CARE ONE ANTIBACTERIAL PEPPERMINT SWIRL- 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 USIGN THIS PRODUCT

STOP USE AND ASK A DOCTOR IF

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 110F (43C).

INACTIVE INGREDIENTS:

WATER (AQUA), ISOPROPYL ALCOHOL, GLYCERIN, CARBOMER, AMINOMETHYL PROPANOL, FRAGRANCE (PARFUM), PROPYLENE GLYCOL, BENZOPHENONE-4, MANNITOL, CELLULOSE, HYDROXYPROPYL METHYLCELLULOSE, TOCOPHERYL ACETATE, ASCORBYL PALMITATE, CHROMIUM HYDROXIDE GREEN (CI 77289), RED 4 (CI 14700), RED 33 (CI 17200), CARAMEL.





Drug Facts

Uses **I** 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 initation 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, Isopropyl Alcohol, Glycerin, Carbomer, Aminomethyl Propanol, Fragrance (Parfum), Propylene Glycol, Benzophenone-4, Mannitol, Cellulose, Hydroxypropyl Methylcellulose, Tocopheryl Acetate, Ascorbyl Palmitate, Chromium Hydroxide Green (CI 77289), Red 4 (CI 14700), Red 33 (CI 17200), Caramel.

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

Distributed by American Sales Company

4201 Walden Avenue, Lancaster, NY 14086 * 1-877-846-9949

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CARE ONE ANTIBACTERIAL PEPPERMINT SWIRL

ethyl alcohol liquid

Product Information

Product Type HUMAN OTC DRUG Item Code (Source) NDC:41520-472

Route of Administration TOPICAL

Active Ingredient/Active Moiety

1	,		
	Ingredient Name	Basis of Strength	Strength
	ALCOHOL (UNII: 3K9958V90M) (ALCOHOL - UNII:3K9958V90M)	ALCOHOL	650 mg in 1 mL
- 1			

Inactive Ingredients	
Ingredient Name	Strength
WATER (UNII: 059QF0KO0R)	
ISOPROPYL ALCOHOL (UNII: ND2M416302)	
GLYCERIN (UNII: PDC6A3C0OX)	
CARBOMER 934 (UNII: Z135WT9208)	
AMINOMETHYLPROPANOL (UNII: LU49E6626Q)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
SULISOBENZONE (UNII: 1W6L629B4K)	
MANNITOL (UNII: 3OWL53L36A)	
POWDERED CELLULOSE (UNII: SMD1X3XO9M)	
HYPROMELLOSES (UNII: 3NXW29 V3WO)	
.ALPHATO COPHEROL ACETATE (UNII: 9E8X80D2L0)	
ASCORBYL PALMITATE (UNII: QN83US2B0N)	
CHROMIUM HYDRO XIDE GREEN (UNII: RV8 FT8 XF5R)	
FD&C RED NO. 4 (UNII: X3W0 AM1JLX)	
D&C RED NO.33 (UNII: 9DBA0SBB0L)	
CARAMEL (UNII: T9D99G2B1R)	

Packaging					
# Item Code	Package Description	Marketing Start Date	Marketing End Date		
1 NDC:41520-472-02	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	09/27/2012				

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(41520-472)		

Revised: 9/2012 AMERICAN SALES COMPANY