#### HIGEEN ANTISEPTIC HAND SANITIZER GEL WITH VITAMIN BEADS FOR KIDS AND ADULTS NINO- 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.

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# HiGeen $^{\ensuremath{\mathbb{R}}}$ Antiseptic Hand Sanitizer Gel with Vitamin Beads For Kids & Adults NiNo

## **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 Yellow No. 10, 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

#### Package - 80mL





Ethyl alcohol 70% V.V .. Antiseptic

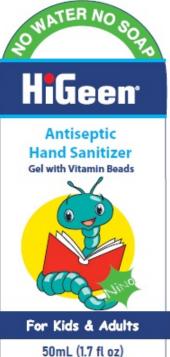
Uses for handwashing to decrease bacteria on the skin. recommended for

Flammable, keep away

When using this product do not get into eyes. In case of contact, rinse eyes

irritation and redness

persist for more than 72



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

ethyl alcohol gel

Pr	oduct Infor	mation								
		mation								
Pro	oduct Type		HUMAN OTC DRUG Item Code (Source)			NDC:71490-037				
Ro	oute of Administration TOPICAL									
Act	tive Ingredi									
	Ingredient Name					trength				
ALCOHOL (UNII: 3K9958V90M) (ALCOHOL - UNII:3K9958V90M)					ALCOHOL 70 mL in 100 m					
na	nctive Ingre	dients								
Ingredient Name Streng										
CARBOMER INTERPOLYMER TYPE A (ALLYL SUCROSE CROSSLINKED) (UNII: 59TL3WG5CO)										
ΟXI	(UN	II: 9500S7VE0Y	)							
CARBOMER HOMOPOLYMER, UNSPECIFIED TYPE (UNII: 0A5MM307FC)										
POWDERED CELLULOSE (UNII: SMD1X3XO9M)										
D&C YELLOW NO. 10 (UNII: 35SW5USQ3G)										
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: 059QF0K00R)										
Pa	ckaging				Marketing Start	Marko	ting End			
#	Item Code		ckage Description		Date		ate			
• 0	5	Product	ITLE; Type 0: Not a Combi		09/18/2017					
۷.	IDC:71490-037- 3	50 mL in 1 BO Product	ITLE; Type 0: Not a Combi	nation	12/08/2021					
Ma	arketing	Informat	ion							
	Marketing Category	Applica	tion Number or Mono Citation	graph	Marketing Start Date		ting End ate			
	monograph not									

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

Establishment									
Name	Address	ID/FEI	<b>Business Operations</b>						
SUKHTIAN-HTM (HOUSEHOLDS & TOILETRIES MFG.CO)		557666494	manufacture(71490-037)						

Revised: 12/2021

SUKHTIAN-HTM ( HOUSEHOLDS & TOILETRIES MFG.CO)