

WE CLEAN HAND SANITIZER ROASTED MARSHMALLOW- 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.

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.

Other information

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

Inactive ingredients

Acrylates/C10-30 alkyl acrylate crosspolymer

Ascorbyl palmitate

Benzyl salicylate

Blue 1 (CI 42090)

Cellulose

Coumarin

Deionized water

Fragrance - Roasted Marshmallow

Glycerin

Hydroxypropyl methylcellulose

Jjoba esters

Lactose

Red 33 (CI 17200)

Tocopheryl acetate

Triethanolamine

Yellow 5 (CI 19140)

Package Label - Principal Display Panel

250 mL NDC: 770006-031-01

- Die line
- Pump: PMS 4625 C
- Gel: PMS 465 C
- Beads: White

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



WE CLEAN HAND SANITIZER ROASTED MARSHMALLOW

alcohol liquid

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:77006-031
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
ASCORBYL PALMITATE (UNII: QN83US2B0N)	
D&C RED NO. 33 (UNII: 9DBA0SBB0L)	
BENZYL SALICYLATE (UNII: WAO5MNK9TU)	
FD&C YELLOW NO. 5 (UNII: I753WB2F1M)	
TROLAMINE (UNII: 9O3K93S3TK)	
DRY BIOCELLULOSE (MW 2000000) (UNII: C8DF2GF8L2)	
HYPROMELLOSE 2208 (100 MPA.S) (UNII: B1QE5P712K)	
.ALPHA.-TOCOPHEROL ACETATE (UNII: 9E8X80D2L0)	
COUMARIN (UNII: A4VZ22K1WT)	

WATER (UNII: 059QF0KO0R)	
HYDROLYZED JOJOBA ESTERS (POTASSIUM SALTS) (UNII: CH428W5O62)	
GLYCERIN (UNII: PDC6A3C0OX)	
DISODIUM N-ETHYL-N-4-((4-(ETHYL((3-SULFOPHENYL)METHYL)AMINO)PHENYL)(2-SULFOPHENYL)METHYLENE)-2,5-CYCLOHEXADIEN-1-YLIDENE)-3-SULFOBENZENEMETHANAMINIUM (UNII: PPQ093M8HR)	
POLYACRYLIC ACID (250000 MW) (UNII: 9G2MAD7J6W)	
ANHYDROUS LACTOSE (UNII: 3SY5LH9PMK)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:77006-031-01	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(77006-031) , label(77006-031) , pack(77006-031)

Revised: 1/2022

WeCool Toys