

DERMATOLOGICAL- 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.

DERMATOLOGICAL SOAP

ACTIVE INGREDIENT SECTION

ACTIVE INGREDIENT Butylhydroxytoluene (BHT) .10 %

ALCOHOL

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 Tallowate, Beef, Sodium Cocoate)
Sodium laureth-3 sulfate

Pomegranate & Sunflower Fragrance

Calendula Officinalis Flower
Edetic Acid

WARNING SECTION

For external use only.

PRINCIPAL DISPLAY PANEL

DERMATOLOGICAL

Topical Soap

125 g

Drug Facts	
Active ingredient. Butylhydroxytoluene (BHT)..... Alcohol.....	PurposeAntifungalAntifungal
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 •	
Inactive ingredients Soap base paste (Sodium Tallowate, Sodium Cocoate), Alcohol, Sodium laureth-3 Sulfate, Pomegranate & Sunflowere Fragrance, , Calendula Officinalis Flower, Butylated Hydroxytoluene, Edetic Acid	
Distributed by	
MADE IN MEXICO	
NET CONTENTS 125 g	

DERMATOLOGICAL

butylated hydroxytoluene soap

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:79577-7000
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
ALCOHOL (UNII: 3K9958V90M) (ALCOHOL - UNII:3K9958V90M)	ALCOHOL	0.001 g in 1 g
BUTYLATED HYDROXYTOLUENE (UNII: 1P9D0Z171K) (BUTYLATED	BUTYLATED	0.001 g

Inactive Ingredients

Ingredient Name	Strength
EDETIC ACID (UNII: 9G34HU7RV0)	0.001 g in 1 g
SODIUM TALLOWATE, BEEF (UNII: 07RIK6QMEW)	0.8622 g in 1 g
CALENDULA OFFICINALIS FLOWER (UNII: P0M7O4Y7YD)	0.1 g in 1 g
SODIUM LAURETH-3 SULFATE (UNII: BPV390UAP0)	0.194 g in 1 g
SODIUM COCOATE (UNII: R1TQH25F4I)	0.0957 g in 1 g

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:79577-7000-1	125 g in 1 POUCH; Type 0: Not a Combination Product	05/04/2023	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part333A	05/04/2023	

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(79577-7000)

Revised: 5/2023

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