## HIGEEN ANTISEPTIC HAND SANITIZER GEL WITH VITAMIN BEADS WILD BERRY 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 Wild Berry With Silicon Holder

#### **Drug Facts**

#### Active ingredient

Ethyl alcohol 70% V/V

#### **Purpose**

**Antiseptic** 

#### Uses

• hand sanitizer 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.

#### Other information

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

#### Inactive ingredients

acrylates (c10-30 alkyl acrylate crosspolymer), benzophenone-3, carbomer, cellulose, D&C Violet No. 2, fragrance, glycerin, hydroxypropyl methylcellulose, lactose, retinyl palmitate (vitamin A palmitate), tocopheryl acetate (vitamin E acetate), triethanolamine, water (aqua).

#### 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 for

Sukhtian Households and Toiletries Manufacturing Co.

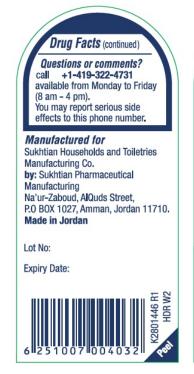
by: Sukhtian Pharmaceutical Manufacturing

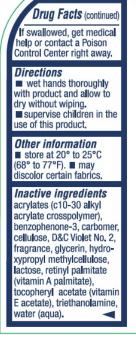
Na'ur-Zaboud, AlQuds Street,

P.O.BOX 1027, Amman, Jordan 11710.

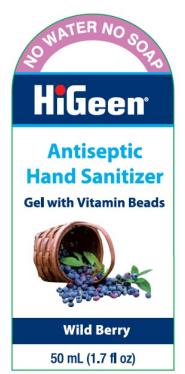
Made in Jordan

#### **Packaging**









HIGEEN ANTISEPTIC HAND SANITIZER GEL WITH VITAMIN BEADS WILD BERRY WITH SILICON HOLDER

ethyl alcohol gel

#### **Product Information**

Product Type HUMAN OTC DRUG Item Code (Source) NDC:71490-027

**Route of Administration** TOPICAL

#### **Active Ingredient/Active Moiety**

Ingredient Name	<b>Basis of Strength</b>	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: 9500S7VE0Y)		
CARBOMER HOMOPOLYMER, UNSPECIFIED TYPE (UNII: 0A5MM307FC)		
POWDERED CELLULOSE (UNII: SMD1X3XO9M)		
D&C VIOLET NO. 2 (UNII: 350KA7O6HK)		
GLYCERIN (UNII: PDC6A3C0OX)		
HYPROMELLOSE, UNSPECIFIED (UNII: 3NXW29V3WO)		
LACTOSE, UNSPECIFIED FORM (UNII: J2B2A4N98G)		
VITAMIN A PALMITATE (UNII: 1D1K0N0VVC)		
.ALPHATOCOPHEROL ACETATE (UNII: 9E8X80D2L0)		
TROLAMINE (UNII: 903K93S3TK)		
WATER (UNII: 059QF0KO0R)		

Packaging					
#	Item Code	Package Description	Marketing Start Date	Marketing End Date	
	NDC:71490-027- 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 PHARMACEUTICAL MANUFACTURING 850389249 manufacture(71490-027)