

HIGEEN ANTISEPTIC HAND SANITIZER GEL WITH VITAMIN BEADS TOGETHER IN LOVE- 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 Together in love

▯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), carbomer, cellulose, 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

Drug Facts (cont.)

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.

Manufactured by:
Sukhtian Households and Toiletries
Manufacturing Co. Al Hizam street
Abu Alanda, Amman, Jordan 11118
P.O.BOX : 1027

Made in Jordan

Lot No:
Expiry Date:




6 251007 632266

Peel K2801320 RO

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),
carbomer, cellulose,
fragrance, glycerin, hydro-
xypropyl 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
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.**

NO WATER NO SOAP

HiGeen®

**Antiseptic
Hand Sanitizer**

Gel with Vitamin Beads



Together in...love

110 mL (3.7 fl oz)

50 ml

Drug Facts **Peel**

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

Drug Facts (continued) **Peel**

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, cellulose,
fragrance, glycerin, hydroxypropyl
methylcellulose, lactose, retinyl
palmitate (vitamin A palmitate),
tocopheryl acetate (vitamin E
acetate), triethanolamine, water
(aqua).

Drug Facts (continued)

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.

Manufactured by:
Sukhtian Households and Toiletries
Manufacturing Co. Al Hizam street
Abu Alanda, Amman, Jordan 11118
P.O.BOX : 1027

Made in Jordan

Lot No:
Expiry Date:




6 251007 63640 0

Peel K2801346 RO

NO WATER NO SOAP

HiGeen®

**Antiseptic
Hand Sanitizer**

Gel with Vitamin Beads



Together in...love

50 mL (1.7 fl oz)

**HIGEEN ANTISEPTIC HAND SANITIZER GEL WITH VITAMIN BEADS
TOGETHER IN LOVE**

ethyl alcohol gel

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:71490-014
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)	
POWDERED CELLULOSE (UNII: SMD1X3XO9M)	
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:71490-014-02	110 mL in 1 BOTTLE; Type 0: Not a Combination Product	09/18/2017	
2	NDC:71490-014-03	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(71490-014)