### XTRACARE WARM VANILLA- ethyl alcohol gel China Ningbo Shangge Cosmetic Technology Corp

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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#### XtraCare Warm Vanilla

#### **Active Ingredient** Purpose

Ethyl Alcohol 62.0% ...... Antimicrobial

#### **□Uses**

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

**Keep out of reach of children.** If swallowed, get medical help or contact a poison control center right away.

XtraCare® Kills 99.9% of germs Instant Hand Sanitizer with moisturizers cucumber melon scent 8 FL OZ / 237 mL

#### **Directions**

- wet hands thoroughly with product
- briskly rub hands together until dry
- supervise children under 6 years in the use of this product

#### **□** Warnings

#### **IFor 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.

#### **Inactive Ingredients**

water, carbomer, triethanolamine, glycerin, propylene glycol, fragrance, aloe barbadensis leaf juice, fd&c red no.33



# Questions/Comments?

1-855-345-5575

DISTRIBUTED BY: REJOICE INTERNATIONAL INC. NORTHVILLE, MI 48168, USA MADE IN CHINA

## **Drug Facts**

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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 ingredients water, carbomer, triethanolamine, glycerin, propylene glycol, fragrance, aloe barbadensis leaf juice, fd&c yellow no.5, fd&c blue no.1, d&c red no.33.



#### XTRACARE WARM VANILLA

ethyl alcohol gel

| <b>Product Information</b> |                |                    |               |
|----------------------------|----------------|--------------------|---------------|
| Product Type               | HUMAN OTC DRUG | Item Code (Source) | NDC:58503-074 |
| Route of Administration    | TOPICAL        |                    |               |

| Active Ingredient/Active Moiety                          |                   |               |  |
|--|-------------------|---------------|--|
| Ingredient Name  | Basis of Strength | Strength      |  |
| ALCOHOL (UNII: 3K9958 V90M) (ALCOHOL - UNII:3K9958 V90M) | ALCOHOL           | 62 g in 100 g |  |

| Inactive Ingredients                         |          |
|--|----------|
| Ingredient Name                              | Strength |
| WATER (UNII: 059QF0KO0R)                     |          |
| CARBOMER COPOLYMER TYPE A (UNII: 71DD5V995L) |          |
| TROLAMINE (UNII: 9O3K93S3TK)                 |          |
| GLYCERIN (UNII: PDC6A3C0OX)                  |          |
| PROPYLENE GLYCOL (UNII: 6DC9Q167V3)          |          |
| ALOE VERA LEAF (UNII: ZY8 1Z8 3H0 X)         |          |
| D&C RED NO. 33 (UNII: 9DBA0SBB0L)            |          |
| FD&C YELLOW NO. 5 (UNII: 1753WB2F1M)         |          |
| FD&C BLUE NO. 1 (UNII: H3R47K3TBD)           |          |

| l | Packaging          |  |                             |                           |
|---|--------------------|--|-----------------------------|---------------------------|
| ı | # Item Code        | Package Description                                  | <b>Marketing Start Date</b> | <b>Marketing End Date</b> |
| ı | 1 NDC:58503-074-01 | 237 g in 1 BOTTLE; Type 0: Not a Combination Product | 02/17/2015                  |                           |

NDC.36503-074-01 257 g iii 1 BO 11LE, 1 ype 0. Not a Combination Product | 02/1//2013

| Marketing Information   |  |                      |                    |  |
|-------------------------|--|----------------------|--------------------|--|
| Marketing Category      | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date |  |
| OTC monograph not final | part333E                                 | 0 2/17/20 15         |                    |  |
|                         |  |                      |                    |  |

# Labeler - China Ningbo Shangge Cosmetic Technology Corp (529287434)

| Establishment                                 |         |           |                            |  |
|---|---------|-----------|----------------------------|--|
| Name  | Address | ID/FEI    | <b>Business Operations</b> |  |
| China Ningbo Shangge Cosmetic Technology Corp |         | 529287434 | manufacture (58503-074)    |  |

Revised: 9/2019 China Ningbo Shangge Cosmetic Technology Corp