

WECLEAN FOAM HAND SANITIZER EUCALYPTUS- benzalkonium chloride liquid

WeCool Toys, 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)

Benzalkonium chloride: 0.20% 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.

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

Deionized water

Didecyldimonium chloride

Glycerin

FD&C Blue 1

FD&C Yellow 5

Fragrance - Eucalyptus & Mint

Limonene

Linalool

PEG-40 hydrogenated castor oil

Polyaminopropyl biguanide

Package Label - Principal Display Panel

NDC: 77006-002

50ml (1.75oz) foaming hand sanitizer / size:112*58mm



front

back

250ml (8.45oz) hand sanitizer wrap label / size:174*100mm



Front

Back

WECLEAN FOAM HAND SANITIZER EUCALYPTUS

benzalkonium chloride liquid

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:77006-002
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety				
Ingredient Name			Basis of Strength	Strength
BENZALKONIUM CHLORIDE (UNII: F5UM2KM3W7) (BENZALKONIUM - UNII: 7N6JUD5X6Y)			BENZALKONIUM CHLORIDE	200 mg in 100 mL
Inactive Ingredients				
Ingredient Name				Strength
PEG-50 HYDROGENATED CASTOR OIL (UNII: R07D3A9614)				
DIDECYLDIMONIUM CHLORIDE (UNII: JXN40O9Y9B)				
LIMONENE, (+)- (UNII: GFD7C86Q1W)				
LINALOOL, (+/-)- (UNII: D81QY6I88E)				
GLYCERIN (UNII: PDC6A3C0OX)				
WATER (UNII: 059QF0KO0R)				
POLIHEXANIDE HYDROCHLORIDE (UNII: 4XI6112496)				
DISODIUM N-ETHYL-N-4-((4-(ETHYL((3-SULFOPHENYL)METHYL)AMINO)PHENYL)(2-SULFOPHENYL)METHYLENE)-2,5-CYCLOHEXADIEN-1-YLIDENE)-3-SULFOBENZENEMETHANAMINIUM (UNII: PPQ093M8HR)				
FD&C YELLOW NO. 5 (UNII: I753WB2F1M)				
Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:77006-002-01	50 mL in 1 BOTTLE; Type 0: Not a Combination Product	03/30/2020	
2	NDC:77006-002-02	250 mL in 1 BOTTLE, PUMP; Type 0: Not a Combination Product	03/30/2020	
Marketing Information				
Marketing Category		Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final		part333E	03/30/2020	

Labeler - WeCool Toys, Inc. (080480202)

Registrant - WeCool Toys, Inc. (080480202)

Establishment

Name	Address	ID/FEI	Business Operations
Landy International		545291775	manufacture(77006-002) , label(77006-002) , pack(77006-002)