

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.

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.

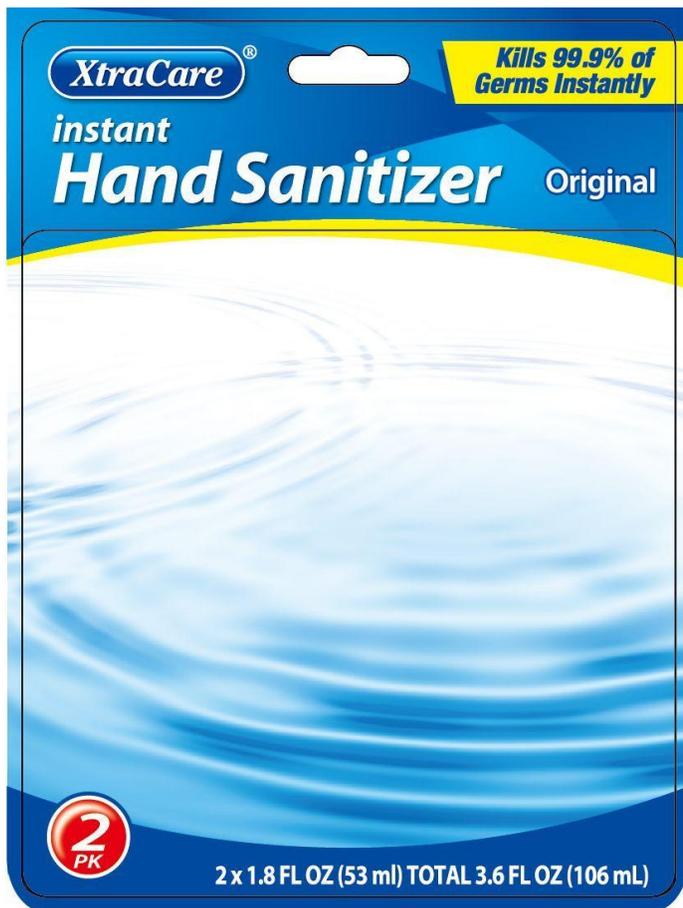
Inactive ingredients:

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



Drug Facts	
Active Ingredient: Ethyl Alcohol 62.0%.....	Purpose Antimicrobial
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.	
When using this product • avoid contact with face, eyes, and broken skin. In case of eye contact, flush with plenty of water and seek medical advice.	
Stop use and ask a doctor if • irritation or redness develops.	
Keep out of reach of children. if swallowed, get medical help or contact a Poison Control Center.	
Directions • wet hands thoroughly with product and rub into skin until dry. • children under 6 years of age should be supervised by an adult when using.	
Other Information: • store at 20°C to 25°C (68°to 77°F) • may discolor certain fabrics	
Inactive ingredients: water, carbomer, triethanolamine, glycerin, propylene glycol, fragrance, tocopheryl acetate (Vitamin E).	

DISTRIBUTED BY:
REJOICE INTERNATIONAL INC.
48325 BINGHAMPTON DR,
NOTRHVILLE, MI 48168, USA
MADE IN CHINA



XtraCare® *Hook it to your backpack, key chain, sports bag, purse, or anywhere you want the hand sanitizer!*

instant Hand Sanitizer Original
For your • key chain • purse • backpack • anywhere

Drug Facts	
Active Ingredient: Ethyl Alcohol 62.0%.....	Purpose Antimicrobial
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.	
When using this product • avoid contact with face, eyes, and broken skin. In case of eye contact, flush with plenty of water and seek medical advice.	
Stop use and ask a doctor if • irritation or redness develops.	
Keep out of reach of children. if swallowed, get medical help or contact a Poison Control Center.	
Directions • wet hands thoroughly with product and rub into skin until dry. • children under 6 years of age should be supervised by an adult when using.	
Other Information: • store at 20°C to 25°C (68°to 77°F) • may discolor certain fabrics	
Inactive ingredients: water, carbomer, triethanolamine, glycerin, propylene glycol, fragrance, tocopheryl acetate (Vitamin E).	

8 19869 05427 3

DISTRIBUTED BY:
REJOICE INTERNATIONAL INC.
48325 BINGHAMPTON DR,
NOTRHVILLE, MI 48168, USA
MADE IN CHINA

INSTANT HAND SANITIZER - ORIGINAL

ethyl alcohol gel

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:64092-317
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
ALCOHOL (UNII: 3K9958V90M) (ALCOHOL - UNII:3K9958V90M)	ALCOHOL	33 mL in 53 mL

Inactive Ingredients

Ingredient Name	Strength
WATER (UNII: 059QF0KO0R)	
CARBOMER HOMO POLYMER TYPE B (UNII: HHT01ZNK31)	
TROLAMINE (UNII: 9O3K93S3TK)	
GLYCERIN (UNII: PDC6A3C0OX)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
.ALPHA.-TOCOPHEROL ACETATE (UNII: 9E8X80D2L0)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:64092-317-02	2 in 1 PACKAGE		
1	NDC:64092-317-01	53 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(64092-317)

Revised: 7/2013

Great Lakes Wholesale & Marketing, LLC