## CAREONE- ethyl alcohol liquid AMERICAN SALES COMPANY

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 FACTS**

## **ACTIVE INGREDIENT**

ETHYL ALCOHOL 62%

## **PURPOSE**

**ANTISEPTIC** 

#### **USES**

TO HELP REDUCE BACTERIA ON THE SKIN.

#### WARNINGS

FOR EXTERNAL USE ONLY. FLAMMABLE. KEEP AWAY FROM FIRE OR HEAT SOURCE.

#### WHEN USING THIS PRODUCT

AVOID CONTACT WITH EYES. IF CONTACT OCCURS, RINSE THOROUGHLY WITH WATER.

STOP USING THIS PRODUCT AND ASK A DOCTOR IF

IRRITATION OR REDNESS DEVELOPS AND LASTS.

KEEP OUT OF REACH OF CHILDREN

IN CASE OF ACCIDENTAL INGESTION, GET MEDICAL HELP OR CONTACT A POISON CONTROL CENTER IMMEDIATELY.

## **DIRECTIONS**

WET HANDS THOROUGHLY AND RUB TOGETHER UNTIL DRY.

## OTHER INFORMATION

STORE AT ROOM TEMPERATURE BELOW 110F (43C).

## INACTIVE INGREDIENTS

WATER, GLYCERIN, ISOPROPYL MYRISTATE, PROPYLENE GLYCOL, TOCOPHERYL ACETATE, AMINOMETHYL PROPANOL, CARBOMER, FRAGRANCE (PARFUM).

## LABEL COPY





**KILLS 99.99% OF GERMS\*** 

15 FL OZ (443 mL)



**Drug Facts** 

Active ingredient

Purpose

Uses . To help reduce bacteria on the skin

For external use only. Flammable. Keep away from fire or heat source When using this product \* avoid contact with eyes. If contact occurs, rinse thoroughly with water.

Stop using this product and ask a doctor if = irritation or redness develops and lasts.

Keep out of reach of children. . In case of accidental ingestion, get medical help or contact a Poison Control Center immediately.

Directions - Wet hands thoroughly and rub together until dry

Other information - Store at room temperature below 110°F (43°C).

Inactive ingredients - Water, Glycerin, Isopropyl Myristate, Propylene Glycol, Tocopheryl Acetate, Aminomethyl Propanol, Carbomer,

\*Effective at eliminating over 99.99% of many common harmful germs and bacteria in as little as 30 seconds.

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NOT FOR RESALE

## **CAREONE**

ethyl alcohol liquid

## **Product Information**

Product Type

HUMAN OTC DRUG

Item Code (Source)

NDC:41520-220

**Route of Administration** 

TOPICAL

## **Active Ingredient/Active Moiety**

**Ingredient Name** 

**Basis of Strength** 

Strength

ALCOHOL (UNII: 3K9958V90M) (ALCOHOL - UNII:3K9958V90M)

ALCOHOL

620 mg in 1 mL

| Inactive Ingredients                         |          |  |  |  |
|--|----------|--|--|--|
| Ingredient Name                              | Strength |  |  |  |
| WATER (UNII: 059QF0KO0R)                     |          |  |  |  |
| GLYCERIN (UNII: PDC6A3C0OX)                  |          |  |  |  |
| ISOPROPYL MYRISTATE (UNII: 0 RE8 K4LNJS)     |          |  |  |  |
| PROPYLENE GLYCOL (UNII: 6 DC9 Q167V3)        |          |  |  |  |
| .ALPHATO COPHEROL ACETATE (UNII: 9E8X80D2L0) |          |  |  |  |
| AMINOMETHYLPROPANOL (UNII: LU49E6626Q)       |          |  |  |  |
| <b>CARBOMER 934</b> (UNII: Z135WT9208)       |          |  |  |  |

| Packaging |                  |                             |                      |                    |  |  |
|-----------|------------------|-----------------------------|----------------------|--------------------|--|--|
| #         | Item Code        | Package Description         | Marketing Start Date | Marketing End Date |  |  |
| 1         | NDC:41520-220-15 | 443 mL in 1 BOTTLE, PLASTIC |                      |                    |  |  |

| Marketing Information   |  |                      |                    |  |  |  |
|-------------------------|--|----------------------|--------------------|--|--|--|
| Marketing Category      | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date |  |  |  |
| OTC monograph not final | part333E                                 | 06/06/2013           |                    |  |  |  |
|                         |  |                      |                    |  |  |  |

# Labeler - AMERICAN SALES COMPANY (809183973)

## **Registrant -** APOLLO HEALTH AND BEAUTY CARE (201901209)

| Establishment                 |         |           |                        |  |  |
|-------------------------------|---------|-----------|------------------------|--|--|
| Name                          | Address | ID/FEI    | Business Operations    |  |  |
| APOLLO HEALTH AND BEAUTY CARE |         | 201901209 | manufacture(41520-220) |  |  |

Revised: 6/2013 AMERICAN SALES COMPANY