# XTRACARE INSTANT HAND SANITIZER - alcohol spray Rejoice International

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 instant Hand Sanitizer Spray**

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# Active ingredient

Ethyl Alcohol 62%

## **Purpose**

Antimicrobial

#### Uses

- hand sanitizer to help reduce bacteria on the skin that may cause disease.
- recommended for repeated use

## **Warnings**

Flammable. Keep away from fire or flame. For external use only

### When using this product

do not use in or near the eyes. In case of contact, rinse eyes thoroughly with water. Avoid contact with broken skin.

#### Stop use and ask a doctor if

irritation or rash appears and lasts.

#### Keep out of reach of children.

if swallowed, get medical help or contact a Poison Control Center right away.

#### **Directions**

- spray enough product in your palm to thoroughly cover your hands
- rub hands together briskly until dry
- children under 6 years of age should be supervised when using this product
- not recommended for infants

#### Other Information

- store below 105<sup>0</sup>F (40<sup>0</sup>C)
- may discolor certain fabrics or surfaces

harmful to wood finishes and plastics

# **Inactive ingredients**

Water, Glycerin, Fragrance, Aloe Barbadensis Leaf Juice, Tocopheryl Acetate, FDandC Blue No. 1, FDandC Yellow No. 5.

#### XtraCare

instant Hand Sanitizer Spray Kills 99.9% of Germs Instantly

- Use anywhere without the need for water
- 100+sprays per bottle

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

XtraCare instant Hand Sanitizer Spray 2 PK 100+SPRAYS Kills 99.9% of Germs Instantly Leaves hands feeling soft with Aloe and Vitamin E Convenient Size for Purse, Pocket or Car PERFECT FOR TRAVEL 2x0.34 fl oz(2x10 ml)

#### **Product Labels**







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#### XTRACARE INSTANT HAND SANITIZER

alcohol spray

#### **Product Information**

Product Type HUMAN OTC DRUG Item Code (Source) NDC:57337-001

**Route of Administration** TOPICAL

#### **Active Ingredient/Active Moiety**

| Ingredient Name   | Basis of Strength | Strength        |
|---|-------------------|-----------------|
| <b>ALCOHOL</b> (UNII: 3K9958 V90M) (ALCOHOL - UNII:3K9958 V90M) | ALCOHOL           | 62 mL in 100 mL |

| Inactive Ingredients |          |
|----------------------|----------|
| Ingredient Name      | Strength |

| WATER (UNII: 059QF0KO0R)                     |  |
|--|--|
| GLYCERIN (UNII: PDC6A3C0OX)                  |  |
| ALOE VERA LEAF (UNII: ZY8 1Z8 3H0 X)         |  |
| .ALPHATO COPHEROL ACETATE (UNII: 9E8X80D2L0) |  |
| FD&C BLUE NO. 1 (UNII: H3R47K3TBD)           |  |
| FD&C YELLOW NO. 5 (UNII: I753WB2F1M)         |  |

| P | Packaging        |                     |                      |                    |
|---|------------------|---------------------|----------------------|--------------------|
| # | Item Code        | Package Description | Marketing Start Date | Marketing End Date |
| 1 | NDC:57337-001-02 | 2 in 1 PACKAGE      |                      |                    |
| 1 | NDC:57337-001-00 | 10 mL in 1 BOTTLE   |                      |                    |

| Marketing Information |  |                      |                    |
|-----------------------|--|----------------------|--------------------|
| Marketing Category    | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date |
| OTC monograph final   | part333E                                 | 02/08/2013           |                    |
|                       |  |                      |                    |

# **Labeler** - Rejoice International (078741245)

| Establishment  |         |           |                        |
|----------------|---------|-----------|------------------------|
| Name           | Address | ID/FEI    | Business Operations    |
| Ningbo Unichem |         | 528196956 | manufacture(57337-001) |

Revised: 2/2013 Rejoice International