

**CUPCAKE - 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.



## CUPCAKE

ethyl alcohol gel

### Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:58194-014
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

<b>Color</b>		<b>Score</b>	
<b>Shape</b>		<b>Size</b>	
<b>Flavor</b>	CUSTARD (cupcake)	<b>Imprint Code</b>	
<b>Contains</b>			

### Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:58 194-014-01	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(58194-014)

Revised: 6/2014

Shanghai Weiyerya Daily Chemicals Factory