INSTANT HAND SANITIZER- 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.

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.

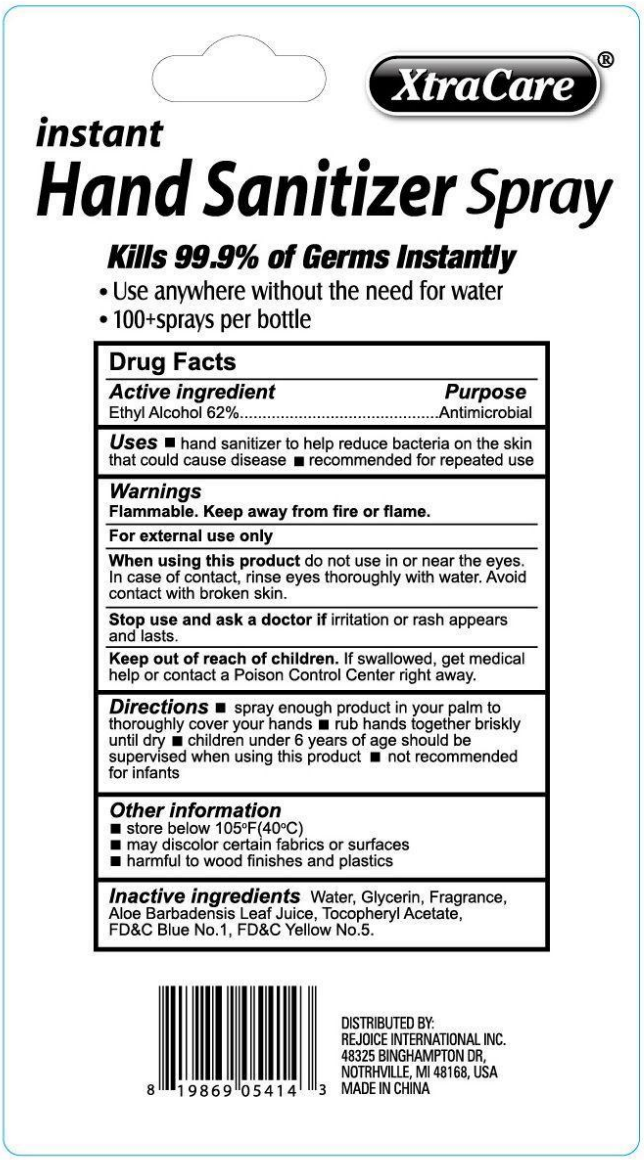
Stop use and ask a doctor if irritation and redness develop and persist for more than 72 hours.

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

ethyl alcohol gel

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:64092-318
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety		
Ingredient Name	**Basis of Strength**	**Strength**
ALCOHOL (UNII: 3K9958V90M) (ALCOHOL - UNII:3K9958V90M)	ALCOHOL	6 mL in 10 mL

Inactive Ingredients	
Ingredient Name	**Strength**
WATER (UNII: 059QF0KO0R)	

GLYCERIN (UNII: PDC6A3C0OX)	
ALOE VERA LEAF (UNII: ZY81Z83H0X)	
.ALPHA.-TOCOPHEROL ACETATE (UNII: 9E8X80D2L0)	
FD&C BLUE NO. 1 (UNII: H3R47K3TBD)	
FD&C YELLOW NO. 5 (UNII: I753WB2F1M)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:64092-318-02	2 in 1 PACKAGE		
1	NDC:64092-318-01	10 mL in 1 BOTTLE		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part333E	07/05/2013	

Labeler - Great Lakes Wholesale & Marketing, LLC (361925498)

Establishment

Name	Address	ID/FEI	Business Operations
China Ningbo Shangge Cosmetic Technology Corp.		529287434	manufacture(64092-318)

Revised: 7/2013 Great Lakes Wholesale & Marketing, LLC