HAND SANITIZER VANILLA SUGAR COOKIE- 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, Vanilla Sugar Cookie

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, Green, Denatonium Benzoate, D&C Red No. 33, FD&C Blue No. 1, FD&C Yellow No. 5, Fragrance, Glycerin, Hydroxypropyl Methylcellulose, Jojoba Esters, Lactose, Propylene Glycol, Sodium Hydroxide,

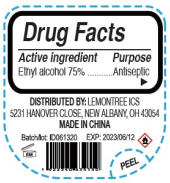
Tocopheryl Acetate, Water.

Package Labeling:

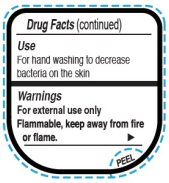
front label

white based label for back side

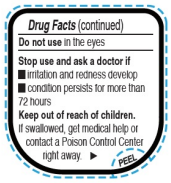
page 1



page 2



page 3



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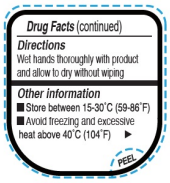

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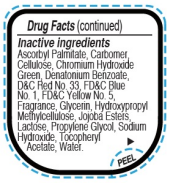
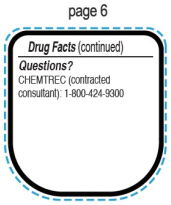


page 6



4 multi-layers labels

HAND SANITIZER VANILLA SUGAR COOKIE

alcohol gel

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:79834-106
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 BLUE NO. 1 (UNII: H3R47K3TBD)	
FD&C YELLOW NO. 5 (UNII: I753WB2F1M)	
GLYCERIN (UNII: PDC6A3C0OX)	
HYPROMELLOSE, UNSPECIFIED (UNII: 3NXW29V3WO)	
LACTOSE, UNSPECIFIED FORM (UNII: J2B2A4N98G)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
SODIUM HYDROXIDE (UNII: 55X04QC32I)	
.ALPHA.-TOCOPHEROL ACETATE (UNII: 9E8X80D2L0)	

WATER (UNII: 059QF0KO0R)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:79834-106-01	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