

HIGEEN ANTISEPTIC HAND SANITIZER GEL WITH VITAMIN BEADS OUD- 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 Oud

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° 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

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| <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>6251007 615764</p> <p>K2801330 R0</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 Green No. 5, D&C Red No. 33 D&C Yellow No. 10, fragrance, glycerin, hydroxypropyl methylcellu- lose, lactose, retinyl palmit- ate (vitamin A palmi- tate), 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>Oud</p> <p>110 mL (3.7 fl oz)</p> |
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50 ml

Drug Facts (cont.)

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Sukhtian Households and Toilettries
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Abu Alanda, Amman, Jordan 11118
P.O.BOX : 1027

Made In Jordan

Lot No:
Expiry Date:




6 251007 1618505

K2801337 R0
Peel

Drug Facts (cont.)

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 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).

Drug Facts

Active ingredient Purpose
Ethyl alcohol 70% V/V .. Antiseptic

Uses ■ for handwashing
to decrease bacteria on the
skin. ■ recommended for
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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.**

NO WATER NO SOAP

HiGeen®

**Antiseptic
Hand Sanitizer**

Gel with Vitamin Beads



Oud

50 mL (1.7 fl oz)

HIGEEEN ANTISEPTIC HAND SANITIZER GEL WITH VITAMIN BEADS OUD
ethyl alcohol gel

| Product Information | | | |
|-------------------------|----------------|--------------------|---------------|
| Product Type | HUMAN OTC DRUG | Item Code (Source) | NDC:71490-009 |
| 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 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:71490-009-02 | 110 mL in 1 BOTTLE; Type 0: Not a Combination Product | 09/18/2017 | |
| 2 | NDC:71490-009-03 | 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(71490-009) |

Revised: 1/2021

SUKHTIAN-HTM (HOUSEHOLDS & TOILETRIES MFG.CO)