

**HIGEEN ANTISEPTIC HAND SANITIZER GEL WITH VITAMIN BEADS PASSION FLOWER- 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 Passion Flower

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), benzophenone-3, carbomer, cellulose, D&C Red No. 33, FD&C Blue No.1, fragrance, glycerin, hydroxypropyl methylcellulose, lactose, retinyl palmitate (vitamin A palmitate), tocopheryl acetate (vitamin E acetate), triethanolamine, water (aqua).

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 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

Drug Facts (continued)
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Lot No: **UNVARNISHED
AREA
17 x 10 mm**

Expiry Date:

6 251007 631764

K2801318 RD
Peel

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Active ingredient Purpose
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Uses ■ hand sanitizer to
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skin. ■ recommended for
repeated use.

Warnings
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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

Passion Flower

110 mL (3.7 fl oz)

HIGEEN ANTISEPTIC HAND SANITIZER GEL WITH VITAMIN BEADS

PASSION FLOWER

ethyl alcohol gel

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:71490-011
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 RED NO. 33 (UNII: 9DBA0SBB0L)	
FD&C BLUE NO. 1 (UNII: H3R47K3TBD)	
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:71490-011-02	110 mL in 1 BOTTLE; Type 0: Not a Combination Product	09/18/2017	
2	NDC:71490-011-03	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 PHARMACEUTICAL MANUFACTURING		850389249	manufacture(71490-011)

Revised: 2/2023

SUKHTIAN-HTM (HOUSEHOLDS & TOILETRIES MFG.CO)