# CARE BEARS COTTON CANDY ANTISEPTIC HAND CLEANSING- alcohol gel Ningbo Pulisi Daily Chemical Products Co., Ltd.

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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### **Drug Fact**

# **Active Ingredient**

Alcohol 62%

#### **Purpose**

Antiseptic

#### Uses

decrease bacteria on hands

#### Warnings

For external use only

Use only as directed

Excessive use or prolonged exposure may cause irritation to skin.

Discontinue use if rash, redness or itching occurs.

Flammable. Keep away from fire or flame.

# When using this product

• keep out of eyes.

#### Discontinue use if

irritation or redness develops. If condition persists for more than 72 hours, consult a doctor.

# Keep out of reach of children.

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

#### **Directions**

Place a Plmful of product in one hand, spread on both hands and rub the skin until dry.

#### Other Information

To report a serious adverse reaction, please write Added Extras, LLC, 350 tth Ave. 7th Floor, New York, NY 10118

#### **Inactive Ingredients**

aloe barbadensis gel, carbomer, fragrance, glycerin, propylene glycol, tocopherol, triethanolamine, water, Acetate, Fragrance, Red 33

# **Product Labeling**





Made In China. 8LLOL AN 'AN Added Extras, LLC Distributed For And By: @TCFC NOT TESTED ON ANIMALS ed act Red33 acetate A be bar badensis leaf Regrance, Viet harolamine, Docapheryl Inactive Ingredients Wate,Glycein Propleneglycd,Carbonet Added Extras, LLC 350 5th Avenue 7th Floor New York, NY 10118. To report a serious adverse reaction please write to Other Information Drug Facts (continued) Place a 'palmful' of product in one hand. Spread on both hands and rub the skin until dry. Directions help or contact a Poison Control Center right away.

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Drug Facts
(continued)

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alcohol gel

| Product Information     |                |                    |               |
|-------------------------|----------------|--------------------|---------------|
| Product Type            | HUMAN OTC DRUG | Item Code (Source) | NDC:40104-354 |
| Route of Administration | TOPICAL        |                    |               |
|                         |                |                    |               |

| Active Ingredient/Active Moiety                        |                   |                 |  |
|--------------------------------------------------------|-------------------|-----------------|--|
| Ingredient Name                                        | Basis of Strength | Strength        |  |
| ALCOHOL (UNII: 3K9958V90M) (ALCOHOL - UNII:3K9958V90M) | ALCOHOL           | 62 mL in 100 mL |  |

| Inactive Ingredients                |          |
|-------------------------------------|----------|
| Ingredient Name                     | Strength |
| ALOE VERA LEAF (UNII: ZY81Z83H0X)   |          |
| GLYCERIN (UNII: PDC6 A3C0 OX)       |          |
| PROPYLENE GLYCOL (UNII: 6DC9Q167V3) |          |
| TOCOPHEROL (UNII: R0ZB2556P8)       |          |
| TROLAMINE (UNII: 9O3K93S3TK)        |          |
| WATER (UNII: 059QF0KO0R)            |          |

| ı | Packaging          |                     |                      |                    |
|---|--------------------|---------------------|----------------------|--------------------|
|   | # Item Code        | Package Description | Marketing Start Date | Marketing End Date |
|   | 1 NDC:40104-354-01 | 30 mL in 1 BOTTLE   |                      |                    |

| Marketing Information   |                                          |                      |                    |  |
|-------------------------|------------------------------------------|----------------------|--------------------|--|
| Marketing Category      | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date |  |
| OTC monograph not final | part333E                                 | 09/02/2014           |                    |  |
|                         |                                          |                      |                    |  |

# Labeler - Ningbo Pulisi Daily Chemical Products Co., Ltd. (529047265)

| Establishment                                   |         |           |                          |  |
|-------------------------------------------------|---------|-----------|--------------------------|--|
| Name                                            | Address | ID/FEI    | Business Operations      |  |
| Ningbo Pulisi Daily Chemical Products Co., Ltd. |         | 529047265 | manufacture(40 10 4-354) |  |

Revised: 9/2014 Ningbo Pulisi Daily Chemical Products Co., Ltd.