WECLEAN HAND SANITIZER PUMPKIN SWIRL- 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.

Alcohol 62% v/v. Purpose: Antiseptic

Antiseptic, Hand Sanitizer

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

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

- \cdot 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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- · Place enough product on hands to cover all surfaces. Rub hands together until dry.
- \cdot Supervise children under 6 years of age when using this product to avoid swallowing.
- · Store between 15-30C (59-86F)
- · Avoid freezing and excessive heat above 40C (104F)

Acrylates/C10-30 alkyl acrylate crosspolymer

Ascorbyl palmitate

Butylphenyl methylpropional Celluose

Citronellol

Coumarin

Deionized waterGeraniol

Fragrance - Pumpkin swirl scent

GlycerinHexyl cinnamal

Hydroxycitronellal

Hydroxypropyl methylcellulose Jojoba esters Lactose Limonene LinaloolRed 4 (CI 14700)

Tocopheryl acetate Triethanolamine

Yellow 5 (CI 19140)

NDC 77006-030



WECLEAN HAND SANITIZER PUMPKIN SWIRL

alcohol liquid

| Product Information | | | |
|---------------------------------|----------------|--------------------|---------------|
| Product Type | HUMAN OTC DRUG | Item Code (Source) | NDC:77006-030 |
| Route of Administration | TOPICAL | | |
| | | | |
| Active Ingredient/Active Moiety | | | |
| Active myreulent/Active molety | | | |

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

| Inactive Ingredients | |
|---|----------|
| Ingredient Name | Strength |
| TROLAMINE (UNII: 903K93S3TK) | |
| BUTYLPHENYL METHYLPROPIONAL (UNII: T7540GJV69) | |
| FD&C YELLOW NO. 5 (UNII: 1753WB2F1M) | |
| .ALPHAHEXYLCINNAMALDEHYDE (UNII: 7X6O37OK2I) | |
| .BETACITRONELLOL, (S)- (UNII: 8RSY5Y5658) | |
| GERANIOL (UNII: L837108USY) | |
| LINALOOL, (+/-)- (UNII: D81QY6I88E) | |
| WATER (UNII: 059QF0KO0R) | |
| GLYCERIN (UNII: PDC6A3C0OX) | |
| DRY BIOCELLULOSE (MW 2000000) (UNII: C8DF2GF8L2) | |
| HYPROMELLOSE 2208 (100 MPA.S) (UNII: B1QE5P712K) | |
| HYDROLYZED JOJOBA ESTERS (POTASSIUM SALTS) (UNII: CH428W5O62) | |
| HYDROXYCITRONELLAL (UNII: 8SQ0VA4YUR) | |
| LIMONENE, (+)- (UNII: GFD7C86Q1W) | |
| COUMARIN (UNII: A4VZ22K1WT) | |
| .ALPHATOCOPHEROL ACETATE (UNII: 9E8X80D2L0) | |
| FD&C RED NO. 4 (UNII: X3W0AM1JLX) | |
| POLYACRYLIC ACID (250000 MW) (UNII: 9G2MAD7J6W) | |
| ANHYDROUS LACTOSE (UNII: 3SY5LH9PMK) | |

Packaging

| | Date | Date |
|---|------------|------|
| 1 NDC:77006- 030-01250 mL in 1 BOTTLE, PUMP; Type 0: Not a Combination Product06 | 06/26/2020 | |

Marketing Information

| Marketing | Application Number or Monograph | Marketing Start | Marketing End |
|----------------------------|---------------------------------|-----------------|---------------|
| Category | Citation | Date | 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(77006-030) , pack(77006-030) , label(77006-030) |

Revised: 1/2022