

**ANTIFUNGAL- butylated hydroxytoluene soap**  
**PROMAQUILA DE COCULA, S.A. DE C.V.**

*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.*

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**BULK ANTIFUNGAL SOAP**

**ACTIVE INGREDIENT SECTION**

ACTIVE INGREDIENT Butylhydroxytoluene (BHT) .10 %

**PURPOSE**

PURPOSE ANTIFUNGAL

**DOSAGE AND ADMINISTRATION**

**DIRECTIONS**

Wet your hands with clean water take the bar of soap and foam it. Thoroughly rub your hands between fingers all inside and outside surfaces,nails. Rinse your hands with clean water.

**WARNINGS**

**WARNING**

FOR EXTERNAL USE ONLY

**WARNINGS AND PRECAUTIONS**

**WARNINGS AND PRECAUTIONS**

When using this product keep out of eyes, ears, and mouth. In case of contact with eyes, rinse eyes thoroughly with water.

**KEEP OUT OF REACH OF CHILDREN**

KEEP OUT OF REACH OF CHILDREN

**STOP USE SECTION**

Stop use and ask a doctor if irritation or rash occurs. These may be signs of a serious condition.

## **USE**

Use[s]

For washing to decrease bacteria and fungus on skin

## **INACTIVE INGREDIENTS**

### INACTIVE INGREDIENTS

Soap base paste (Sodium Sebate, Sodium Cocoate)

Calcium carbonate

Ethylenediaminetetraacetic Acid  
(EDTA)

Titanium Dioxide

Alcohol Based Garlic Extract, allium sativum l. bulb extract

Glycerin

Sodium lauryl ether sulfate

## **WARNING SECTION**

For external use only.

## **PRINCIPAL DISPLAY PANEL**

# ANTIFUNGAL

## Topical Soap

100 g



### Drug Facts

#### Active ingredient.

Butylhydroxytoluene (BHT)

#### Purpose

Antifungal

#### Use[s]

For washing to decrease bacteria and fungus on skin

#### Warnings

For external use only.

#### Do not use

- in children less than 2 months of age

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.

#### Directions

Wet your hands with clean water take the bar of soap and foam it. Thoroughly rub your hands between fingers all inside and outside surfaces, nails. Rinse your hands with clean water.

#### Other information

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**Inactive ingredients** Soap base paste (Sodium Sebate, Sodium Cocoate), Calcium carbonate, Ethylenediaminetetraacetic Acid (EDTA), Titanium Dioxide, Alcohol Based Garlic Extract, Glycerin, Sodium lauryl ether sulfate

Distributed by

MADE IN MEXICO

NET  
CONTENTS

100 g

## ANTIFUNGAL

butylated hydroxytoluene soap

### Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:79577-9000
Route of Administration	TOPICAL		

### Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
BUTYLATED HYDROXYTOLUENE (UNII: 1P9D0Z171K) (BUTYLATED HYDROXYTOLUENE - UNII:1P9D0Z171K)	BUTYLATED HYDROXYTOLUENE	0.001 g in 1 g

ALCOHOL (UNII: 3K9958V90M) (ALCOHOL - UNII:3K9958V90M)

ALCOHOL

0.001 g  
in 1 g

### Inactive Ingredients

Ingredient Name	Strength
EDETIC ACID (UNII: 9G34HU7RV0)	0.001 g in 1 g
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	0.001 g in 1 g
SODIUM LAURYL SULFATE (UNII: 368GB5141J)	0.018 g in 1 g
GLYCERIN (UNII: PDC6A3C0OX)	0.065 g in 1 g
SODIUM BICARBONATE (UNII: 8MDF5V39QO)	0.8579 g in 1 g
CALCIUM CARBONATE (UNII: H0G9379FGK)	0.046 g in 1 g
GARLIC OIL (UNII: 4WG8U28833)	0.001 g in 1 g

### Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:79577-9000-9	8000 g in 1 BOX; Type 0: Not a Combination Product	06/23/2022	

### Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part333A	06/23/2022	

**Labeler** - PROMAQUILA DE COCULA, S.A. DE C.V. (812760470)

**Registrant** - PROMAQUILA DE COCULA, S.A. DE C.V. (812760470)

### Establishment

Name	Address	ID/FEI	Business Operations
PROMAQUILA DE COCULA, S.A. DE C.V.		812760470	manufacture(79577-9000)

Revised: 6/2022

PROMAQUILA DE COCULA, S.A. DE C.V.