CARE ONE ANTIBACTERIAL TANGERINE SPICE- 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

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 ANDS THOROUGHLY AND RUB TOGETHER UNTIL DRY.

OTHER INFORMATION

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

INACTIVE INGREDIENTS:

WATER (AQUA), pROPYLENE GLYCOL, CARBOMER, GLYCERIN, ISOPROPYL MYRISTATE, FRAGRANCE (PARFUM), AMINOMETHYL PROPANOL, TOCOPHERYL ACETATE, TRIETHYL CITRATE, MICA, ACRYLATES/AMMONIUM METHACRYLATE COPOLYMER, TALC, TITANIUM DIOXIDE, IRON OXIDES (CI 77491), IRON OXIDES (CI 77492), RED 4 (CI 14700), ORANGE 4 (CI 15510).





CARE ONE ANTIBACTERIAL TANGERINE SPICE

ethyl alcohol liquid

Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:41520-470

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)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
CARBOMER 934 (UNII: Z135WT9208)	
GLYCERIN (UNII: PDC6A3C0OX)	
ISOPROPYL MYRISTATE (UNII: 0 RE8 K4LNJS)	
AMINOMETHYLPROPANOL (UNII: LU49E6626Q)	
.ALPHATO COPHEROL ACETATE (UNII: 9E8X80D2L0)	
TRIETHYL CITRATE (UNII: 8Z96QXD6UM)	
MICA (UNII: V8A1AW0880)	
METHACRYLIC ACID - METHYL METHACRYLATE COPOLYMER (1:1) (UNII: 74G4R6TH13)	
TALC (UNII: 7SEV7J4R1U)	
TITANIUM DIO XIDE (UNII: 15FIX9 V2JP)	
FERRIC OXIDE RED (UNII: 1K09F3G675)	
FERRIC OXIDE YELLOW (UNII: EX438O2MRT)	
FD&C RED NO. 4 (UNII: X3W0 AM1JLX)	
D&C ORANGE NO. 4 (UNII: Q1LIY3BO0U)	

Packaging			
# Item Code	Package Description	Marketing Start Date	Marketing End Date
1 NDC:41520-470-02	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	09/25/2012	

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(41520-470)

Revised: 9/2012 AMERICAN SALES COMPANY