

WECLEAN HAND SANITIZER GEL - EUCALYPTUS- alcohol liquid
WeCoolToys, Inc.

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(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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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.

Inactive ingredients

Acrylates/C10-30 alkyl acrylate crosspolymer

Ascorbyl palmitate

Cellulose

Deionized Water

Glycerin

Fragrance - Eucalyptus & Mint

Hydroxypropyl methylcellulose

Jojoba esters

Limonene

Linalool

Lactose

Tocopheryl acetate

Triethanolamine

Ultramarines (CI 77007)

Other information

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

Package Label - Principal Display Panel

1000 mL NDC: 77006-001

1L/34.1 fl. hand sanitizer wrap label



WECLEAN HAND SANITIZER GEL - EUCALYPTUS

alcohol liquid

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:77006-001
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

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

Inactive Ingredients

Ingredient Name	Strength
GLYCERIN (UNII: PDC6A3C0OX)	
TROLAMINE (UNII: 9O3K93S3TK)	
WATER (UNII: 059QF0KO0R)	
ANHYDROUS LACTOSE (UNII: 3SY5LH9PMK)	
ULTRAMARINE BLUE (UNII: I39WR998BI)	
LIMONENE, (+)- (UNII: GFD7C86Q1W)	

LINALOOL, (+/-)- (UNII: D81QY6I88E)	
HYDROLYZED JOJOBA ESTERS (POTASSIUM SALTS) (UNII: CH428W5O62)	
POLYACRYLIC ACID (250000 MW) (UNII: 9G2MAD7J6W)	
DRY BIOCELLULOSE (MW 2000000) (UNII: C8DF2GF8L2)	
ASCORBYL PALMITATE (UNII: QN83US2B0N)	
HYMPROMELLOSE 2208 (100 MPA.S) (UNII: B1QE5P712K)	
ALPHA-TOCOPHEROL ACETATE (UNII: 9E8X80D2L0)	

Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:77006-001-01	60 mL in 1 BOTTLE; Type 0: Not a Combination Product	05/14/2020	
2	NDC:77006-001-02	30 mL in 1 BOTTLE; Type 0: Not a Combination Product	05/08/2020	
3	NDC:77006-001-03	248.4 mL in 1 BOTTLE, PUMP; Type 0: Not a Combination Product	05/08/2020	
4	NDC:77006-001-04	1010 mL in 1 BOTTLE, PUMP; Type 0: Not a Combination Product	05/08/2020	

Marketing Information			
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part333A	05/08/2020	

Labeler - WeCoolToys, Inc. (080480202)

Registrant - WeCool Toys, Inc. (080480202)

Establishment			
Name	Address	ID/FEI	Business Operations
Landy International		545291775	manufacture(77006-001) , pack(77006-001) , label(77006-001)