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).





Drug Facts

Active ingredient

Purpose

Ethyl Alcohol 65 %..

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 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, Cellulose, Tocopheryl Acetate, Retinyl Palmitate, Hydroxypropyl Methylcellulose, Titanium Dioxide (Cl 77891), Red 33 (Cl 17200), Yellow 5 (Cl 19140), Blue 1 (Cl 42090)

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

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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 COPHERO L ACETATE (UNII: 9E8 X80 D2L0)	
VITAMIN A PALMITATE (UNII: 1D1K0 N0 VVC)	
HYPROMELLOSES (UNII: 3NXW29 V3WO)	
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)	

Packaging						
#	Item Code	Package Description	Marketing Start Date	Marketing End Date		
1	NDC:41520-476-02	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	02/14/2013				

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)		

Revised: 2/2013 AMERICAN SALES COMPANY