TOPCARE APPLE POMEGRANATE- ethyl alcohol liquid TOPCO ASSOCIATES LLC

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 62%

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 USING THIS PRODUCT AND ASK 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 110F (43C).

INACTIVE INGREDIENTS

WATER (AQUA), PROPYLENE GLYCOL, CARBOMER, FRAGRANCE (PARFUM), GLYCERIN, BENZOPHENONE-4, MANNITOL, CELLULOSE, HYDROXYPROPYL METHYLCELLULOSE, TOCOPHERYL ACETATE, ISOPROPYL PALMITATE, IRON OXIDES (CI 77491), RED 4 (CI 14700), BLUE 1 (CI 42090), YELLOW 5 (CI 19140), RED 33 (CI 17200).

QUESTIONS OR COMMENTS?

1-888-423-0139

LABEL COPY





2 FL OZ (59mL)

TOPCARE APPLE POMEGRANATE

ethyl alcohol liquid

Product Information

Product Type

HUMAN OTC DRUG

Item Code (Source)

NDC:36800-262

Route of Administration

TOPICAL

Active Ingredient/Active Moiety

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

Basis of Strength

Strength

ALCOHOL (UNII: 3

ALCOHOL

 $620\ mg\ in\ 1\ mL$

Inactive	Ingredients	
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Ingredient Name	Strength
WATER (UNII: 059QF0KO0R)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
CARBOMER 934 (UNII: Z135WT9208)	
GLYCERIN (UNII: PDC6 A3C0 OX)	
SULISOBENZONE (UNII: 1W6L629B4K)	
MANNITOL (UNII: 3OWL53L36A)	
PO WDERED CELLULO SE (UNII: SMD1X3XO9M)	

HYPROMELLOSES (UNII: 3NXW29V3WO)	
.ALPHATO COPHEROL ACETATE (UNII: 9E8X80D2L0)	
ISOPROPYL PALMITATE (UNII: 8 CRQ2TH63M)	
FERRIC OXIDE RED (UNII: 1K09F3G675)	
FD&C RED NO. 4 (UNII: X3W0 AM1JLX)	
FD&C BLUE NO. 1 (UNII: H3R47K3TBD)	
FD&C YELLOW NO. 5 (UNII: I753WB2F1M)	
D&C RED NO. 33 (UNII: 9DBA0SBB0L)	

]	Packaging			
7	# Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:36800-262-02	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	03/18/2013	

Labeler - TOPCO ASSOCIATES LLC (006935977)

Registrant - APOLLO HEALTH AND BEAUTY CARE (201901209)

Establishment				
Name	Address	ID/FEI	Business Operations	
APOLLO HEALTH AND BEAUTY CARE		201901209	manufacture(36800-262)	

Revised: 3/2013 TOPCO ASSOCIATES LLC