

**ANTIBACTERIAL FOAMING - triclosan liquid
H E B**

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 0.46%

Purpose

Antibacterial

Uses

For washing to decrease bacteria on the skin.

Warnings

For external use only.

When using this product

Avoid contact with eyes. If contact occurs, rinse eyes thoroughly with water.

Stop using this product and ask doctor if

Irritation or redness develops and lasts.

Keep out of reach of children

In case of accidental ingestion, get medical help and contact a Poison Control Center immediately.

Directions

Apply onto dry hands, work into rich foamy lather, rinse and dry thoroughly.

Questions or Comments

1-866-695-3030

Inactive Ingredients

WATER, SODIUM XYLENE SULFONATE, DIPROPYLENE GLYCOL, GLYCERIN, SODIUM PCA, AMMONIUM LAURYL SULFATE, COCAMIDOPROPYL BETAINE, POLYQUATERNIUM-10, FRAGRANCE, DISODIUM PHOSPHATE, CETYL ALCOHOL, ALOE BARBADENSIS LEAF JUICE, CITRIC ACID, METHYLPARABEN, PROPYLPARABEN, RED 4 (CI 14700), YELLOW 5 (CI 19140).

Label Copy



Drug Facts	
Active ingredient Triclosan 0.46%	Purpose Antibacterial
Uses ■ For washing to decrease bacteria on the skin	
Warnings	
For external use only	
When using this product ■ avoid contact with the eyes. If contact occurs, rinse eyes thoroughly with water	
Stop using this product and ask a doctor if ■ irritation or redness develops and lasts	
Keep out of reach of children. ■ In case of accidental ingestion, get medical help or contact a Poison Control Center immediately	
Directions ■ Apply onto dry hands, work into rich foamy lather, rinse and dry thoroughly	
Questions/Comments? 1-866-695-3030	
<i>Inactive ingredients:</i> water (aqua), sodium xylenesulfonate, dipropylene glycol, glycerin, sodium pca, ammonium lauryl sulfate, cocamidopropyl betaine, polyquaternium-10, fragrance (parfum), disodium phosphate, cetyl alcohol, aloe barbadensis leaf juice, citric acid, methylparaben, propylparaben, red 4 (CI 14700), yellow 5 (CI 19140)	
Datos farmacológicos	
Ingrediente activo Triclosán al 0.46%	Función Antibacterial
Usos • Para lavarse y reducir la presencia de bacterias sobre la piel	
Advertencias • Para uso externo únicamente	
Al usar este producto • evite que entre en contacto con los ojos. Si esto sucede, enjuáguese con agua	
Deje de usar este producto y consulte con el médico si • aparece y persiste irritación o enrojecimiento	
Mantenga el producto lejos del alcance de los niños • En caso de ingestión accidental, solicite asistencia médica o llame de inmediato a un centro de control de intoxicaciones	
Manera de usar • Use el producto para rellenar su recipiente surtidor de jabón espumoso. • Vierta del recipiente surtidor sobre las manos secas. Frota para formar espuma y enjuáguese bien	
Preguntas/comentarios? 1-866-695-3030 (Sólo en EUA)	
<i>Ingredientes inactivos:</i> agua, xilensulfonato de sodio, dipropilenglicol, glicerina, sodio PCA, lauril sulfato de amonio, cocamidopropil betaina, poliquaternio-10, perfume, fosfato disódico, alcohol cetílico, jugo de hoja de sábila (Aloe barbadensis), ácido cítrico, metilparabeno, propilparabén, rojo no.4 (CI 14700), amarillo no. 5 (CI 19140)	
DISTRIBUTED BY: H-E-B, SAN ANTONIO, TX 78204 • MADE IN CANADA • Lot Number: on package We hope you are satisfied with this product. If not, we will cheerfully refund your money.	
IMPORTADO Y DISTRIBUIDO POR: SUPERMERCADOS INTERNACIONALES H-E-B, S.A. DE C.V. EMILIO ZOLA 743 COL. OBISPADO, MONTERREY, N.L. 64060, MEXICO PRODUCTO DE CANADA Numero de Lote: ver envase	
06-16179	

ANTIBACTERIAL FOAMING

triclosan liquid

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:37808-177
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
TRICLOSAN (UNII: 4NM5039Y5X) (TRICLOSAN - UNII:4NM5039Y5X)	TRICLOSAN	0.46 mL in 100 mL

Inactive Ingredients

Ingredient Name	Strength
WATER (UNII: 059QF0K00R)	
SODIUM XYLENESULFONATE (UNII: G4LZF950UR)	
DIPROPYLENE GLYCOL (UNII: E107L85C40)	
GLYCERIN (UNII: PDC6A3C0OX)	
SODIUM PYRROLIDONE CARBOXYLATE (UNII: 469OTG57A2)	
AMMONIUM LAURYL SULFATE (UNII: Q7AO2R1M0B)	
COCAMIDOPROPYL BETAINE (UNII: 5OCF3011KX)	

POLYQUATERNIUM-10 (400 CPS AT 2%) (UNII: HB1401PQFS)	
SODIUM PHOSPHATE, DIBASIC, DIHYDRATE (UNII: 94255I6E2T)	
CETYL ALCOHOL (UNII: 936JST6JCN)	
ALOE VERA LEAF (UNII: ZY81Z83H0X)	
CITRIC ACID MONOHYDRATE (UNII: 2968PHW8QP)	
METHYL PARABEN (UNII: A2I8C7HI9T)	
PROPYL PARABEN (UNII: Z8IX2SC1OH)	
FD&C RED NO. 4 (UNII: X3W0AM1JLX)	
FD&C YELLOW NO. 5 (UNII: I753WB2F1M)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:37808-177-08	222 mL in 1 BOTTLE, PUMP		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part333E	09/09/2011	

Labeler - HEB (007924756)

Registrant - APOLLO HEALTH AND BEAUTY CARE (201901209)

Establishment

Name	Address	ID/FEI	Business Operations
APOLLO HEALTH AND BEAUTY CARE		201901209	manufacture