CARE ONE 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 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

APPLY A SMALL AMOUNT TO YOUR PALM AND RUB HANDS TOGETHER BRISKLY UNTIL DRY. CHILDREN UNDER 6 YEARS OLD SHOULD BE SUPERVISED WHEN USING THIS PRODUCT

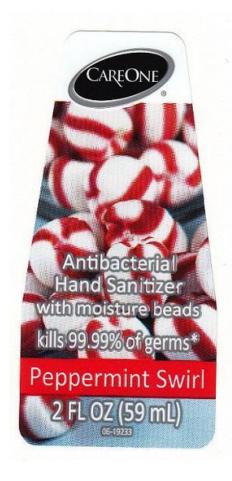
OTHER INFORMATION

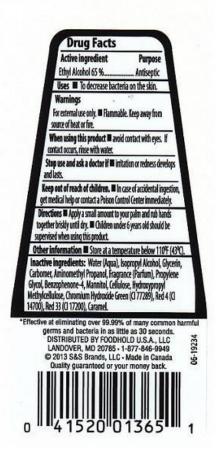
STORE AT A TEMPERATURE BELOW 110°F (43°C)

INACTIVE INGREDIENTS

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

LABEL COPY





CARE ONE PEPPERMINT SWIRL

ethyl alcohol liquid

Prod	nct '	Info	rma	tion
PIOC				

Product Type HUMAN OTC DRUG Item Code (Source) NDC:41520-497

Route of Administration TOPICAL

Active Ingredient/Active Moiety

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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)			
ISOPROPYL ALCOHOL (UNII: ND2M416302)			
GLYCERIN (UNII: PDC6A3C0OX)			
CARBOMER 934 (UNII: Z135WT9208)			
AMINO METHYLPRO PANOL (UNII: LU49 E6626Q)			
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)			
SULISO BENZO NE (UNII: 1W6 L6 29 B4K)			

MANNITOL (UNII: 3OWL53L36A)	
PO WDERED CELLULO SE (UNII: SMD1X3XO9M)	
HYPROMELLOSES (UNII: 3NXW29 V3WO)	
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)	

F	ackaging			
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:41520-497-02	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	10/27/2013		

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(41520-497)	

Revised: 10/2013 AMERICAN SALES COMPANY