HIGEEN ANTISEPTIC HAND SANITIZER GEL WITH VITAMIN BEADS FOR KIDS AND ADULTS BIBO- 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 For Kids & Adults BiBo

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 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.

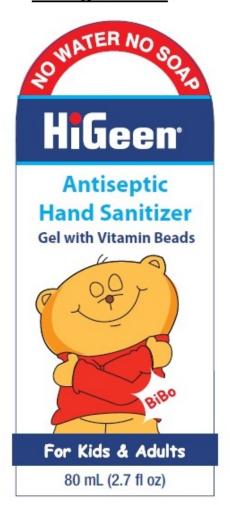
NO WATER NO SOAP

Manufactured by:

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

Made in Jordan

Packaging



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Made in Jordan

Lot No: Expiry Date:



(2801460 RC

Package - 50 ml

Drug Facts (cont.)

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50mL (1.7 fl oz)

HIGEEN ANTISEPTIC HAND SANITIZER GEL WITH VITAMIN BEADS FOR KIDS AND ADULTS BIBO

ethyl alcohol gel

Product Information				
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:71490-034	
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: 9500S7VE0Y)			
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)			
.ALPHATOCOPHEROL ACETATE (UNII: 9E8X80D2L0)			
TROLAMINE (UNII: 903K93S3TK)			
WATER (UNII: 059QF0KO0R)			

Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:71490-034- 05	80 mL in 1 BOTTLE; Type 0: Not a Combination Product	09/18/2017	
2	NDC:71490-034- 03	50 mL in 1 BOTTLE; Type 0: Not a Combination Product	12/07/2021	

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(71490-034)	

Revised: 12/2021 SUKHTIAN-HTM (HOUSEHOLDS & TOILETRIES MFG.CO)