

LEMON X HAND SANITIZER- alcohol gel

DCI Binzel Chemical Laboratories

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.

LEMON X

Drug Facts

Active Ingredient(s)

Ethyl Alcohol 73% v/v. Purpose: Antiseptic

Antiseptic, Hand Sanitizer

Use

Hand Sanitizer to help reduce bacteria on the skin.

Recommended for repeated use.

Warnings

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

Do not use

- When using this product do not use in or near the eyes.
- In case of contact, rinse eyes thoroughly with water.

Do not drink. Not edible. In case of accidental ingestion, seek professional assistance or contact a Poison Control Center immediately.

Discontinue use if irritation or redness develops. If condition persists for more than 72 hours, consult a doctor.

Keep out of reach of children. Children should only use this product under adult supervision.

Directions

- Place enough product in your palm to thoroughly spread on both hands and rub into the skin until dry.
- Recommended for repeated use.

Other information

- Do not store above 105F.

- May discolor some fabrics.
- Harmful to wood finishes and plastics.

Inactive Ingredients

Deionized water, Glycerin, Carbomer, Triethanolamine, Fragrance, Vitamin E (Tocopheryl Acetate), FD&C Yellow No. 6

Package Label - Principal Display Panel

1 Gallon 128 oz. (3.78L) NDC: 77584-103-01



LEMON X HAND SANITIZER

alcohol gel

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:77584-103
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
ALCOHOL (UNII: 3K9958V90M) (ALCOHOL - UNII:3K9958V90M)	ALCOHOL	73 mL in 100 mL

Inactive Ingredients

Ingredient Name	Strength
FD&C YELLOW NO. 5 (UNII: I753WB2F1M)	0.5 mL in 100 mL

WATER (UNII: 059QF0KO0R)	22 mL in 100 mL
GLYCERIN (UNII: PDC6A3C00X)	1.5 mL in 100 mL
FRAGRANCE LEMON ORC2001060 (UNII: K1725A7G95)	0.5 mL in 100 mL
DENATONIUM BENZOATE (UNII: 4YK5Z54AT2)	0.0001 mL in 100 mL
ALPHA-TOCOPHEROL (UNII: H4N855PNZ1)	1.5 mL in 100 mL
CARBOMER HOMOPOLYMER TYPE A (UNII: F68VH75CJC)	0.75 mL in 100 mL
TRIETHANOLAMINE 2-CYCLOHEXYL-4,6-DINITROPHENOLATE (UNII: N2TK31JIAH)	0.25 mL in 100 mL

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:77584-103-01	3785 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	07/20/2020	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part333A	07/20/2020	

Labeler - DCI Binzel Chemical Laboratories (117517678)

Registrant - DCI Binzel Chemical Laboratories (117517678)

Establishment

Name	Address	ID/FEI	Business Operations
DCI Binzel Chemical Laboratories		117517678	manufacture(77584-103)

Revised: 12/2021

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