# HIGEEN ANTISEPTIC HAND SANITIZER GEL WITH VITAMIN BEADS PAPAYA WITH SILICON HOLDER- 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 Papaya With Silicon Holder

#### **Drug Facts**

#### **Active** ingredient

Ethyl alcohol 70% V/V

#### **Purpose**

Antiseptic

#### $\Box$ 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 persist 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 Yellow No.10, fragrance, glycerin, hydroxypropyl methylcellulose, lactose, retinyl palmitate (vitamin A palmitate), tocopheryl acetate (vitamin E acetate), triethanolamine, water (aqua).

#### **Other information**

• store at  $20^{\circ}$  to  $25^{\circ}$  C ( $68^{\circ}$  to  $77^{\circ}$  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.

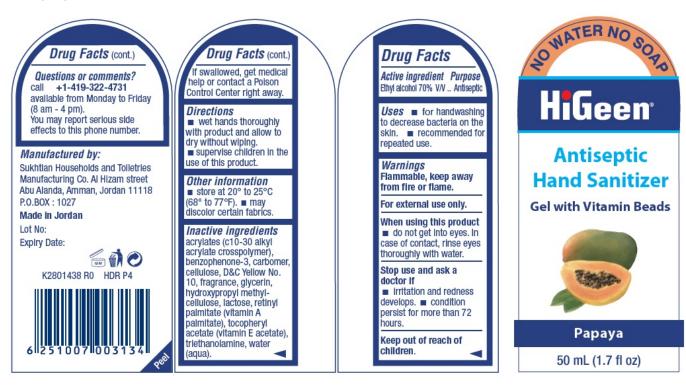
#### NO WATER NO SOAP

#### Manufactured by:

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

P.O.Box: 1027 **Made in Jordan** 

#### **Packaging**



## HIGEEN ANTISEPTIC HAND SANITIZER GEL WITH VITAMIN BEADS PAPAYA WITH SILICON HOLDER

ethyl alcohol gel

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Product Information					
Product Type	HUMAN OTC DRUG	Item Code	(Source)	NDC:71490-018	
Route of Administration	TOPICAL				
Active Ingredient/Active Moiety					
Ingred	lient 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: 950OS7VE0Y)	
CARBOMER HOMOPOLYMER, UNSPECIFIED TYPE (UNII: 0 A5MM307FC)	
POWDERED CELLULOSE (UNII: SMD1X3XO9M)	
D&C YELLOW NO. 10 (UNII: 35SW5USQ3G)	
GLYCERIN (UNII: PDC6 A3C0 OX)	
HYPROMELLOSE, UNSPECIFIED (UNII: 3NXW29V3WO)	
LACTOSE, UNSPECIFIED FORM (UNII: J2B2A4N98G)	
VITAMIN A PALMITATE (UNII: 1D1K0 N0 VVC)	
.ALPHATO COPHEROL ACETATE (UNII: 9E8 X80 D2L0)	
TROLAMINE (UNII: 9O3K93S3TK)	
WATER (UNII: 059QF0KO0R)	

Packaging			
# Item Code	Package Description	<b>Marketing Start Date</b>	<b>Marketing End Date</b>
1 NDC:71490-018-03	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	<b>Business Operations</b>	
SUKHTIAN-HTM (HOUSEHOLDS & TOILETRIES MFG.CO)		557666494	manufacture(71490-018)	

Revised: 1/2021 SUKHTIAN-HTM (HOUSEHOLDS & TOILETRIES MFG.CO)