# INSTANT HAND SANITIZER - ORIGINAL- ethyl alcohol gel Great Lakes Wholesale & Marketing, LLC

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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#### **Active Ingredient**

Purpose

Ethyl Alcohol 62.0%.....Antimicrobial

XtraCare Instant Hand Sanitizer - Original

Kills 99.9% of Germs with Moisturizers & Vitamin E

*Keep out of reach of children.* If swallowed, get medical help or contact a Poison Control Center right away.

# **USE:**

• hand sanitizer to help reduce bacteria on the skin that may cause disease

# **Warnings:**

for external use only.

Flammable. Keep away from heat and flame.

**Do not use** in the eyes. In case of contact, rinse eyes thoroughly with water.

**Stop use and ask a doctor if** irritation and redness develop and persist for more than 72 hours.

#### Directions:

- wet hands thoroughly with product
- briskly rub hands together until dry
- children under 6 years of age should be supervised by an adult when using.

# **Inactive ingredients:**

carbomer, glycerin, propylene glycol, tocopheryl acetate (vitamin E), triethanolamine, water, fragrance.



**INSTANT HAND SANITIZER - ORIGINAL** ethyl alcohol gel

Anim cols (county)         Route of Administration         TOPICAL         Active Ingredient/Active Moiety         Active Ingredient/Active Moiety         Ingredient Name       Basis of Strength       Stren         ALCOHOL (UNIE: 3K9958V90M) (ALCOHOL - UNIE:3K9958V90M)       ALCOHOL (UNIE: 3K9958V90M) (ALCOHOL - UNIE:3K9958V90M)         Ingredient Name       Stren         Matter (UNIE: 059QF0K00R)       CARBOMER HOMOPOLYMER TYPE B (UNIE: HHT012NK31)       Stren         VATER (UNIE: 059QF0K00R)       CARBOMER HOMOPOLYMER TYPE B (UNIE: HHT012NK31)       Stren         POPYLENE GLYCOL (UNIE: 6DC9Q167V3)       Stren         ALPHATO COPHEROL ACETATE (UNIE: 9E8 X80D2L0)       Stren         Packaging         #       Item Code       Package Description       Marketing Start Date       Marketing End I         NDC:64092-317-01       S3 mL in 1 BOTTLE       Stren         Marketing Information         Marketing Category       Application Number or Monograph Citation       Marketing Start Date       Marketing End I </th <th></th> <th></th> <th></th> <th></th> <th>n</th> <th>ct Information</th> <th>Prod</th>					n	ct Information	Prod					
Active Ingredient/Active Moiety Ingredient Name ALCOHOL (UNIE: 3K9958 V90M) (ALCOHOL - UNIE3K9958 V90M) ALCOHOL - UNIE3K9353 TK - UNIE3K9374 ALCOHOL - UNIE3K938 TR - UNIE3K978 TR - UN	Source) NDC:64092-317	Item Code (Source)		HUMAN OTC DRUG		: Туре	Produ					
Ingredient Name       Basis of Strength       Stren         ALCOHOL (UNIE 3K9958 V90M) (ALCOHOL - UNIE3K9958 V90M)       ALCOHOL       33 mL in 5         Ingredients         Ingredient Name       Stren         Matter (UNIE 059QF0K00R)         Karen WATER (UNIE 059QF0K00R)         CARBO MER HOMOPOLYMER TYPE B (UNIE HHT01ZNK31)       Stren         TROLAMINE (UNIE 903K93S3TK)       Stren         GLYCERIN (UNIE 903K93S3TK)       Stren         GLYCERIN (UNIE 6DC9Q167V3)       Stren         ALPHATO COPHEROL ACETATE (UNIE 9E8X80D2L0)       Stren         Marketing Code       Package Description       Marketing Start Date       Marketing End I         NDC:64092-317-02       2 in 1PACKAGE       Stren         NDC:64092-317-01       53 mL in 1BOTTLE       Stren         Marketing Information         Marketing Category       Application Number or Monograph Citation       Marketing Start Date       Marketing Etat				TOPICAL	n	f Administration	Route					
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Ingredient Name       Stren         WATER (UNII: 059QF0K000)         CARBOMER HOMOPOLYMER TYPE B (UNII: HHT0 12NK31)         TROLAMINE (UNII: 903K9353TK)         GLYCERIN (UNII: 903K9353TK)         GLYCERIN (UNII: 902K03C00X)         PYLENE GLYCOL (UNII: 6DC9Q167V3)         ALPHATO COPHEROL ACETATE (UNII: 9E8X80D2L0)         PYLENE GLYCOL (UNII: 9E8X80D2L0)         PYLENE												
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Labeler - Great Lakes Wholesale & Marketing, LLC (361925498)

Establishment			
Name	Address	ID/FEI	<b>Business Operations</b>
China Ningbo Shangge Cosmetic Technology Corp.		529287434	manufacture(64092-317)

Revised: 7/2013

Great Lakes Wholesale & Marketing, LLC