

HIGEEN ANTISEPTIC HAND SANITIZER GEL FRAGRANCE FREE- 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 Fragrance Free

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), carbomer, glycerin, triethanolamine, water (aqua).

Questions or comments?

call **+1-419-322-4731**

available from Monday to Friday (8:00 am – 4:00 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



PACKAGE - 500 mL

<p>Drug Facts</p> <p>Active ingredient Purpose Ethyl alcohol 70% V/V .. Antiseptic</p> <p>Uses ■ hand sanitizer 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>Directions ■ wet hands thoroughly with product and allow to dry without wiping. ■ supervise children in the use of this product.</p>	<p>NO WATER.. NO SOAP..</p>  <p>Antiseptic Hand Sanitizer Gel</p>  <p>Fragrance Free</p> <p>500 mL (16.9 fl oz)</p>	<p>Drug Facts (continued)</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), carbomer, glycerin, triethanolamine, water (aqua).</p> <p>Questions or comments? call +1-419-322-4731 available from Monday to Friday (8:00 am - 4:00 pm). You may report serious side effects to this phone number.</p> <p>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</p> <p>Lot No: UNVARNISHED AREA Expiry Date: 18 x 10 mm</p>  <p>6 25 1 007 1000 4 47 K2801462 R1</p>
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PACKAGE - 1000 mL

<p>Drug Facts (continued)</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), carbomer, glycerin, triethanolamine, water (aqua).</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 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</p> <p>Lot No: UNVARNISHED AREA Expiry Date: 18 x 10 mm</p>  <p>K2803644 R0 6 25 1 007 1007 2 4 8</p>	<p>Drug Facts</p> <p>Active ingredient Purpose Ethyl alcohol 70% V/V Antiseptic</p> <p>Uses ■ hand sanitizer 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>Directions ■ wet hands thoroughly with product and allow to dry without wiping. ■ supervise children in the use of this product.</p>	<p>NO WATER NO SOAP</p>  <p>Antiseptic Hand Sanitizer Gel</p> <p>FRAGRANCE FREE</p> <p>1000 mL (33.8 fl oz)</p>
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PACKAGE - 500 mL

<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 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</p> <p>Lot No: UNVARNISHED AREA Expiry Date: 18 x 10 mm</p>  <p>6 25 1 007 1008 5 7 1</p>	<p>Drug Facts (continued)</p> <p>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>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), carbomer, glycerin, triethanolamine, water (aqua).</p>	<p>Drug Facts</p> <p>Active ingredient Purpose Ethyl alcohol 70% V/V Antiseptic</p> <p>Uses ■ hand sanitizer 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</p>	<p>NO WATER.. NO SOAP..</p>  <p>Antiseptic Hand Sanitizer Gel</p> <p>FRAGRANCE FREE</p> <p>500 mL (16.9 fl oz)</p>
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HIGEEN ANTISEPTIC HAND SANITIZER GEL FRAGRANCE FREE

ethyl alcohol gel

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:71490-042
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)	
CARBOMER HOMOPOLYMER, UNSPECIFIED TYPE (UNII: 0A5MM307FC)	
GLYCERIN (UNII: PDC6A3C0OX)	
TROLAMINE (UNII: 903K93S3TK)	
WATER (UNII: 059QF0KO0R)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:71490-042-04	500 mL in 1 BOTTLE, PUMP; Type 0: Not a Combination Product	09/18/2017	
2	NDC:71490-042-01	1000 mL in 1 BOTTLE, PUMP; Type 0: Not a Combination Product	06/19/2023	
3	NDC:71490-042-07	500 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	06/19/2023	

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(71490-042)