## INSTANT HAND SANITIZER - COCOA BUTTER- 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 IngredientPurpose

Ethyl Alcohol 62.0%.....Antimicrobial

Health Care Instant Hand Sanitizer - Ice Clear - Extra Enriched with Vitamin E Bead & Aloe

Kills 99.9% of Germs without water or towels!

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

#### **USE:**

- for handwashing to decrease bacteria on the skin
- recommended for repeated use

#### **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
- supervise children in the use of this product

#### **Inactive ingredients:**

aloe vera leaf juice, carbomer, glycerin, propylene glycol, tocopheryl acetate (vitamin E), triethanolamine, water.

#### **Other information:**

- store at 20oC to 25oC (68o to 77oF)
- may discolor certain fabrics





### Drug Facts Active ingredient Purpose Ethyl Alcohol 62.0%. Antimicrobial Uses • for handwashing to decrease bacteria on the skin • recommended for repeated use 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. 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 - briskly rub hands together until dry • supervise children under 6 years in the use of this product Other information store at 20°C to 25°C (68°to 77°F) may discolor certain fabrics Inactive inaredients water, carbomer, triethanolamine, glycerin, propylene glycol, fragrance, titanium dioxide, cocoa seed butter. DISTRIBUTED BY: REJOICE INTERNATIONAL INC. 48325 BINGHAMPTON DR, NOTRHVILLE, MI 48168, USA

#### INSTANT HAND SANITIZER - COCOA BUTTER

IIIO MADEIN CHINA

ethyl alcohol gel

# Product Information Product Type HUMAN OTC DRUG Item Code (Source) NDC:64092-315 Route of Administration TOPICAL

|   | Active Ingredient/Active Moiety                        |                   |                  |
|---|--------------------------------------------------------|-------------------|------------------|
| l | Ingredient Name                                        | Basis of Strength | Strength         |
| ı | ALCOHOL (UNII: 3K9958V90M) (ALCOHOL - UNII:3K9958V90M) | ALCOHOL           | 147 mL in 237 mL |

| Inactive Ingredients                            |          |
|-------------------------------------------------|----------|
| Ingredient Name                                 | Strength |
| COCOA BUTTER (UNII: 5120 YT1CRR)                |          |
| CARBOMER HOMOPOLYMER TYPE B (UNII: HHT01ZNK31)  |          |
| GLYCERIN (UNII: PDC6A3C0OX)                     |          |
| PROPYLENE GLYCOL (UNII: 6 DC9 Q 16 7 V3)        |          |
| .ALPHATO COPHERO L ACETATE (UNII: 9E8 X80 D2L0) |          |
| TROLAMINE (UNII: 903K93S3TK)                    |          |
| WATER (UNII: 059QF0KO0R)                        |          |

| P | Packaging        |                     |                      |                    |  |  |
|---|------------------|---------------------|----------------------|--------------------|--|--|
| # | Item Code        | Package Description | Marketing Start Date | Marketing End Date |  |  |
| 1 | NDC:64092-315-01 | 236 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    | <b>Business Operations</b> |  |
| China Ningbo Shangge Cosmetic Technology Corp. |         | 529287434 | manufacture(64092-315)     |  |

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