

HAND SANITIZER BERRY HOLIDAYS- 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, Berry Holidays

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

Carbomer, Denatonium Benzoate, D&C Red No. 33, FD&C Blue No. 1, FD&C Yellow No. 5, Fragrance, Glycerin, Propylene Glycol, Sodium Hydroxide, Water.

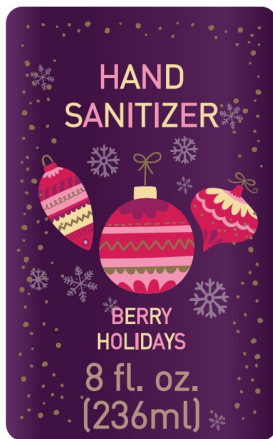
Questions?

CHEMTREC(contracted consultant):1-800-424-9300

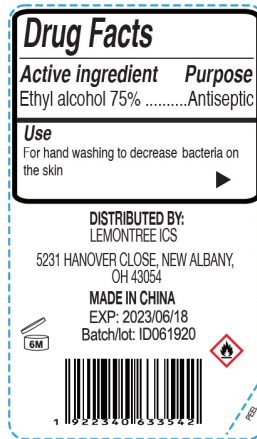
Package Labeling:



front label

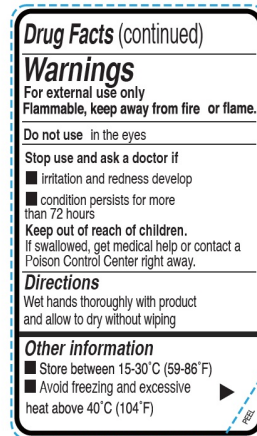


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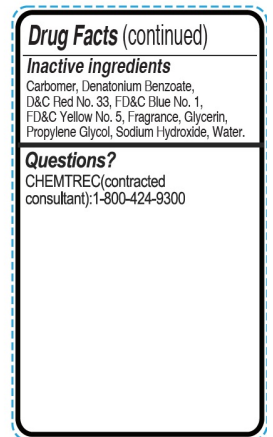


white based label for back side

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2 multi-layers labels

HAND SANITIZER BERRY HOLIDAYS

alcohol gel

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:79834-108
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
CARBOMER HOMO POLYMER, UNSPECIFIED TYPE (UNII: 0A5MM307FC)	
DENATONIUM BENZOATE (UNII: 4YK5Z54AT2)	
D&C RED NO. 33 (UNII: 9DBA0SBB0L)	

FD&C BLUE NO. 1 (UNII: HBR47K3TBD)	
FD&C YELLOW NO. 5 (UNII: I753WB2F1M)	
GLYCERIN (UNII: PDC6A3C0OX)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
SODIUM HYDROXIDE (UNII: 55X04QC32I)	
WATER (UNII: 059QF0KO0R)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:79834-108-08	236 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

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