

GERMICIDA ANTIMICROBIAL- triclosan soap

Laboratorios Roldan, S.A.

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.

Drug Facts

Active Ingredient

Triclosan 2%

Purpose

Antiseptic

Use To decrease bacteria on the skin. Recommended for repeated use.

Warnings For external use only. Do not use • on broken skin • otherwise than as directed.

When using this product • avoid with eyes or on mucous membranes

Stop use and ask a doctor if • condition worsens • irritation or redness develops • if condition persists for more than 3 days

Keep out of the reach of children. If swallowed contact a doctor or Poison Control Center immediately.

Directions Wet skin. Rub bar vigorously over the skin for approximately 2 minutes. Rinse and repeat.

Inactive ingredients Coconut Oil, FDC Blue 1, Phenol, Tallow and titanium dioxide

Package Label

Drug Facts (continue)
Stop use and ask a doctor if: Condition worsens • redness or irritation develops
 • condition persists for more than 3 days.
Keep out of reach of children. If swallowed, contact a doctor or Poison Control Center immediately.
Directions: Wet skin. Rub bar vigorously over the skin for approximately 2 minutes. Rinse and repeat.
Inactive ingredients: Coconut oil, FD&C Blue 1, Phenol, Tallow and Titanium Dioxide.

Información Farmacéutica
Ingrediente Activo **Propósito**
Triclosan 2% **Antiséptico**
Uso: Para disminuir las bacterias en la piel. Es recomendado para uso diario.
Precaución:
 Para uso externo solamente • No use sobre la piel irritada, usarlo en forma recomendada
 Cuando use este producto: Evite el contacto con los ojos y las membranas mucosas.
 Discontinúe su uso y consulte al doctor si: • Las condiciones se empeoran • aparecen irritaciones en la piel • la condición persiste por más de 3 días.
 Manténgase fuera del alcance de los niños • Si es ingerido, entre en contacto con Centro de Control del Veneno o vaya al médico inmediatamente.

Fab. en Rep. Dom. por
ROLDAN
 S.A. de C.A. SUCURSAL
 SAN PABLO DOMINICANA

Información Farmacéutica (Continuación)
Forma de uso: Humedezca la piel, frota con el jabón, hacer espuma, dejar reposar por 2 minutos y luego enjuagar con abundante agua.
Otros ingredientes: Aceite de Coco, Azul FD&C #1, Fenol, Sobo y Dióxido de Titanio.

JABON GERMICIDA ROLDAN

2% Triclosan

JABON GERMICIDA® ROLDAN

ANTIMICROBIAL SOAP
 JABON ANTI-BACTERIANO

Net. Wt. / Peso Neto
 2.63 Oz (75 g)

Reg. Ind. No. 9355
 Reg. San. No. 2006-1303



Made in Dom. Rep. by
ROLDAN
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 SAN PABLO DOMINICANA

Drug Facts
Active ingredient **Purpose**
Triclosan 2% **Antiseptic**
Use: To decrease bacteria on the skin. Recommended for repeat use.
Warnings: For external use only. Do not use on broken skin • otherwise than as directed.
 When using this product, avoid contact with the eyes or on mucous membranes.

GERMICIDA ANTIMICROBIAL

triclosan soap

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:66449-004
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
TRICLOSAN (UNII: 4NM5039Y5X) (TRICLOSAN - UNII:4NM5039Y5X)	TRICLOSAN	2.0 g in 100 g

Inactive Ingredients

Ingredient Name	Strength
COCONUT OIL (UNII: Q9L0O73W7L)	
FD&C BLUE NO. 1 (UNII: HBR47K3TBD)	
PHENOL (UNII: 339NCG44TV)	
BEEF TALLOW (UNII: 98HPY76U4W)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:66449-004-01	75 g in 1 BOX		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part333A	06/30/2012	

Labeler - Laboratorios Roldan, S.A. (871410015)

Establishment

Name	Address	ID/FEI	Business Operations
Laboratorios Roldan, S.A.		871410015	manufacture