

**WE CLEAN HAND SANITIZER CARAMEL APPLE- alcohol liquid**  
**WeCool Toys**

*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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**Active Ingredient(s)**

Alcohol 62% v/v. Purpose: Antiseptic

**Purpose**

Antiseptic, Hand Sanitizer

**Use**

Hand Sanitizer to help reduce bacteria that potentially can cause disease. For use when soap and water are not available.

**Warnings**

For external use only. Flammable. Keep away from heat or flame

**Do not use**

- in children less than 2 months of age
- on open skin wounds

When using this product keep out of eyes, ears, and mouth. In case of contact with eyes, rinse eyes thoroughly with water.

Stop use and ask a doctor if irritation or rash occurs. These may be signs of a serious condition.

Keep out of reach of children. If swallowed, get medical help or contact a Poison Control Center right away.

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Keep out of reach of children. If swallowed, get medical help or contact a Poison Control Center right away.

**Directions**

- Place enough product on hands to cover all surfaces. Rub hands together until dry.
- Supervise children under 6 years of age when using this product to avoid swallowing.

**Other information**

- Store between 15-30C (59-86F)
- Avoid freezing and excessive heat above 40C (104F)

**Inactive ingredients**

Acrylates/C10-30 alkyl acrylate crosspolymer

Amyl cinnamal

Ascorbyl palmitate

Blue 1 (CI 42090)

Butylphenyl methylpropional

Cellulose

Deionized water

Fragrance - Caramel Apple

Glycerin

Hydroxypropyl methylcellulose

Jjoba esters

Lactose

Tocopheryl acetate

Triethanolamine

Ultramarines (CI 77492)

Yellow 5 (CI 19140)

**Package Label - Principal Display Panel**

250 mL NDC: 77006-034-01

- Die line
- Pump: PMS 4625 C
- Gel: PMS 7427 C
- Beads: PMS 186 C

Need Printer Guidance  
Print Burst at 85% and fade to clear.

215X90MM

**DRUG FACTS**

ACTIVE INGREDIENT(S)	Purpose
Ethyl Alcohol 62% v/v	Antiseptic

**USE(S):** helps eliminate bacteria on hands

**WARNINGS:**  
• For external use only • Flammable, keep away from heat or flame

**DO NOT USE**  
• On children less than 2 months of age • On open skin wounds

**WHEN USING THIS PRODUCT:** keep out of eyes, ears, and mouth. In case of contact with eyes, rinse eyes thoroughly with water.

**STOP USE AND ASK A DOCTOR** if irritation or rash occurs. These may be a sign of a serious condition.

**KEEP OUT OF REACH OF CHILDREN,** except under adult supervision. If swallowed, get medical help or contact a Poison Control Center right away.

**DIRECTIONS**  
• Place enough product on hands to cover all surfaces.  
• Rub hands together until dry.  
• Supervise children under 6 years of age when using this product to avoid swallowing.

**Other Information**  
• Store between 15-30C (59-86F)  
• Avoid freezing and excessive heat above 40C (104F)

**INACTIVE INGREDIENTS:**  
Acrylates/C10-30 alkyl acrylate copolymer, Acetyl palmitate, Amyl cinnamal, Blue 1 (CI 42090), Cellulose, G1796L, Fragrance (Parfum), Glycerin, Hydroxypropyl methylcellulose, Jojoba Esters, Lactose, Red 33 (CI 17200), Red 40 (CI 14700), Triethanolamine, Tocopheryl acetate, Water(Aqua).

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## WE CLEAN HAND SANITIZER CARAMEL APPLE

alcohol liquid

### Product Information

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:77006-034
<b>Route of Administration</b>	TOPICAL		

### Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
<b>ALCOHOL</b> (UNII: 3K9958V90M) (ALCOHOL - UNII:3K9958V90M)	ALCOHOL	58.36 g in 100 mL

### Inactive Ingredients

Ingredient Name	Strength
<b>GLYCERIN</b> (UNII: PDC6A3C0OX)	
<b>HYPROMELLOSE 2208 (100 MPA.S)</b> (UNII: B1QE5P712K)	
<b>.ALPHA.-TOCOPHEROL ACETATE</b> (UNII: 9E8X80D2L0)	
<b>ASCORBYL PALMITATE</b> (UNII: QN83US2B0N)	
<b>FERRIC OXIDE YELLOW</b> (UNII: EX43802MRT)	
<b>HYDROLYZED JOJOBA ESTERS (POTASSIUM SALTS)</b> (UNII: CH428W5O62)	
<b>DISODIUM N-ETHYL-N-4-((4-(ETHYL((3-SULFOPHENYL)METHYL)AMINO)PHENYL)(2-SULFOPHENYL)METHYLENE)-2,5-CYCLOHEXADIEN-1-YLIDENE)-3-SULFOBENZENEMETHANAMINIUM</b> (UNII: PPQ093M8HR)	

<b>.ALPHA.-AMYL CINNAMALDEHYDE</b> (UNII: WC51CA3418)	
<b>BUTYLPHENYL METHYLPROPIONAL</b> (UNII: T7540GJV69)	
<b>DRY BIOCELLULOSE (MW 2000000)</b> (UNII: C8DF2GF8L2)	
<b>WATER</b> (UNII: 059QF0K00R)	
<b>TROLAMINE</b> (UNII: 9O3K93S3TK)	
<b>ANHYDROUS LACTOSE</b> (UNII: 3SY5LH9PMK)	
<b>FD&amp;C YELLOW NO. 5</b> (UNII: I753WB2F1M)	
<b>POLYACRYLIC ACID (250000 MW)</b> (UNII: 9G2MAD7J6W)	

### Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:77006-034-01	250 mL in 1 BOTTLE, PUMP; Type 0: Not a Combination Product	06/26/2020	

### Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part333A	06/26/2020	

**Labeler** - WeCool Toys (080480202)

**Registrant** - WeCool Toys (080480202)

### Establishment

Name	Address	ID/FEI	Business Operations
Landy		545291775	manufacture(77006-034) , pack(77006-034) , label(77006-034)

Revised: 1/2022

WeCool Toys