

HAND SANITIZER CANDY APPLE- alcohol gel
Lemontree ICS

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.

Hand Sanitizer, Candy Apple

Drug Facts

Active ingredient

Ethyl alcohol 75%

Purpose

Antiseptic

Use

For hand washing to decrease bacteria on the skin

Warnings

For external use only

Flammable, keep away from fire or flame

Do not use

in the eyes

Stop use and ask a doctor if

- irritation and redness develop
- condition persists for more than 72 hours

Keep out of reach of children.

If swallowed, get medical help or contact a Poison Control Center right away.

Directions

Wet hands thoroughly with product and allow to dry without wiping

Other information

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

Inactive ingredients

Ascorbyl Palmitate, Carbomer, Cellulose, Chromium Hydroxide Green, Denatonium Benzoate, D&C Red No. 33, FD&C Red No. 4, FD&C Blue No. 1, Fragrance, Glycerin, Hydroxypropyl Methylcellulose, Jojoba Esters, Lactose, Propylene Glycol, Sodium Hydroxide,

Tocopheryl Acetate, Water.

Package Labeling:



4 multi-layers labels

HAND SANITIZER CANDY APPLE			
alcohol gel			
Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:79834-101
Route of Administration	TOPICAL		
Active Ingredient/Active Moiety			
Ingredient Name		Basis of Strength	Strength
ALCOHOL (UNII: 3K9958V90M) (ALCOHOL - UNII:3K9958V90M)		ALCOHOL	0.75 mL in 1 mL
Inactive Ingredients			
Ingredient Name			Strength
ASCORBYL PALMITATE (UNII: QN83US2B0N)			
CARBOMER HOMOPOLYMER, UNSPECIFIED TYPE (UNII: 0A5MM307FC)			
POWDERED CELLULOSE (UNII: SMD1X3XO9M)			
CHROMIUM HYDROXIDE GREEN (UNII: RV8FT8XF5R)			
DENATONIUM BENZOATE (UNII: 4YK5Z54AT2)			
D&C RED NO. 33 (UNII: 9DBA0SBB0L)			
FD&C RED NO. 4 (UNII: X3W0AM1JLX)			
FD&C BLUE NO. 1 (UNII: H3R47K3TBD)			
GLYCERIN (UNII: PDC6A3C0OX)			
HYPMELLOSE, UNSPECIFIED (UNII: 3NXW29V3WO)			
LACTOSE, UNSPECIFIED FORM (UNII: J2B2A4N98G)			
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)			
SODIUM HYDROXIDE (UNII: 55X04QC32I)			
.ALPHA.-TOCOPHEROL ACETATE (UNII: 9E8X80D2L0)			
WATER (UNII: 059QF0K00R)			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:79834-101-01	30 mL in 1 BOTTLE; Type 0: Not a Combination Product	09/15/2020	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part333E	09/15/2020	

Labeler - Lemontree ICS (117589151)

Revised: 8/2020

Lemontree ICS