CARE ONE VANILLA APPLE BLOSSOM- 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 FOM 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), FRAGRANCE (PARFUM), CARBOMER, AMINOMETHYL PROPANOL, ISOPROPYL ALCOHOL, GLYCERIN, PROPYLENE GLYCOL, BENZOPHENONE-4, MANNITOL, CELLULOSE, TOCOPHERYL ACETATE, RETINYL PALMITATE, HYDROXYPROPYL METHYLCELLULOSE, TITANIUM DIOXIDE (CI 77891), RED 33 (CI 17200), YELLOW 5 (CI 19140), BLUE 1 (CI 42090).

LABEL COPY



Drug Facts

Active ingredient Ethyl Alcohol 65% Purpose.... Antiseptic

Usas • To decrease bacteria on the skin.

Warnings

develops and lasts.

For external use only.
Flammable. Keep away
from source of heat or fire.

When using this product a avoid contact with eyes. If contact occurs, rinse with

Step using this product and ask doctor if a irritation or redness

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 (Aqua), Fragrance (Parfum), Carbomer, Aminomethyl Propanol, Isopropyl Alcohol, Glycerin, Propylene Glycol, Benzophenone-4, Mannitol, Cellulosa, Tocopheryl Acetate, Retinyl Palmitate, Hydroxypropyl Methylcellulose, Titanium Dioxide (Ci 77891), Red 33 (Ci 17200), Yellow 5 (Ci 19140), Blue 1 (Ci 42090).

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

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05-18447

CARE ONE VANILLA APPLE BLOSSOM

ethyl alcohol liquid

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:41520-476
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)		
CARBOMER 934 (UNII: Z135WT9208)		
AMINOMETHYLPROPANOL (UNII: LU49E6626Q)		
ISOPROPYL ALCOHOL (UNII: ND2M416302)		
GLYCERIN (UNII: PDC6A3C0OX)		
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)		
SULISOBENZONE (UNII: 1W6L629B4K)		
MANNITOL (UNII: 30WL53L36A)		
POWDERED CELLULOSE (UNII: SMD1X3XO9M)		
.ALPHATO CO PHERO L ACETATE (UNII: 9E8X80D2L0)		
VITAMIN A PALMITATE (UNII: 1D1K0 N0 VVC)		
HYPROMELLOSES (UNII: 3NXW29V3WO)		
TITANIUM DIO XIDE (UNII: 15FIX9 V2JP)		
D&C RED NO. 33 (UNII: 9DBA0SBB0L)		
FD&C YELLOW NO. 5 (UNII: I753WB2F1M)		
FD&C BLUE NO. 1 (UNII: H3R47K3TBD)		

P	ackaging			
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:41520-476-09	259 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	02/06/2013	

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(41520-476)	