

CANDY APPLE - ethyl alcohol gel
Shanghai Weierya Daily Chemicals Factory

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

Inactive Ingredients

carbomer 940, PEG-12
dimethicone, tocopheryl
acetate, triethanolamine,
blue 1, water

Active Ingredient

Ethyl Alcohol, 65 % v/v

Purpose Antimicrobial

Uses

hand sanitizer to help
reduce bacteria on skin

Do not use in or near the eyes.

In case of contact, rinse eyes
thoroughly with water.

Stop use and ask a doctor if

irritation, excessive redness
or rash develops.

Keep out of reach of children.

If swallowed, get medical help or contact a Poison
Control Center right away.

Directions

Put a dime sized drop onto hands
and rub together briskly until dry.

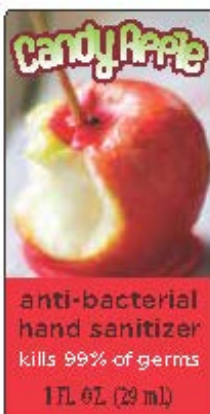
Other information

Store below 110 F (43 C)

Warning

For external use only

Flammable, keep away from fire or flame.



CANDY APPLE

ethyl alcohol gel

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:58194-012
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
ALCOHOL (UNII: 3K9958V90M) (ALCOHOL - UNII:3K9958V90M)	ALCOHOL	65 mL in 100 mL

Inactive Ingredients

Ingredient Name	Strength
CARBOMER HOMOPOLYMER TYPE C (ALLYL PENTAERYTHRITOL CROSSLINKED) (UNII: 4Q93RCW27E)	
PEG-12 DIMETHICONE (300 CST) (UNII: ZEL54N6W95)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
.ALPHA.-TOCOPHEROL ACETATE (UNII: 9E8X80D2L0)	
TROLAMINE (UNII: 9O3K93S3TK)	
FD&C BLUE NO. 1 (UNII: H3R47K3TBD)	
WATER (UNII: 059QF0K00R)	

Product Characteristics

Color		Score	
Shape		Size	
Flavor	APPLE (candy apple)	Imprint Code	
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:58 194-012-01	29 mL in 1 BOTTLE		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part333A	06/01/2014	

Labeler - Shanghai Weiyerya Daily Chemicals Factory (420359333)

Establishment

Name	Address	ID/FEI	Business Operations
Shanghai Weiyerya Daily Chemicals Factory		420359333	manufacture(58194-012)

Revised: 6/2014

Shanghai Weiyerya Daily Chemicals Factory