CARE ONE INSTANT SANITIZER- 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.

ACTIVE INGREDIENT

ETHYL ALCOHOL 70%

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 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

- 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, PROPYLENE GLYCOL, GLYCERIN, ISOPROPYL MYRISTATE, TOCOPHERYL ACETATE, ACRYLATES/C10-30 ALKYL ACRYLATE CROSSPOLYMER, AMINOMETHYL PROPANOL, FRAGRANCE (PARFUM), ETHYLHEXYLGLYCERIN, RED 4 (CI 14700), YELLOW 5 (ci 19140)

LABEL COPY





CARE ONE INSTANT SANITIZER

ethyl alcohol liquid

Product Information

Product Type HUMAN OTC DRUG Item Code (Source) NDC:41520-042

Route of Administration TOPICAL

Active Ingredient/Active Moiety				
Ingredient Name	Basis of Strength	Strength		
ALCOHOL (UNII: 3K9958 V90M) (ALCOHOL - UNII:3K9958 V90M)	ALCOHOL	700 mg in 1 mL		

Inactive Ingredients	
Ingredient Name	Strength
WATER (UNII: 059QF0KO0R)	
ISOPROPYL ALCOHOL (UNII: ND2M416302)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
GLYCERIN (UNII: PDC6A3C0OX)	
ISOPROPYL MYRISTATE (UNII: 0 RE8 K4LNJS)	
.ALPHATO COPHEROL ACETATE (UNII: 9E8X80D2L0)	
CARBOMER COPOLYMER TYPE A (ALLYL PENTAERYTHRITOL CROSSLINKED) (UNII: 71DD5V995L)	
METHACRYLIC ACID - METHYL METHACRYLATE COPOLYMER (1:1) (UNII: 74G4R6TH13)	
AMINO METHYLPRO PANO L (UNII: LU49 E6626Q)	
ETHYLHEXYLGLYCERIN (UNII: 147D247K3P)	
FD&C RED NO. 4 (UNII: X3W0 AM1JLX)	
FD&C YELLOW NO. 5 (UNII: I753WB2F1M)	

Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:41520-042- 08	236 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product		

Marketing Information					
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date		
OTC monograph not final	part333E	05/28/2015			

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(41520-042)	

Revised: 5/2015 AMERICAN SALES COMPANY