

CRAZY CLEAN HAND SANITIZER - BERRY SWIRL- alcohol 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)

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

Ascorbyl palmitate

Cellulose

Deionized Water

Fragrance - Blueberry

Glycerin

Hydroxypropyl methylcellulose

Jobba esters

Lactose

Tocopheryl acetate

Triethanolamine

Ultramarines (CI 77007)

Package Label - Principal Display Panel

975 mL NDC: 77006-013

247x155mm



DRUG FACTS	
ACTIVE INGREDIENT(S)	Purpose
Ethyl Alcohol 62% w/v	Antiseptic
USE(S) : helps reduce 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. 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/10-30 Alkyl Acrylate Copolymer, Ascorbyl Palmitate, Blue 1 (4090), Cellulose, Fragrance (Parfum), Glycerin, Hydroxypropyl Methylcellulose, Jojoba Esters, Lactose, Limonene, Lindool, Red 33 (17200), Tocopheryl Acetate, Triethanolamine, Ultramarines (17700), Water (aqua)	

CRAZY CLEAN HAND SANITIZER - BERRY SWIRL

alcohol liquid

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:77006-013
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)	
WATER (UNII: 059QF0KO0R)	
TROLAMINE (UNII: 903K93S3TK)	
ASCORBYL PALMITATE (UNII: QN83US2B0N)	
HYDROLYZED JOJOBA ESTERS (POTASSIUM SALTS) (UNII: CH428W5O62)	
POLYACRYLIC ACID (250000 MW) (UNII: 9G2MAD7J6W)	

ANHYDROUS LACTOSE (UNII: 3SY5LH9PMK)	
DRY BIOCELLULOSE (MW 2000000) (UNII: C8DF2GF8L2)	
HYPROMELLOSE 2208 (100 MPA.S) (UNII: B1QE5P712K)	
ULTRAMARINE BLUE (UNII: I39WR998BI)	
.ALPHA.-TOCOPHEROL ACETATE (UNII: 9E8X80D2L0)	

Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:77006-013-03	60 mL in 1 BOTTLE; Type 0: Not a Combination Product	03/30/2020	
2	NDC:77006-013-01	30 mL in 1 BOTTLE; Type 0: Not a Combination Product	03/30/2020	
3	NDC:77006-013-02	249 mL in 1 BOTTLE, PUMP; Type 0: Not a Combination Product	03/30/2020	
4	NDC:77006-013-04	975 mL in 1 BOTTLE, PUMP; Type 0: Not a Combination Product	07/23/2020	

Marketing Information			
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part333A	03/30/2020	

Labeler - WeCool Toys, Inc. (080480202)

Registrant - WeCool Toys, Inc. (080480202)

Establishment			
Name	Address	ID/FEI	Business Operations
Landy International		545291775	manufacture(77006-013) , label(77006-013) , pack(77006-013)

Revised: 1/2022

WeCool Toys, Inc.