

HIGEEN ANTISEPTIC HAND SANITIZER GEL WITH VITAMIN BEADS GOLD- 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 Gold

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 (ammonium methacrylate copolymer), acrylates (c10-30 alkyl acrylate crosspolymer), Carbomer, Caprylic (capric triglyceride), Cellulose, Fragrance, Glycerin, Hydroxypropyl methyl cellulose, manuka honey, Mannitol, Mica, Talc, Tocopheryl acetate (vitamin E acetate), Triethanolamine, Triethyl citrate, 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**

With Exotic Aroma D'amore

Manufactured by:

Sukhtian Households and Toiletries Manufacturing Co. Al Hizam street, Abu Alanda, Amman, Jordan 11118

P.O.Box : 1027

Made in Jordan

Packaging



HIGEEN ANTISEPTIC HAND SANITIZER GEL WITH VITAMIN BEADS GOLD

ethyl alcohol gel

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:71490-029
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
AMMONIUM METHACRYLATE (UNII: J2243103QO)	
CARBOMER INTERPOLYMER TYPE A (ALLYL SUCROSE CROSSLINKED) (UNII: 59TL3WG5CO)	
CARBOMER HOMOPOLYMER, UNSPECIFIED TYPE (UNII: 0A5MM307FC)	
MEDIUM-CHAIN TRIGLYCERIDES (UNII: C9H2L21V7U)	
POWDERED CELLULOSE (UNII: SMD1X3XO9M)	
GLYCERIN (UNII: PDC6A3C0OX)	
HYPROMELLOSE, UNSPECIFIED (UNII: 3NXW29V3WO)	
LEPTOSPERMUM SCOPARIUM WHOLE (UNII: H910P27WW5)	
MANNITOL (UNII: 3OWL53L36A)	
MICA (UNII: V8A1AW0880)	
TALC (UNII: 7SEV7J4R1U)	
.ALPHA.-TOCOPHEROL ACETATE (UNII: 9E8X80D2L0)	
TROLAMINE (UNII: 9O3K93S3TK)	
TRIETHYL CITRATE (UNII: 8Z96QXD6UM)	
WATER (UNII: 059QF0K00R)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:71490-029-03	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(71490-029)

Revised: 1/2021

SUKHTIAN-HTM (HOUSEHOLDS & TOILETRIES MFG.CO)