CARE ONE LEMON VERBENA- 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.

DRUG FACTS

ACTIVE INGREDIENT

ETHYL ALCOHOL 65%

PURPOSE

ANTISEPTIC

USES

TO DECREASE BACTERIA ON THE SKIN.

WARNINGS

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

WHEN USING THIS PRODUCT

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

STOP USE 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 RUN TOGETHER UNTIL DRY.

OTHER INFORMATION

STORE AT A TEMPERTAURE BELOW 110F (43C)

INACTIVE INGREDIENTS:

WATER (AQUA), CARBOMER, AMINOMETHYL PROPANOL, FRAGRANCE (PARFUM), ISOPROPYL ALCOHOL, GLYCERIN, PROPYLENE GLYCOL, BENZOPHENONE-4, MANNITOL, CELLULOSE, CAPRYLIC/CAPRIC TRIGLYCERIDE, HYDROXYPROPYL METHYLCELLULOSE, IRON OXIDES (CI 77492), IRON OXIDES (CI 77499), BLUE 1 (CI 42090), YELLOW 5 (CI 19140).

LABEL COPY



Drug Facts

Active ingredient Ethyl Alcohol 65 %....

Purpose Antiseptic

Uses To decrease bacteria on the skin.

Warnings

For external use only. Flammable. Keep away from source of heat or fire.

When using this product ■ avoid contact with eyes. If contact occurs, rinse with water.

Stop use 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 a temperature below 110°F (43°C).

Inactive ingredients: Water (Aqua), Carbomer, Aminomethyl Propanol, Fragrance (Parfum), Isopropyl Alcohol, Glycerin, Propylene Glycol, Benzophenone-4, Mannitol, Cellulose, Caprylic/Capric Triglyceride, Hydroxypropyl Methylcellulose, Iron Oxides (Cl 77492), Iron Oxides (Cl 77491), Iron Oxides (Cl 77499), Blue 1 (Cl 42090), Yellow 5 (Cl 19140).

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

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CARE ONE LEMON VERBENA

ethyl alcohol liquid

Product Information

Product Type

HUMAN OTC DRUG

Item Code (Source)

NDC:41520-479

Route of Administration

TOPICAL

Active Ingredient/Active Moiety

Ingredient Name

Basis of Strength

Strength

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

ALCOHOL

 $650~mg~in~1\,mL$

Inactive Ingredients

Ingredient Name	Strength
WATER (UNII: 059QF0KO0R)	
CARBOMER 934 (UNII: Z135WT9208)	
AMINOMETHYLPROPANOL (UNII: LU49E6626Q)	
ISOPROPYL ALCOHOL (UNII: ND2M416302)	
GLYCERIN (UNII: PDC6A3C0OX)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
SULISOBENZONE (UNII: 1W6L629B4K)	
MANNITOL (UNII: 3OWL53L36A)	
PO WDERED CELLULO SE (UNII: SMD1X3XO9 M)	
MEDIUM-CHAIN TRIGLYCERIDES (UNII: C9H2L21V7U)	
HYPROMELLOSES (UNII: 3NXW29 V3WO)	
FERRIC OXIDE YELLOW (UNII: EX438O2MRT)	
FERRIC OXIDE RED (UNII: 1K09F3G675)	
FERROSOFERRIC OXIDE (UNII: XM0 M87F357)	
FD&C BLUE NO. 1 (UNII: H3R47K3TBD)	
FD&C YELLOW NO. 5 (UNII: I753WB2F1M)	

F	Packaging					
#	Item Code	Package Description	Marketing Start Date	Marketing End Date		
1	NDC:41520-479-02	59 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	02/14/2013				

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(41520-479)		

Revised: 2/2013 AMERICAN SALES COMPANY