and ask a  
doctor if**  
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develops. ■ condition  
persist for more than 72  
hours.

**Keep out of reach of  
children.**

**NO WATER NO SOAP**

**HiGeen®**

**Antiseptic  
Hand Sanitizer**

**Gel with Vitamin Beads**

**Red Fruits**

**110 mL (3.7 fl oz)**

**Packaging**

**Drug Facts** Peel

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**Drug Facts** (continued) Peel

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Abu Alanda, Amman, Jordan 11118  
P.O.BOX : 1027

**Made in Jordan**

Lot No:  
Expiry Date:



6 251007 617904

K2801334 R0

**NO WATER NO SOAP**

**HiGeen®**

**Antiseptic Hand Sanitizer**

**Gel with Vitamin Beads**



**Red Fruits**

**50 mL (1.7 fl oz)**

## HIGEEN ANTISEPTIC HAND SANITIZER GEL WITH VITAMIN BEADS RED FRUITS

ethyl alcohol gel

### Product Information

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:71490-003
<b>Route of Administration</b>	TOPICAL		

### Active Ingredient/Active Moiety

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

### Inactive Ingredients

Ingredient Name	Strength
CARBOMER INTERPOLYMER TYPE A (ALLYL SUCROSE CROSSLINKED) (UNII: 59TL3WG5CO)	
OXYBENZONE (UNII: 95OOS7VE0Y)	
CARBOXYPOLYMETHYLENE (UNII: 0A5MM307FC)	
POWDERED CELLULOSE (UNII: SMD1X3XO9M)	
D&C RED NO. 33 (UNII: 9DBA0SBB0L)	
GLYCERIN (UNII: PDC6A3C0OX)	
HYPROMELLOSE, UNSPECIFIED (UNII: 3NXW29V3WO)	
LACTOSE, UNSPECIFIED FORM (UNII: J2B2A4N98G)	
VITAMIN A PALMITATE (UNII: 1D1K0N0VVC)	
.ALPHA.-TOCOPHEROL ACETATE (UNII: 9E8X80D2L0)	

**TROLAMINE** (UNII: 9O3K93S3TK)

**WATER** (UNII: 059QF0KO0R)

### Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:71490-003-02	110 mL in 1 BOTTLE; Type 0: Not a Combination Product	09/18/2017	
2	NDC:71490-003-03	50 mL in 1 BOTTLE; Type 0: Not a Combination Product	09/18/2017	

### Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part333A	09/18/2017	

**Labeler** - SUKHTIAN-HTM ( HOUSEHOLDS & TOILETRIES MFG.CO) (557666494)

### Establishment

Name	Address	ID/FEI	Business Operations
SUKHTIAN-HTM ( HOUSEHOLDS & TOILETRIES MFG.CO)		557666494	manufacture(71490-003)

Revised: 10/2017

SUKHTIAN-HTM ( HOUSEHOLDS & TOILETRIES MFG.CO)