

HIGEEN ANTISEPTIC HAND SANITIZER GEL WITH VITAMIN BEADS PAPAYA- 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.

HiGeen Antiseptic Hand Sanitizer Gel with Vitamin Beads Papaya

▯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 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[▯] 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

110 ml

<p>Drug Facts (cont.)</p> <p>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.</p> <p>Manufactured by: Sukhtian Households and Toiletries Manufacturing Co. Al Hizam street Abu Alanda, Amman, Jordan 11118 P.O.BOX : 1027</p> <p>Made in Jordan</p> <p>Lot No: Expiry Date:</p>   <p>6 251007 613562 K2801331 RD</p> <p>Peel</p>	<p>Drug Facts (cont.)</p> <p>If swallowed, get medical help or contact a Poison Control Center right away.</p> <p>Directions</p> <ul style="list-style-type: none">■ wet hands thoroughly with product and allow to dry without wiping.■ supervise children in the use of this product. <p>Other information</p> <ul style="list-style-type: none">■ store at 20° to 25°C (68° to 77°F).■ may discolor certain fabrics. <p>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).</p>	<p>Drug Facts</p> <p>Active ingredient Purpose Ethyl alcohol 70% V/V .. Antiseptic</p> <p>Uses ■ for handwashing to decrease bacteria on the skin. ■ recommended for repeated use.</p> <p>Warnings Flammable, keep away from fire or flame.</p> <p>For external use only.</p> <p>When using this product ■ do not get into eyes. In case of contact, rinse eyes thoroughly with water.</p> <p>Stop use and ask a doctor if ■ irritation and redness develops. ■ condition persist for more than 72 hours.</p> <p>Keep out of reach of children.</p>	<p>NO WATER NO SOAP</p> <p>HiGeen®</p> <p>Antiseptic Hand Sanitizer</p> <p>Gel with Vitamin Beads</p>  <p>Papaya</p> <p>110 mL (3.7 fl oz)</p>
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50 ml

<p>Drug Facts <i>Peel</i></p> <p>Active ingredient Purpose Ethyl alcohol 70% V/V .. Antiseptic</p> <p>Uses ■ for handwashing to decrease bacteria on the skin. ■ recommended for repeated use.</p> <p>Warnings Flammable, keep away from fire or flame.</p> <p>For external use only.</p> <p>When using this product ■ do not get into eyes. In case of contact, rinse eyes thoroughly with water.</p> <p>Stop use and ask a doctor if ■ irritation and redness develops. ■ condition persist for more than 72 hours.</p> <p>Keep out of reach of children. If swallowed, get medical help or contact a Poison Control Center right away.</p>	<p>Drug Facts (continued) <i>Peel</i></p> <p>Directions ■ wet hands thoroughly with product and allow to dry without wiping. ■ supervise children in the use of this product.</p> <p>Other information ■ store at 20° to 25°C (68° to 77°F). ■ may discolor certain fabrics.</p> <p>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).</p>	<p>Drug Facts (continued)</p> <p>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.</p> <p>Manufactured by: Sukhtian Households and Toiletries Manufacturing Co. Al Hizam street Abu Alanda, Amman, Jordan 11118 P.O.BOX : 1027</p> <p>Made in Jordan</p> <p>Lot No: Expiry Date:</p>   <p>6 251007 4618000 K2801336 R0</p>	<p>NO WATER NO SOAP</p> <p>HiGeen®</p> <p>Antiseptic Hand Sanitizer</p> <p>Gel with Vitamin Beads</p>  <p>Papaya</p> <p>50 mL (1.7 fl oz)</p>
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HIGEEN ANTISEPTIC HAND SANITIZER GEL WITH VITAMIN BEADS PAPAYA

ethyl alcohol gel

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:71490-004
Route of Administration	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 HOMO POLYMER, UNSPECIFIED TYPE (UNII: 0A5MM307FC)	
POWDERED CELLULOSE (UNII: SMD1X3XO9M)	
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: 059QF0KO0R)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:71490-004-02	110 mL in 1 BOTTLE; Type 0: Not a Combination Product	09/18/2017	
2	NDC:71490-004-03	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(71490-004)

Revised: 1/2021

SUKHTIAN-HTM (HOUSEHOLDS & TOILETRIES MFG.CO)