HIGEEN ANTISEPTIC HAND SANITIZER GEL WITH VITAMIN BEADS FOR KIDS AND ADULTS FILO- 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 $^{\ensuremath{\mathbb{R}}}$ Antiseptic Hand Sanitizer Gel with Vitamin Beads For Kids & Adults FiLo

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.

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 Violet No. 2, 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

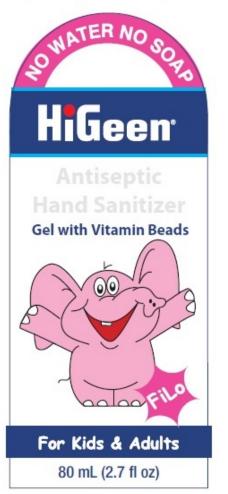
Manufactured by:

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

Made in Jordan

Packaging

Package - 80mL



Package - 50mL



Drug Facts

for repeated use.

Warnings

Active ingredient

Ethyl alcohol 70% V/V ..

Uses for handwashing to decrease

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recommended

Flammable, keep away from fire or

Purpose

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Drug Facts

(continued)

50mL (1.7 fl oz)

Inactive ingredients acrylates (c10-30 alkyl acrylate cross-

polymer), benzophenone-3, carbomer, cellulose, D&C Violet No. 2, fragrance,

glycerin, hydroxypropyl methylcellulose, lactose, retinyl palmitate (vitamin A

palmitate), tocopheryl acetate (vitamin E acetate), triethanolamine, water (aqua).

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ethyl alcohol gel

Product Infor	mation								
Product Type		HUMAN OTC DRUG	ltem C	ode (Source)	NDC:714	NDC:71490-032			
Route of Admin	stration	TOPICAL							
Active Ingred	ent/Active	Moiety							
Ingredient Name Basis of Strengt				h Strength					
ALCOHOL (UNII: 3K9958V90M) (ALCOHOL - UNII:3K9958V90M) ALCOHOL						70 mL in 100 mL			
nactive Ingre	dients								
Ingredient Name									
CARBOMER INTERPOLYMER TYPE A (ALLYL SUCROSE CROSSLINKED) (UNII: 59TL3WG5CO)									
OXYBENZONE (UNII: 9500S7VE0Y)									
CARBOMER HOMOPOLYMER, UNSPECIFIED TYPE (UNII: 0A5MM307FC)									
	· ·	· ·							
D&C VIOLET NO. 2 (UNII: 350KA7O6HK)									
GLYCERIN (UNII: PDC6A3C0OX)									
HYPROMELLOSE, UNSPECIFIED (UNII: 3NXW29V3WO)									
LACTOSE, UNSPECIFIED FORM (UNII: J2B2A4N98G) VITAMIN A PALMITATE (UNII: 1D1K0N0VVC)									
ALPHATOCOPHEROL ACETATE (UNII: 9E8X80D2L0)									
TROLAMINE (UNII: 903K93S3TK)									
WATER (UNII: 059QF0K00R)									
Packaging									
# Item Code	Pa	ckage Description		Marketing Start Date		ting End Date			
0 5	Product	TTLE; Type 0: Not a Combir		09/18/2017					
2 NDC:71490-032- 03	50 mL in 1 BO Product	TTLE; Type 0: Not a Combir	nation	12/08/2021					
Marketing	Informat	ion							
Marketing Category	Applica	tion Number or Monog Citation	graph	Marketing Start Date		eting End Date			
	t								

Labeler - SUKHTIAN-HTM (HOUSEHOLDS & TOILETRIES MFG.CO) (557666494)

Establishment								
Name	Address	ID/FEI	Business Operations					
SUKHTIAN-HTM (HOUSEHOLDS & TOILETRIES MFG.CO)		557666494	manufacture(71490-032)					

Revised: 12/2021

SUKHTIAN-HTM (HOUSEHOLDS & TOILETRIES MFG.CO)