HIGEEN ANTISEPTIC HAND SANITIZER GEL WITH VITAMIN BEADS RED FRUITSethyl 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 Red Fruits

Drug Facts

Active ingredient

Ethyl alcohol 70% V/V

Purpose

Antiseptic

\Box Uses

• for handwashing to decrease bacteria on the skin. • recommended for repeated use.

□ Warnings

IFlammable, 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 if1 • 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 Red No. 33, 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

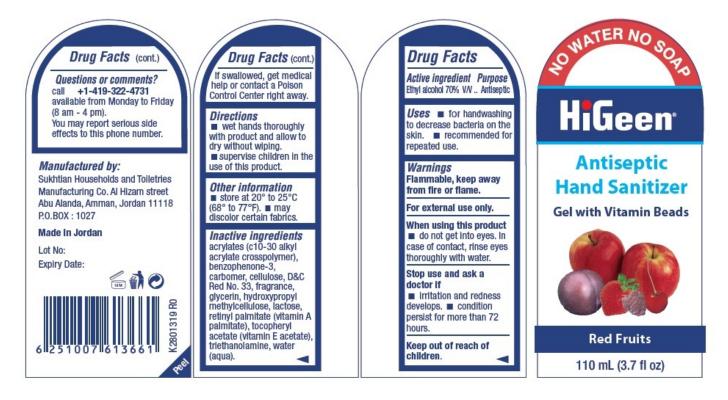
NO SOAP

Manufactured by:

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

P.O.Box: 1027 **Made in Jordan**

Packaging



Packaging



HIGEEN ANTISEPTIC HAND SANITIZER GEL WITH VITAMIN BEADS RED FRUITS

ethyl alcohol gel

Product Information				
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:71490-003	
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: 950OS7VE0Y)		
CARBO XYPO LYMETHYLENE (UNII: 0 A5MM307FC)		
POWDERED CELLULOSE (UNII: SMD1X3XO9M)		
D&C RED NO. 33 (UNII: 9DBA0SBB0L)		
GLYCERIN (UNII: PDC6A3C0OX)		
HYPROMELLOSE, UNSPECIFIED (UNII: 3NXW29V3WO)		
LACTOSE, UNSPECIFIED FORM (UNII: J2B2A4N98G)		
VITAMIN A PALMITATE (UNII: 1D1K0N0VVC)		
.ALPHATO COPHEROL ACETATE (UNII: 9E8X80D2L0)		

TROLAMINE (UNII: 9O3K93S3TK)	
WATER (UNII: 059QF0KO0R)	

l	Packaging			
l	# Item Code	Package Description	Marketing Start Date	Marketing End Date
l	1 NDC:71490-003-02	110 mL in 1 BOTTLE; Type 0: Not a Combination Product	09/18/2017	
	2 NDC:71490-003-03	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(71490-003)	

Revised: 10/2017 SUKHTIAN-HTM (HOUSEHOLDS & TOILETRIES MFG.CO)