

HAND SANITIZER - ITALIAN LEMON AND LIME- alcohol liquid
Phenom Marketing Group, Inc.

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.

Active Ingredient(s)

Alcohol 85% v/v. Purpose: Antiseptic

Benzalkonium Chloride 0.1%. Purpose: Antimicrobial

Purpose

Antiseptic, Antimicrobial

Use

Hand Sanitizer to help reduce bacteria on the skin

Warnings

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

Do not use

- On children under 2 months
- On broken skin

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 and persists

Keep out of reach of children. If swallowed, get medical help

Directions

- Spray product on hands to cover all surfaces
- Rub hands together until dry
- Supervise children under 6 years

Other information

Store below 110F

Inactive ingredients

Fragrance, purified water, vegetable glycerin

Package Label - Principal Display Panel

59 mL NDC: 80038-003-01

ROYCE & BAXTER

Premium Hand Sanitizer Spray

Alcohol Antiseptic 85% With Natural Moisturizer

2.0 FL OZ (59mL)

ITALIAN LEMON & LIME

ROYCE & BAXTER

Premium Hand Sanitizer Spray

Active ingredients	Purpose
Alcohol 85% v/v.....	Antiseptic
Benzalkonium Chloride 0.1%.....	Antimicrobial

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Manufactured By:
Phenom Marketing Group, Inc., Benicia, California, (800) 431-9173
WWW.ROYCEANDBAXTER.COM
NDC:80038-003-01

BATCH
USE BY
8 17190 02149 0

236 mL NDC: 80038-003-02

ROYCE & BAXTER

Premium Hand Sanitizer Spray

Alcohol Antiseptic 85% With Natural Moisturizer

8.0 FL OZ (236mL)

ITALIAN LEMON & LIME

ROYCE & BAXTER

Premium Hand Sanitizer Spray

Active ingredients	Purpose
Alcohol 85% v/v.....	Antiseptic
Benzalkonium Chloride 0.1%.....	Antimicrobial

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NDC:80038-003-02

BATCH
USE BY
8 17190 02150 16

946 mL NDC: 80038-003-03



ROYCE & BAXTER

Premium Hand Sanitizer Spray

Spray Refill

Alcohol Antiseptic 85%
With Natural Moisturizer

32.0 FL OZ (946mL)

ROYCE & BAXTER

Premium Hand Sanitizer Spray

Drug Facts

Active ingredients	Purpose
Alcohol 85% w/v	Antiseptic
Benzalkonium Chloride 0.1%	Antimicrobial

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Warnings

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NDC:80038-003-03

ITALIAN LEMON & LIME

BATCH USE BY

HAND SANITIZER - ITALIAN LEMON AND LIME

alcohol liquid

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:80038-003
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
BENZALKONIUM CHLORIDE (UNII: F5UM2KM3W7) (BENZALKONIUM - UNII: 7N6JUD5X6Y)	BENZALKONIUM CHLORIDE	0.1 g in 100 mL
ALCOHOL (UNII: 3K9958V90M) (ALCOHOL - UNII: 3K9958V90M)	ALCOHOL	85 mL in 100 mL

Inactive Ingredients

Ingredient Name	Strength
GLYCERIN (UNII: PDC6A3C0OX)	0.72 mL in 100 mL
WATER (UNII: 059QF0KO0R)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:80038-003-01	59 mL in 1 BOTTLE, SPRAY; Type 0: Not a Combination Product	10/06/2020	

2	NDC:80038-003-02	236 mL in 1 BOTTLE, SPRAY; Type 0: Not a Combination Product	10/06/2020	
3	NDC:80038-003-03	946 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	10/06/2020	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part333A	10/06/2020	

Labeler - Phenom Marketing Group, Inc. (046354714)

Establishment

Name	Address	ID/FEI	Business Operations
Phenom Marketing Group, Inc.		046354714	manufacture(80038-003)

Revised: 2/2022

Phenom Marketing Group, Inc.