## MODESA - 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.

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## **Drug Facts**

**Inactive Ingredients** carbomer 940, glycerin, propylene glycol, red 33, tocopheryl acetate, triethanolamine, water **Active Ingredient** Ethyl Alcohol 65 % v/v Purpose Antimicrobial Warnings For external use only. Keep out of reach of children. If swallowed, get medical help or contact a Poison Control Center right away. Uses hand sanitizer to reduce bacteria on skin Directions Put a dime sized drop onto hands and rub briskly until dry. 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. Flammable. Keep away from fire or flame. Other Information Store below 110 F (43 C)



Product Information Item Code (Source) NDC:58194-∪1   Product Type HUMAN OTC DRUG Item Code (Source) NDC:58194-∪1   Route of Administration TOPICAL NDC:58194-U1 NDC:58194-U1   Active Ingredient/Active Moiser Strength Strength   Active Ingredient/Active Moiser Strength Strength   Active Ingredient/Active Moiser Strength Strength   AlcOHOL (UNII: 3K9958V90M) (AL UNII: 3K9958V90M) AlcOHOL - UNII: 3K9958V90M) (AL UNII: 3K9958V90M) Strength   Inactive Ingredients Ingredient Name Strength Strength   CARBOMER HOMOPOLYMER TYPE (ALLYL PENTAERYTHRITUE UNII: 4Q93RUUII: 4Q93RUUII: 4Q93RUUII: PDC6A3C00X) Strength Strength	MODESA						
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Active Ingredient/Active Moiety    Active Ingredient/Active Moiety Basis of Strength Strength   Alcohol (UNII: 3K9958V90M) (Alcohol - UNII:3K9958V90M) Alcohol 65 ml in 100 ml   Alcohol (UNII: 3K9958V90M) (Alcohol - UNII:3K9958V90M) Alcohol 65 ml in 100 ml   Inactive Ingredients Strengt   Ingredient Name Streng   GARBOMER HOMOPOLYMER TYPE C (ALLYL PENTAERYTHRITOL CROSSINKED) (UNII: 4Q93RCWIT) 5	Product T ype	HUMAN OTC DRUG	Item Code	(Source)	NDC:58194	-021	
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Ingredient Name Basis of Strength Strength   ALCOHOL (UNII: 3K9958V90M) (ALCOHOL - UNII:3K9958V90M) ALCOHOL 65 mL i 10 mL   Inactive Ingredients Strength Strength   CARBOMER HOMOPOLYMER TYPE C (ALLYL PENTAERYTHRITOL CROSSLINKED) (UNII: 4Q93RCW27E) Strength   GLYCERIN (UNII: PDC6A3C0OX) Strength Strength							
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GLYCERIN (UNII: PDC6A3C0OX)	Ing	redient Name		<u> </u>		-	
	Ing ALCOHOL (UNII: 3K9958V90M) (A	redient Name ALCOHOL - UNII:3K9958V90M)		<u> </u>		-	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	Ing ALCOHOL (UNII: 3K9958V90M) (A Inactive Ingredients	redient Name ALCOHOL - UNII:3K9958V90M) Ingredient Name		ALCOHOL	65 mL i	n 100 mL	
	Ing ALCOHOL (UNII: 3K9958V90M) (A Inactive Ingredients CARBOMER HOMOPOLYMER TY	redient Name ALCOHOL - UNII:3K9958V90M) Ingredient Name		ALCOHOL	65 mL i	n 100 mL	
D&C RED NO.33 (UNII: 9DBA0SBB0L)	Ing a ALCOHOL (UNII: 3K9958V90M) (A Inactive Ingredients CARBOMER HOMOPOLYMER TY GLYCERIN (UNII: PDC6A3C0OX)	redient Name LCOHOL - UNII:3K9958V90M) Ingredient Name PE C (ALLYL PENTAERYTHRIT		ALCOHOL	65 mL i	n 100 mL	
	Ing a ALCOHOL (UNII: 3K9958V90M) (A Inactive Ingredients CARBOMER HOMOPOLYMER TY GLYCERIN (UNII: PDC6A3C0OX) PROPYLENE GLYCOL (UNII: 6DC	redient Name ALCOHOL - UNII:3K9958V90M) Ingredient Name PE C (ALLYL PENTAERYTHRIT 9Q167V3)		ALCOHOL	65 mL i	n 100 mL	
.ALPHATO COPHEROL ACETATE (UNII: 9E8X80D2L0)	Ing a ALCOHOL (UNII: 3K9958V90M) (A Inactive Ingredients CARBOMER HOMOPOLYMER TY GLYCERIN (UNII: PDC6A3C0OX) PROPYLENE GLYCOL (UNII: 6DC D&C RED NO.33 (UNII: 9DBA0SB)	redient Name LCOHOL - UNII:3K9958V90M) Ingredient Name PE C (ALLYL PENTAERYTHRIT 9Q167V3) 30L)		ALCOHOL	65 mL i	n 100 mL	
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.ALPHATO COPHEROL ACETATE (UNII: 9E8X80D2L0)	Ing ALCOHOL (UNII: 3K9958V90M) (A Inactive Ingredients CARBOMER HOMOPOLYMER TY GLYCERIN (UNII: PDC6A3C0OX) PROPYLENE GLYCOL (UNII: 6DC D&C RED NO. 33 (UNII: 9DBA0SB) ALPHATOCOPHEROL ACETAT	redient Name LCOHOL - UNII:3K9958V90M) Ingredient Name PE C (ALLYL PENTAERYTHRIT 9Q167V3) 30L)		ALCOHOL	65 mL i	n 100 mL	

Packaging					
# Item Code	Package Description	Marketing	Start Date	Ma	rketing End Date
<b>1</b> NDC:58194-021-01	29 mL in 1 BOTTLE				
Marketing Infor	mation				
Marketing Category	Application Number or Monog	raph Citation	Marketing Start	Date	Marketing End Date
OTC monograph not final	part333A		09/01/2014		

Labeler - Shanghai Weierya Daily Chemicals Factory (420359333)

## Establishment

Name	Address	ID/FEI	Business Operations
Shanghai Weierya Daily Chemicals Factory		420359333	manufacture(58194-021)

Revised: 1/2015

Shanghai Weierya Daily Chemicals Factory