

**HIGEEN ANTISEPTIC HAND SANITIZER GEL WITH VITAMIN BEADS OUD 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 Oud With Silicon Holder**

**▯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 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 Green No. 5, D&C Red No. 33, 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<sup>▯</sup> to 25<sup>▯</sup> C (68<sup>▯</sup> to 77<sup>▯</sup> 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**

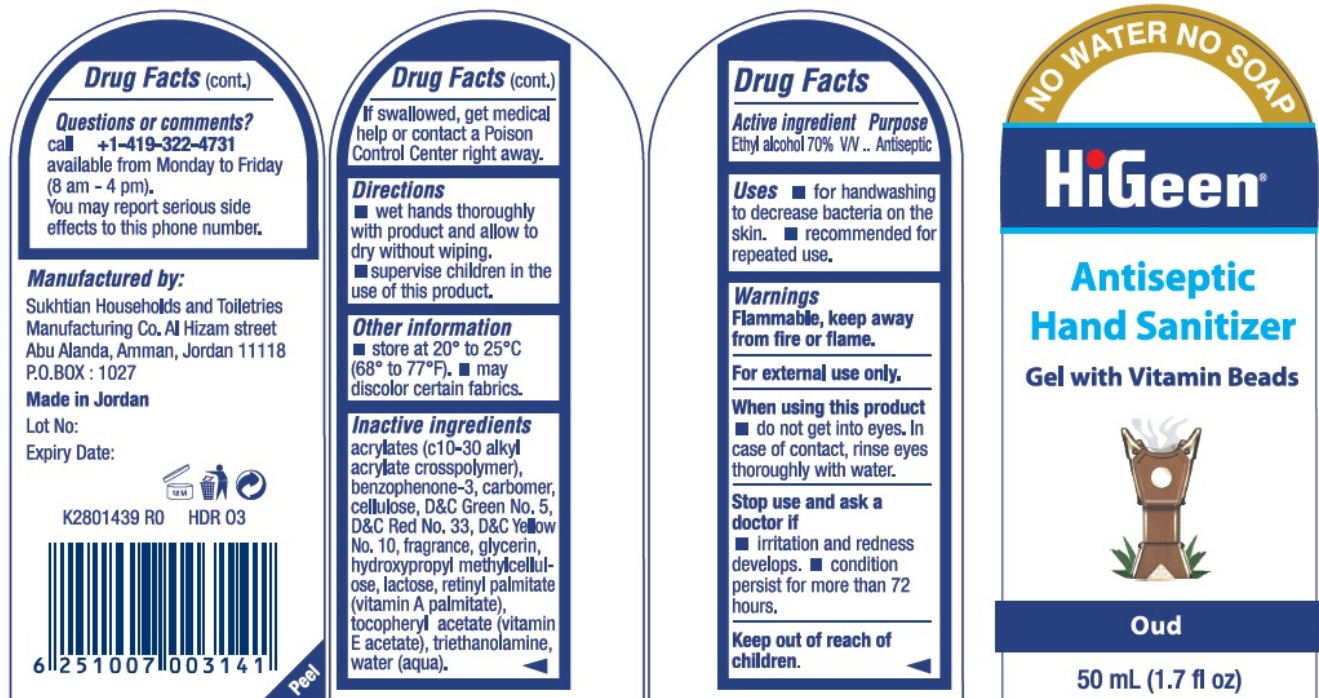
**Manufactured by:**

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 OUD WITH SILICON HOLDER**

ethyl alcohol gel

**Product Information**

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:71490-023
<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)	
CARBOMER HOMOPOLYMER, UNSPECIFIED TYPE (UNII: 0A5MM307FC)	
POWDERED CELLULOSE (UNII: SMD1X3XO9M)	
D&C GREEN NO. 5 (UNII: 8J6RDU8L9X)	
D&C RED NO. 33 (UNII: 9DBA0SBB0L)	
D&C YELLOW NO. 10 (UNII: 35SW5USQ3G)	
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: 059QF0K00R)	

## Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:71490-023-03	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(71490-023)

Revised: 1/2021

SUKHTIAN-HTM (HOUSEHOLDS & TOILETRIES MFG.CO)