

BACTERIA BLASTER- alcohol solution
Port Royal Distillers 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

Alcohol 80% v/v.

Purpose

Antiseptic

Use

Hand Sanitizer to help reduce bacteria that potentially can cause disease. For use when soap and water are not available.

Warnings

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

Do not use

- in children less than 2 months of age
- on open skin wounds

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. These may be signs of a serious condition. Keep out of reach of children. If swallowed, get medical help or contact a Poison Control Center right away.

Stop use and ask a doctor if

irritation or rash occurs. These may be signs of a serious condition.

Keep out of reach of children.

If swallowed, get medical help or contact a Poison Control Center right away.

Directions

- Place enough product on hands to cover all surfaces. Rub hands together until dry.
- Supervise children under 6 years of age when using this product to avoid swallowing.

Other information

- Store between 15-30C (59-86F)
- Avoid freezing and excessive heat above 40C (104F)

Inactive ingredients

glycerin, hydrogen peroxide, purified water USP

Principal Display Panel

NDC 76653-080-01

HAND AND SURFACE SANITIZER

REFILL

BACTERIA BLASTER

80% ALCOHOL

WORLD HEALTH ORGANIZATION APPROVED FORMULA

Fragrance Free

Alcohol Antiseptic 80% Topical Solution

Non-sterile Solution

3780 mL

1 US Gal.

HAND & SURFACE SANITIZER

REFILL

BACTERIA BLASTER

80% Alcohol

 **World Health Organization**
APPROVED FORMULATION

Fragrance Free

Alcohol Antiseptic 80% Topical Solution

3780 mL

1 US Gal.

Non-sterile Solution



World Health Organization

Patient Safety

A World Alliance for Safer Health Care

SAVE LIVES

Clean Your Hands

Drug Facts

Active ingredient[s]	Purpose
Alcohol 80% v/v	Antiseptic

Use[s]

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Bacteria Blaster

PO Box 474 STN Main
Moncton, NB E1C 8L9

BACTERIA BLASTER

alcohol solution

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:76653-080
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
ALCOHOL (UNII: 3K9958V90M) (ALCOHOL - UNII:3K9958V90M)	ALCOHOL	80 mL in 100 mL

Inactive Ingredients

Ingredient Name	Strength
GLYCERIN (UNII: PDC6A3C0OX)	1.45 L in 100 mL
HYDROGEN PEROXIDE (UNII: BBX060AN9V)	0.125 L in 100 mL
WATER (UNII: 059QF0KO0R)	18.425 L in 100 mL

Packaging

#	Item Code	Package Description	Marketing Start	Marketing End

#	Item Code	Package Description	Date	Date
1	NDC:76653-080-01	3780 mL in 1 CONTAINER; Type 0: Not a Combination Product	04/24/2020	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part333A	04/24/2020	

Labeler - Port Royal Distillers Inc. (202611745)

Registrant - Port Royal Distillers Inc. (202611745)

Establishment

Name	Address	ID/FEI	Business Operations
Port Royal Distillers Inc.		202611745	manufacture(76653-080)

Revised: 4/2020

Port Royal Distillers Inc.