TOPCARE VITAMIN E- 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 70% V/V

PURPOSE

ANTISEPTIC

USES

TO HELP REDUCE 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 THOROUGHLY WITH WATER

STOP USE AND ASK A DOCTOR IF

IRRITATION OR REDNESS DEVELOP AND LAST

KEEP OUT OF REACH OF CHILDREN

IN CASE OF ACCIDENTAL INGESTION, GET MEDICAL HELP OR CONTACT A POISON CONTROL CENTER IMMEDIATELY

DIRECTIONS

PUT ENOUGH PRODUCT IN YOUR PALM TO COVER HANDS AND RUB HANDS TOGETHER UNTIL DRY. CHILDREN UNDER 6 YEARS SHOULD BE SUPERVISED WHEN USING THIS PRODUCT

OTHER INFORMATION

STORE AT A TEMPERATURE BELOW 110°F (43°C). MAY DISCOLOR SOME FABRICS OR SURFACES

INACTIVE INGREDIENTS

WATER (AQUA), ISOPROPYL ALCOHOL, ETHYLHEXYLGLYCERIN, GLYCERIN, ISOPROPYL MYRISTATE, PROPYLENE GLYCOL, TOCOPHERYL ACETATE, ACRYLATES/C10-30 ALKYL ACRYLATE CROSSPOLYMER, AMINOMETHYL PROPANOL, FRAGRANCE (PARFUM)

QUESTIONS OR COMMENTS?

1-888-423-0139

LABEL COPY





TOPCARE VITAMINE

ethyl alcohol liquid

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Pro	duct	Into	mation

Product Type HUMAN OTC DRUG Item Code (Source) NDC:36800-078

Route of Administration TOPICAL

Active Ingredient/Active Moiety

Ingredient NameBasis of StrengthStrengthALCOHOL (UNII: 3K9958 V90M) (ALCOHOL - UNII:3K9958 V90M)ALCOHOL700 mg in 1 mL

Inactive Ingredients	
Ingredient Name	Strength
WATER (UNII: 059QF0KO0R)	
ISOPROPYL ALCOHOL (UNII: ND2M416302)	
ETHYLHEXYLGLYCERIN (UNII: 147D247K3P)	
GLYCERIN (UNII: PDC6 A3C0 OX)	
ISOPROPYL MYRISTATE (UNII: 0 RE8K4LNJS)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	

.ALPHATO COPHERO L ACETATE (UNII: 9E8X80D2L0)	
CARBOMER COPOLYMER TYPE A (ALLYL PENTAERYTHRITOL CROSSLINKED) (UNII: 71DD5V995L)	
AMINOMETHYLPROPANOL (UNII: LU49E6626Q)	

Packaging			
# Item Code	Package Description	Marketing Start Date	Marketing End Date
1 NDC:36800-078-02	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	12/26/2013	

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(36800-078)

Revised: 12/2013 TOPCO ASSOCIATES LLC