

HAND SANITIZER - ORANGE BLOSSOM- 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: 80038-004-01

ROYCE & BAXTER
Premium Hand Sanitizer Spray
Alcohol Antiseptic 85% With Natural Moisturizer
 2.0 FL OZ (59mL)

ORANGE BLOSSOM

ROYCE & BAXTER

Drug Facts	Purpose
Active ingredients Alcohol 85% v/v.....	Antiseptic
Benzalkonium Chloride 0.1%.....	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	
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Directions • Spray product on hands to cover all surfaces • Rub hands together until dry • Supervise children under 6 years	
Other information Store below 110°F	
Inactive ingredients Fragrance, purified water, vegetable glycerin	

Manufactured By:
Phenom Marketing Group, Inc., Benicia, California, (800) 431-9173
WWW.ROYCEANDBAXTER.COM
NDC:80038-004-01

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BATCH USE BY

236 mL NDC: 80038-004-02

ROYCE & BAXTER
Premium Hand Sanitizer Spray
Alcohol Antiseptic 85% With Natural Moisturizer
 8.0 FL OZ (236mL)

ORANGE BLOSSOM

ROYCE & BAXTER
Premium Hand Sanitizer Spray

Drug Facts	Purpose
Active ingredients Alcohol 85% v/v.....	Antiseptic
Benzalkonium Chloride 0.1%.....	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 110°F	
Inactive ingredients Fragrance, purified water, vegetable glycerin	

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NDC:80038-004-02

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BATCH USE BY

946 mL NDC: 80038-004-03



**ROYCE &
BAXTER**

*Premium
Hand Sanitizer
Spray*

Spray Refill

*Alcohol Antiseptic 8.5%
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

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 110°F

Inactive ingredients Fragrance, purified water, vegetable glycerin



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NDC:80038-004-03

ORANGE BLOSSOM

BATCH USE BY

HAND SANITIZER - ORANGE BLOSSOM

alcohol liquid

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:80038-004
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:80038-004-01	59 mL in 1 BOTTLE, SPRAY; Type 0: Not a Combination Product	10/06/2020	

2	NDC:80038-004-02	236 mL in 1 BOTTLE, SPRAY; Type 0: Not a Combination Product	10/06/2020	
3	NDC:80038-004-03	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(80038-004)

Revised: 2/2022

Phenom Marketing Group, Inc.